UNITED STATES COPYRIGHT OFFICE

Petition to Renew a Current Exemption Under 17 U.S.C. § 1201

9th Triennial Rulemaking

Please submit a separate petition for each current exemption for which renewal is sought.

NOTE: Use this form if you want to renew a current exemption without modification. If you are seeking to engage in activities not currently permitted by an existing exemption, including those that would require the expansion of a current exemption, you must submit a petition for a new exemption using the form available at **copyright.gov/1201/2024/new-petition.pdf**.

If you are seeking to expand a current exemption, we recommend that you submit both a petition to renew the current exemption without modification using this form, and, separately, a petition for a new exemption that identifies the current exemption and addresses only those issues relevant to the proposed expansion of that exemption.

ITEM A. PETITIONERS AND CONTACT INFORMATION

Please identify the petitioners and provide a means to contact the petitioners and/or their representatives, if any. The "petitioner" is the individual or entity seeking renewal.

Petitioners:

Jordan Health Products, LLC (dba Avante Health Solutions)
1751 Lake Cook Road, Suite 550
Deerfield, IL 60015

Transtate Equipment Company, Inc (dba Avante Diagnositic Imaging)
1040 Denta Road, Suite A
Concord, NC 28027

Global Medical Imanging, LLC (dba Avante Ultrasound)
1040 Denta Road, Suite A
Concord, NC 28027

Representative for all three Petitioners:
James Leitl, President & CEO, Jordan Health Products, LLC (dba Avante Health Solutions)

Counsel:
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Privacy Act Advisory Statement: Required by the Privacy Act of 1974 (P.L. 93-579)
The authority for requesting this information is 17 U.S.C. §§ 1201(a)(1) and 705. Furnishing the requested information is voluntary. The principal use of the requested information is publication on the Copyright Office website and use by Copyright Office staff for purposes of the rulemaking proceeding conducted pursuant to 17 U.S.C. § 1201(a)(1). NOTE: No other advisory statement will be given in connection with this application. Please keep this statement and refer to it if we communicate with you regarding this petition.

Item B. Identify Which Current Exemption Petitioners Seek to Renew

Check the appropriate box below that corresponds with the current temporary exemption (see **37 C.F.R. § 201.40**) the petitioners seek to renew. Please check only one box. If renewal of more than one exemption is sought, a separate petition must be submitted for each one.

Motion Pictures *(including television programs and videos)*:

- ○ Excerpts for use in documentary filmmaking or other films where use is in parody or for a biographical or historically significant nature
- ○ Excerpts for use in noncommercial videos
- ○ Excerpts for use in nonfiction multimedia e-books
- ○ Excerpts for educational purposes by college and university faculty, students, or employees acting at the direction of faculty, or K–12 educators and students
- ○ Excerpts for educational purposes by faculty and employees acting at the direction of faculty in massive open online courses ("MOOCs")
- ○ Excerpts for educational purposes in digital and literacy programs offered by libraries, museums, and other nonprofits
- ○ For the provision of captioning and/or audio description by disability services offices or similar units at educational institutions for students, faculty, or staff with disabilities
- ○ For the preservation or the creation of a replacement copy of the motion picture by libraries, archives, or museums
- ○ For text and data mining by a researcher affiliated with a nonprofit institution of higher education, or by student or staff at the direction of such researcher, for the purpose of scholarly research and teaching

Literary Works:

- ○ Literary works distributed electronically for text and data mining by a researcher affiliated with a nonprofit institution of higher education, or by student or staff at the direction of such researcher, for the purpose of scholarly research and teaching
- ○ Literary works or previously published musical works that have been fixed in the form of text or notation whose technological protection measures interfere with assistive technologies
- ○ Literary works consisting of compilations of data generated by medical devices or their personal corresponding monitoring systems, to access personal data

Computer Programs and Video Games:

