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UNITED STATES COPYRIGHT OFFICE

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

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ITEM A. COMMENTER INFORMATION

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ITEM B. PROPOSED CLASS ADDRESSED

Proposed Class 12: Computer Programs—Repair (specifically, Medical Devices)

ITEM C. OVERVIEW

Petitioner Summit Imaging, Inc. ("Summit") is an independent service provider ("ISO") for medical imaging devices. Summit provides repair services and replacement parts for diagnostic medical imaging equipment to hospitals and other medical providers nationwide. Summit focuses its services on ultrasound and mammography diagnostic imaging devices.

Today, medical imaging devices are controlled by computers installed on-board the devices. The computers are integral to the operation and maintenance of the systems. These computers typically run on standard operating system environments such as Microsoft Windows. The original equipment manufacturer ("OEM") adds its own application software to the computer to provide both for the clinical operation of the device and its maintenance.

Servicing of medical devices and their components requires the use of the installed software and data files. For example, to diagnose error or faults in a medical imaging device requires access to error log files stored on the system. And access to the error log files requires access to the software driving the system.

OEMs, however, restrict access to diagnostic software and data files in their medical imaging systems through the use of access codes, passwords, keys, or other similar technological measures ("TPMs"). OEMs use TPMs and the anti-circumvention provision of the DMCA to deter owners, lessees, and their ISO agents from accessing the software, including error log files, by threatening and filing lawsuits. OEMs allege that their TPMs constitute a "technological measure that effectively controls access to a work protected under [Title 17]" the circumvention of which is prohibited by the DMCA. And yet, OEMs use these threats and lawsuits to prevent access to all data files on their systems, including error logs, configuration files, and other unprotected works. By using TPMs to restrict access to both protected and unprotected works, OEMs are using the DMCA to prevent access to unprotected works and interfere with basic service for medical imaging devices.

Summit itself is currently the subject of a pending lawsuit by an OEM claiming that Summit has violated the anti-circumvention provisions of the DMCA. *Philips North America LLC, et al. v. Summit Imaging, Inc*., at al., Case No. 2:19-cv-01745 (W.D. Wash. 2019). In this case, Philips specifically alleges that Summit is liable under the DMCA for accessing log files on Philips ultrasound systems. Philips' case against Summit is not unique. Over just the last few years, Philips has filed numerous lawsuits against ISOs stating DMCA claims for allegedly circumventing Philips' access controls in connection with the service of Philips medical imaging devices. *E.g., Philips Med. Sys. Nederland B.V., TEC Holdings, Inc., et al*., Case No. 3:20-cv-00021 (W.D.N.C. 2020); *Philips Med. Sys. Puerto Rico, Inc., et al. v. Alpha Biomedical and Diagnostic Corp*., Case No. 3:19-cv-01488 (D.P.R. 2019), *Philips N. Am. LLC, et al. v. 626 Holdings, Inc.,* et al., Case No. 9:19-cv-81263 (S.D. Fla. 2019); *Philips N. Am. LLC v. KPI Healthcare Inc*., Case No. 19-1765 (C.D. Cal. 2019).

OEMs' use of TPMs to prevent access to software and files needed to service medical devices is particularly pernicious when it comes to older equipment that OEMs no longer support because they claim they have reached the end of their commercial life. For such older equipment, OEMs do not provide access codes at all. Thus owners and their ISO agents are preventing from accessing the computer programs and data files needed to service their equipment. Medical providers operating under tight budgets desire to keep older equipment properly serviced. OEMs' use of TPMs prevents them from doing that.

ITEM D. TECHNOLOGICAL PROTECTION MEASURE(S) AND METHOD(S) OF CIRCUMVENTION

As described above, OEMs restrict access to the computer programs and data files on their medical devices using access codes, passwords, and keys. For example, one method used by Philips is an access key contained on a flash drive or dongle. The access key must be present to

identify the access level of the user. Philips provides dongles to its field service engineers that give them access to the software and data needed to service Philips equipment. For owners, however, Philips only provides basic access to the clinical features of the device unless they purchase an expensive service contract. This limited access is insufficient to allow owners or their ISO agents to service the device.

Another method OEMs use to restrict access is a combination of username and password to access a medical device system. As with the dongles, owners' passwords will not provide access to the software and files needed to service the medical device.

ITEM E. ASSERTED ADVERSE EFFECTS ON NONINFRINGING USES

Adverse Effects Caused by Prohibition

Hospitals and other medical providers who own medical devices are directly adversely affected by the DMCA anti-circumvention provision. They are affected in two primary ways. First, the prohibition reduces competition from ISOs. Medical providers are left to seek service from OEMs who charge much higher prices for service than ISOs. Absent effective competition from ISOs, OEMs can be expected to charge higher prices still. Second, the DMCA prevents medical providers from servicing their own equipment using in-house service departments. Without access to the software and files needed to service their equipment, medical providers are captive to the OEMs and cannot troubleshoot and conduct repairs promptly.

This last adverse effect highlights the most significant adverse effect: harm to public health and safety. Delayed repair of medical equipment has real effects on patient outcomes. The longer needed medical equipment remains out of service, the longer patients are denied the benefit of that equipment. In smaller facilities such as rural hospitals or clinics, that may result in the delay of essential medical service that requires the use of that equipment. Delayed medical services, in turn, can lead to negative patient outcomes.[1]

Much has been written on this subject, particularly recently in light of the COVID-19 pandemic. In the case of ventilators, the availability of a working ventilator can make the difference between life and death. Over 300 medical device technicians signed a letter in May calling for OEMs to stop withholding what technicians need to fix their medical devices such as ventilators.[2] Five state treasurers called on OEMs to release service information to repair

[1] *See, e.g.*, Rona Bahreini, Leila Doshmangir, and Ali Imani, Influential factors on medical maintenance management In search of a framework, Journal of Quality in Maintenance Engineering, Volume 25, Issue 1 (June 12, 2018) ("Lack of proper maintenance of medical equipment leads to equipment downtime, reduces the level of device performance, and wastes costs and resources . . . If preventive maintenance [on a medical device] is not well monitored in a hospital, patients' lives are in grave danger").
[2] https://calpirg.org/news/cap/hospital-repair-professionals-just-let-us-fix-life-saving-devices-ventilators.

ventilators.[3] Nader Hammoud, manager of biomedical engineering at John Muir Health in Walnut Cree, California stated in May:

> It's not that it could mean life or death—it's definitely life or death, especially during a pandemic. … I had situations in the past, before Covid-19, where we had to come into the hospital in the middle of the night and try to pull parts from different devices, different sources, because a patient was waiting on a device. We've had to do this multiple times throughout my career.[4]

This is one of the reasons why Senator Wyden recently introduced his bill entitled The Critical Medical Infrastructure Right to Repair Act, seeking immediate exemptions for the DMCA during the pandemic.[5]

When the proper functioning of a machine can be a difference between life and death, hospitals and other machine owners need as many service options as possible to keep their