- ○ Computer programs that operate wireless devices, to allow connection to an alternative wireless network ("unlocking")
- ○ Computer programs that operate smartphones and portable all-purpose mobile computing devices to allow the device to interoperate with or to remove software applications ("jailbreaking")
- ○ Computer programs that operate smart televisions to allow the device to interoperate with software applications on the television for purposes other than gaining unauthorized access to copyrighted works ("jailbreaking")
- ○ Computer programs that operate voice assistant devices to allow the device to interoperate with or to remove software applications for purposes other than gaining unauthorized access to copyrighted works ("jailbreaking")
- ○ Computer programs that operate routers and dedicated network devices to allow the device to interoperate with software applications on the device for purposes other than gaining unauthorized access to copyrighted works ("jailbreaking")
- ○ Computer programs that control motorized land vehicles, marine vessels, or mechanized agricultural vehicles or vessels for purposes of diagnosis, repair, or modification of the vehicle, including to access diagnostic data
- ○ Computer programs that control devices designed primarily for use by consumers for diagnosis, maintenance, or repair of the device or system
- ◉ Computer programs that control medical devices or systems, and related data files, for diagnosis, maintenance, or repair of the device or system
- ○ Computer programs for purposes of good-faith security research
- ○ Video games for which outside server support has been discontinued, to allow individual play by gamers and preservation of games by libraries, archives, and museums (as well as necessary jailbreaking of console computer code for preservation uses only), and discontinued video games that never required server support, for preservation by libraries, archives, and museums
- ○ Computer programs other than video games, for the preservation of computer programs and computer program-dependent materials by libraries, archives, and museums
- ○ Computer programs that operate 3D printers, to allow use of alternative material
- ○ Computer programs for purpose of investigating potential infringement of free and open source computer programs
- ○ Video games in the form of computer programs for purpose of allowing an individual with a physical disability to use alternative software or hardware input methods

ITEM C. EXPLANATION OF NEED FOR RENEWAL

Provide a brief explanation summarizing the continuing need and justification for renewing the exemption. The Office anticipates that petitioners will provide a paragraph or two detailing this information, but there is no page limit. While it is permissible to attach supporting documentary evidence as exhibits to this petition, it is not necessary. Below is a hypothetical example of the kind of explanation that the Office would regard as sufficient to support renewal of the unlocking exemption. The Office notes, however, that explanations can take many forms and may differ significantly based on the individual making the declaration and the exemption at issue.

I. Introduction

Petitioner Jordan Health Products is the parent company to, among other independent service organizations (ISOs), petitioners Transtate Equipment Company ("Transtate") and Global Medical Imaging, LLC ("GMI"). These ISOs provide post-warranty period servicing of medical systems and devices for hospitals and a variety of health care organizations throughout the United States. Transtate diagnoses, maintains, and repairs diagnostic X-ray systems (commonly referred to as cath labs);. GMI diagnoses, maintains, and repairs ultrasound systems. In order to provide these services, which the FDA has deemed "critical to the functioning of the U.S. healthcare system,"[1] ISOs must use software tools embedded in these systems. To prevent such use, Philips North America LLC et al. ("Philips") – an Original Equipment Manufacturer (OEM) – has filed lawsuits against both petitioners under Section 1201(a)(1)(A) of the Digital Millennium Copyright Act (DMCA). The lawsuits are: Philips Med. Sys. Nederland B.V. et al. v. TEC Holdings, Inc. et al., Case No: 3:20-cv-00021-MOC-DCK (W.D.N.C.) (Count V at 48-54) and Philips North America LLC. et al. v. Global Medical Imaging, LLC et al., Case No: 1:21-cv-03615-SCS-SMF (N.D.IL) (Count I at 19-23).

As detailed in Transtate's 2020 petition for the Exemption (adopted at 37 C.F.R. §201.40(b)(15)), medical devices and systems in the past were composed of mechanical and electrical parts only (i.e., hardware). For example, X-ray machines initially were analog devices and consisted of an X-ray tube to radiate X-rays and film for capturing an image. Later, digital image capturing devices replaced film, which transitioned X-ray machines from analog to digital. The specifications and other information relating to the functions of these older analog medical devices and systems were provided in hard copy manuals. The devices and systems could be serviced by technicians with access to these hard copy manuals, as well as with the relevant mechanical and electrical knowledge, experience, and tools.

However, computing processors and software have since replaced hardware components. As a result of this technological advancement, medical equipment now operate and are maintained with computerized functions. For example, stand-alone computers used to control the digital image capturing devices in X-ray systems. Subsequently, devices have increasingly incorporated computers to control functions such that the devices, computers (i.e., the "hardware"), and the software are inseparable. Now, large sophisticated systems such as MRI and catheterization and cath lab systems are completely controlled by specially programmed computers that are integrated into the systems.

Today, medical devices and systems are, for all intents and purposes, specialized computers, although some use software running in common operating system environments such as Linux or Microsoft Windows®. The devices and systems often include software specific to the medical devices. In other words, software from one OEM for one type of device is likely incompatible with a similar device from another OEM. Further, the devices are integrated to such a degree that the devices cannot function without the software. Functionally, an ISO often cannot fully service a device without using the installed software and data files. Indeed, to properly diagnose faults and errors in the operation of a device, an ISO must access error logs to decipher the causes of errors, and this requires access to use certain software.

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1. FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices, Published May 15, 2018, available at https://www.fda.gov/media/113431/download ("The continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system.").

ITEM C. EXPLANATION OF NEED FOR RENEWAL *(CONT'D)*

OEMs also often provide manuals and other service information via electronic media, sometimes as data files installed on the medical systems or devices. Additionally, electronic servicing materials may be stored on other electronic media where access is prevented or hindered by technological protective measures ("TPMs") (e.g., encryption) even if they are not stored within the medical systems or devices. In order to perform servicing activities, therefore, an ISO requires access to, and use of, computer programs or modules thereof, electronic data files, including databases, and electronic manuals (collectively also referred to herein as, "electronic service materials").

To be sure, the transition to integrated software conceptually is not an issue. Issues arise, however, because OEMs overwhelmingly equip modern medical systems and devices with TPMs such as encryption, embedded software, and challenge-response mechanisms, involving access codes, passwords, keys, or digital signatures. These TPMs prevent or hinder medical equipment owners, lessees, and their agents (i.e. ISOs) from diagnosing, servicing, or maintaining the medical systems and devices they own or lease by restricting or denying access to use necessary electronic service materials installed in the medical equipment or otherwise provided via electronic media.

OEMs have been able to exploit the DMCA anti-circumvention provision against ISOs by tying mere "access" to allegedly protected works regardless of whether the works are actually used or are comingled with unprotectable works. For example, the protected works and unprotected works – such as data files, error logs, configuration files, and other unprotected works – are all comingled behind the same TPMs. This results in unprotected works being inaccessible because, in order to access the unprotected works, one must also access allegedly protected works (as defined in the DMCA) and therefore risk violating or being accused of violating the DMCA. Thus, by comingling protected and unprotected works, OEMs are able to thwart even the most basic servicing of the medical equipment by preventing ISOs from accessing and using unprotected works.

Further, OEMs have exploited the DMCA to interfere with a system or device owners' right to repair. Judge Cogburn in the Transtate litigation recognized this point, stating in his Order granting Philips summary judgment on its DMCA count: "The Court does agree with Defendants, however, that this case exemplifies the problems with the DMCA and the right to repair." DE 641 at 28. The Court explained that, "[w]hereas the DMCA was originally enacted to protect copyright owners from digital privacy," the law is being abused by "powerful corporations" who are "putting digital locks on their products as a tool to capture and retain a huge market share over the repair industry." Id. at 28–29. This practice "reduc[es] consumer choice and rais[es] repair costs" and "cannot be what Congress intended when it passed the DMCA." Id. at 29. A copy of the Order is attached as Exhibit A.[2][3]

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2. Transtate disagrees with the court's DMCA judgment because the Order ignores the appellate holdings denying DMCA applicability in situations where copyright infringement or facilitation of copyright infringement is not implicated (Chamberlain Grp. V. Skylink Techs., Inc. 381 F.3d 1178, 1196–97 (Fed. Cir. 2004), Storage Tech. Corp. v. Custom Hardware Engineering & Consulting, Inc., 421 F.3d 1307, 1318 (Fed. Cir. 2005), and Chambers v. Amazon.com Inc., 632 Fed. Appx. 742, 744 (4th Cir. 2015)), or where circumvention only enables use of a functional work without access to any expression of the work (Lexmark Int'l, Inc. v. Static Control Components, Inc., 387 F.3d 522, 548-49 (6th Cir. 2004).

3. Transtate disagrees with the court's CFAA judgment because the Order ignores the lack of any alleged technological harm required by Van Buren v. United States, 141 S. Ct. 1648 (2021) and district court cases discussed in Section IV, infra.

ITEM C. EXPLANATION OF NEED FOR RENEWAL *(CONT'D)*

II. The Continuing Need for the Exemption

A. TPMs Are Still Employed in Medical Systems and Devices

As noted in Transtate's petition for the current Exemption, the use of TPMs in medical systems and devices is widespread among the types of systems and devices and among the OEMs. There is no sign that the OEMs will discontinue the use of TPMs. Indeed, OEMs have developed new systems that further restrict access to use of necessary software tools. For example, Philips' more recent Azurion® line of cath lab systems utilize updated Microsoft platforms that make obsolete tools that were previously used to access embedded servicing software tools. Petitioners are not aware of any TPMs having been removed from existing or older systems or devices.

B. The Exemption Has Been Impactful

The Exemption has been critical to Petitioners' defense of lawsuits filed by Philips under the DMCA. For example, Petitioners have been able to invoke the current Exemption ("Computer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system") to cut short liability or potential liability for servicing medical systems and devices.

Continuing the Exemption will help prevent OEMs from exploiting the DMCA to prevent Petitioners and other ISOs and owners and lessees of the medical systems and medical devices from performing critical services that may allegedly circumvent a TPM controlling access to use of the software. The Exemption also prevents OEMs from taking advantage of the unintended consequences of copyright law that was enacted for developers of software applications for stand-alone computers, and applying it to specialty medical equipment integrated with software. Further, the Exemption allows the medical systems or devices owners or lessees to exercise their right to repair their own systems and devices without fear of liability under the DMCA.

C. The Exemption Tames Abuse of the DMCA

Numerous courts have recognized that use of a password, even an "unauthorized password", does not constitute circumvention under the DMCA. In Burroughs Payment Systems Inc. v. Symco Group, Inc., 2011 WL 13217738 (N.D. Ga. Nov. 13, 2011) the court held that an ISO's use of keys to diagnose and repair software systems without authorization was insufficient to state a claim upon which relief may be granted under the DMCA. In Navistar, Inc. v. New Balt. Garage, Inc., 2012 U.S. Dist. LEXIS 134369 *; 2012 WL 4338816 (N.D. Il. 2012) the court dismissed a DMCA count stating that "using a password to access a copyrighted work, even without authorization, does not constitute 'circumvention' under the DMCA because it does not involve descrambling, decrypting, or otherwise avoiding, bypassing, removing, deactivating, or impairing a 'technological measure.'" In I.M.S. Inquiry Management Systems, Ltd. v. Berkshire Information Systems, Inc., 307 F. Supp. 2d 521, 532-33 (S.D.N.Y. 2004) held that use of an authorized password by an unauthorized party is not violation of the DMCA. In Egilman v. Keller & Heckman, LLP., 401 F.Supp.2d 105 (D.D.C. 2005), the court held that the 'use' of a password without the authority of the copyright owner is not a violation of the DMCA's circumvention provision. In Ground Zero Museum Workshop v. Wilson, 813 F. Supp. 2d 678 (D. Md. 2011), the court, citing Egilman and I.M.S., held that a former manager of a museum's website did not circumvent a technological measure by using an expired or unauthorized password when he accessed and deleted some of the museum's files and redirected the website to a critical New York Post article. Id. at 691-92.

ITEM C. EXPLANATION OF NEED FOR RENEWAL *(CONT'D)*

Despite these rulings that application of a password, key, or certificate even whether "unauthorized" or "fake" does not meet the statutory requirement for "circumvention," OEMs, such as Philips, have aggressively invoked the anti-circumvention restriction of the DMCA claiming that the use of such keys or passwords does constitute circumvention, thus subjecting the ISOs to actual or potential onerous litigation. In addition to the lawsuits against Petitioners, Philips has filed lawsuits against other ISOs alleging such violations of the DMCA. See, Philips Med. Sys. Puerto Rico, Inc., et al v. Alpha Biomedical and Diagnostic Corp., Case No: 3:19-cv-01488-CCC (D.P.R.) (Third Cause of Action at 25-26); Philips N. Am. LLC et al v. 626 Holdings, Inc. et al., Case No: 9:19-cv-81263 RS (S.D. Fla.) (Count VI at 22-25); Philips, et al. v. Zetta Med. Techs. LLC, et al, C.A. No. 17-3425 (N.D. Ill.) (Count III at 18-19); Philips N. Am. LLC v. KPI Healthcare Inc., C.A. No. 8:19-cv-1765 (C.D. Cal.) (Fourth Cause of Action at 28-30); Philips N. Am. LLC et al. v. Summit Imaging Inc. et al., Case No: 2:19-cv- 01745-JLR (W.D. Wash.) (First Cause of Action at ¶¶ 77-106); and Philips North America LLC v. Advanced Imaging Services, Inc. et al., Case No. 2:2021-cv-00876 (E. D. Cal.) (Count III at 12-13). While the parties have settled some of these lawsuits, Petitioners are informed that other ISOs are unwilling to join this petition due to their settlement agreements.

Additionally, the DMCA specifically omits liability for circumventing a TPM that only controls a right of a copyright owner, such as use of a work, without access or exposure to the expression of the work . Lexmark Int'l, Inc. v. Static Control Components, Inc., 387 F.2d 522, 548 (6th Cir. 2004) is the leading decision to recognize and explain this distinction in the context of use of computer software. The Court ruled that mere invocation of compiled code does not amount to access to the protected work. As explained by the Sixth Circuit, "[t]he copyrightable expression in the Printer Engine Program, by contrast, operates on only one plane: in the literal elements of the program, its source and object code. Unlike the code underlying video games or DVDs, "using" or executing the Printer Engine Program does not in turn create any protected expression." The Sixth Circuit further noted that "[n]owhere in its deliberations over the DMCA did Congress express an interest in creating liability for the circumvention of technological measures designed to prevent consumers from using consumer goods while leaving the copyrightable content of a work unprotected." Similarly, an ISO's invocation of functional service code via a menu, does not amount to access to a copyrightable expression because there is no visual or audible copyrightable expression, and does not amount to access to a protected work.

Despite this purposeful omission of liability, OEMs have threatened to file, or have filed lawsuits under the DMCA, such as those mentioned above even though the software is only used via an interface with no actual access to the underlying software. The Exemption necessarily prevents OEMs from extending the reach of the DMCA to situations that Congress did not envision.

Thus, renewal of the Exemption will curtail these abusive assertions and the ensuing onerous litigation.

III. The Alleged Circumventions Only Occur When Necessary

Petitioners adhere to the Exemptions' requirement that the alleged "circumvention" only occur "when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system."

For example, Transtate's use of the Exemption is occasional and on an as-needed basis. Transtate's tool to enable use of software on certain Philips cath labs was developed as a back-up tool to use when Philips' IST certificates (on flash drives) malfunction, or cannot be renewed timely, or otherwise do not provide the full access needed to properly diagnose, repair, or maintain a system. See excerpt of testimony of Robert A. Wheeler on April 17, 2023, 2708:18-2710:23, attached as Exhibit B.

GMI's use of a key generated by its key generator is also limited. When a GMI customer authorizes GMI to replace a part on its Philips system, or otherwise to service its Philips system, GMI only accesses the system user interface to diagnose and service the system. On some occasions, GMI uses the system user interface to update the system to recognize a newly installed part and/or to make a full backup of the system so that the system can be reloaded with all of its original settings. DEFENDANT GLOBAL MEDICAL IMAGING, LLC'S RESPONSES AND OBJECTIONS TO PLAINTIFFS' FIRST SET OF INTERROGATORIES, Response to Interrogatory No. 2 (Dec. 10, 2021) (Attached as Exhibit C).

ITEM C. EXPLANATION OF NEED FOR RENEWAL *(CONT'D)*

IV. The Alleged Circumventions Do Not Involve a Violation of Any other Law

These alleged circumventions do not violate any other law. While Philips has alleged a violation of the Computer Fraud and Abuse Act (18 U.S.C. 1030) in its various lawsuits, the U.S. Supreme Court has since explained why the CFAA is not applicable.

In Van Buren v. United States, 141 S. Ct. 1648 (2021), the Supreme Court explained why the Government's position of liability of exceeding authorized access had a structural defect, noting the CFAA provision also gives rise to civil liability. The Court explained that "the term 'loss' likewise relates to costs caused by harm to computer data, programs, systems, or information services. The statutory definitions of 'damage' and 'loss' thus focus on technological harms [...] of the type unauthorized users cause." 141 S. Ct. at 1660. The Court also stated that "[l] imiting "damage" and "loss" in this way makes sense in a scheme "aimed at preventing the typical consequences of hacking." Id. The Court then stated that "t]he term's definitions are ill fitted, however, to remediating 'misuse' of sensitive information that employees may permissibly access using their computers." Id. The Court concluded "Van Buren's situation is illustrative: His run of the license plate did not impair the "integrity or availability" of data, nor did it otherwise harm the database system itself." Id.

Although no appellate court appears to have considered compensatory damages in the context of Van Buren, the Ninth Circuit has indicated that Van Buren changes how compensatory damages are determined. hiQ Labs, Inc. v. LinkedIn Corp., 31 F.4th 1180, 1195 n.12 (9th Cir. 2022) ("Van Buren reviewed the statutory definitions of 'damage' and 'loss' and concluded that this civil remedies provision requires a showing of 'technological harms—such as the corruption of files—of the type unauthorized users cause to computer systems and data.' LinkedIn has not alleged that hiQ's scraping of public profiles caused any such technological harms.").

Further, some courts have relied on Van Buren to redefine what constitutes "loss" under the CFAA. Better Holdco, Inc. v. Beeline Loans, Inc., No. 20-CV-8686 (JPC), 2021 WL 3173736, at *3 (S.D.N.Y. July 26, 2021) ("This Court agrees with these authorities and, consistent with the Supreme Court's discussion in Van Buren, and interprets 'costs of responding to an offense' as limited to situations involving damage to or impairment of the protected computer."); El Omari v. Buchanan, No. 20 CIV. 2601 (VM), 2021 WL 5889341, at *14 (S.D.N.Y. Dec. 10, 2021), aff'd, No. 22-55-CV, 2022 WL 4454536 (2d Cir. Sept. 26, 2022); see also Acrison, Inc. v. Rainone, No. CV221176KMESK, 2022 WL 16695116, at *8 (D.N.J. Nov. 3, 2022); Saffron Rewards, Inc. v. Rossie, No. 22-CV-02695-DMR, 2022 WL 2918907, at *8 (N.D. Cal. July 25, 2022); CoStar Grp., Inc. v. Leon Cap. Grp., LLC, No. 21-CV-2227 (CRC), 2022 WL 2046096, at *9 (D.D.C. June 7, 2022); Deck v. Courtney, No. 121-CV-01078, 2021 WL 3474043, at *1 (S.D. Ind. Aug. 6, 2021). Because diagnosis, repair, and maintenance of a system are the opposite of causing damage or impairment to a system, the CFAA should not apply. Simply put, there is no existence of a requisite technological harm. Philips' CFAA allegations should ultimately fail due to the absence of the requisite technological harm.

V. The Register's Fair Use Analysis Was Correct

Petitioners are aware and have been following the action filed by Medical Imaging & Technology Alliance (MITA) and Advanced Medical Technology Association (AdvaMed) (collectively "Appellants") against The Library Congress challenging the adoption of the current Exemption. Judge Beryl Howell dismissed the action and granted summary judgment in favor of The Library of Congress. That decision is on appeal before the United States Court of Appeals for the District of Columbia, as Case No. 23-5067. In that appeal, Appellants argue that the Librarian's fair use analysis was improper because (1) the analysis improperly considered prior analyses in connection with other software enabled devices such as automobiles that Appellants contend are irrelevant to "complex medical devices," (2) improperly concluded that the use of the software embedded in the medical devices is transformative when there is no modification of or creation of new software," and (3) improperly considered "how granting the Exemption would improve competition with copyright holders and thus lower prices, even though the central purpose of copyright laws is to stimulate creativity by protecting the right of producers of copyrightable work to recoup the expense of there creative labors." Appellants' Opening Brief, pages 47-49 (June 8, 2023). A copy of that brief is

attached as Exhibit D.

However, Appellants do not even try to explain why other software devices should not have been considered other than to dismissively state they are unrelated without analyzing why this would make a difference. Automobiles are similarly complex machines, often with many computers and much software generating much data. Automobile software is used to diagnose the state of an automobile, and parameters can be adjusted to return an automobile to its specified operational condition. Thus, the analogy and prior analysis is not only relevant, but instructive, and the Librarian properly considered the prior analysis of automobile systems.

Further, the fair use limitation to the exclusive rights of a copyright owner (17 U.S.C. §107) includes a list of non-exclusive factors to be considered. The first factor is "the purpose and character of the use." Courts have considered the transformative nature of the use as one way of analyzing the use under this factor. However, "transformative use is not absolutely necessary for a finding of fair use." See, Campbell v. Acuff Rose Music, Inc. 510 U.S. 569, 579 (1994), citing, Sony Corp. of America v. Universal City Studios, Inc., 464 U.S. 417, 455, n. 40 (1984)(videotaping of broadcast content for time-shifted viewing deemed fair use). See also Google LLC v. Oracle Am., Inc., 141 S. Ct. 1183, 1203 (2021)(In determining whether a use is transformative, one considers the copying's more specifically described purposes and character).

In the medical device situation, the embedded software is being used to diagnose, repair, or maintain the specific systems for which the software was uniquely designed. The software is functional or utilitarian and runs within the system or device. Typically, no one is exposed to the software itself, only to the user interface. Modifying the software would likely lead to the system being considered remanufactured, which is not the purpose of diagnose, repair, or maintenance. Indeed, remanufacturing is to be avoided. Further, the creation of new software or derivative software is meaningless because there is no use for such derivative software; the systems already have the software that is uniquely designed for them and approved by the FDA. Thus, the Librarian correctly noted that the purpose and character of the use was to diagnose, repair, or maintain a system by making it work or restoring it to a state of working in accordance with its original specifications and any changes to those specifications authorized for that device or system.

Finally, the Librarian's consideration of competition was completely acceptable. The factors listed in Section 107 are not exclusive, and the consideration of the benefits to the medical service providers is relevant. In this situation, as noted above, the software tools are invoked for diagnosis, repair, or maintenance, which enables medical service providers to provide their services and diagnose and treat patients. In doing so, it benefits the public, reduces the after warranty period control of the servicing of medical systems and devices by OEMs, and promotes a very healthy and critical third party servicing market [4] that, in turn, promotes a very healthy medical system infrastructure. Further, as noted above, the Exemption tames the unintended consequences of the DMCA's prohibition on the right to repair decried by Judge Cogburn.

For all the foregoing reasons, renewal of the Exemption is warranted and requested.

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4. See, fn. 1, supra.

Item D. Declaration and Signature

The declaration is a sworn statement made under penalty of perjury and must be signed by one of the petitioners named above.

I declare under penalty of perjury under the laws of the United States of America that the following is true and correct:

1. **Based on my own personal knowledge and experience, I have a good faith belief that but for the above-selected exemption's continuation during the next triennial period (October 2024–October 2027), technological measures controlling access to relevant copyrighted works are likely to diminish the ability of relevant users to make noninfringing uses of these works, and such users are likely to rely upon the above-selected exemption during the next triennial period.**
2. **To the best of my knowledge, there has not been any material change in the facts, law, or other circumstances set forth in the prior rulemaking record (available at copyright.gov/1201/2021) that originally demonstrated the need for the above-selected exemption, such that renewal of the exemption would not be justified.**
3. **To the best of my knowledge, the explanation provided in Item C above is true and correct and supports the above statements.**

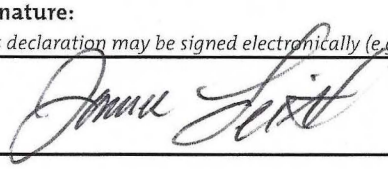
Name/Organization:

If the petitioner is an entity, this declaration must be signed by an individual at the organization having appropriate personal knowledge.

Jordan Health Products LCC (dba Avante Health Solutions)
Transtate Equipment Company, Inc. (dba Avante Diagnositic Imaging)
Global Medical Imaging, LLC (dba Avante Ultrasound)

Signature:

This declaration may be signed electronically (e.g., "/s/ John Smith").



Date:

July 3, 2023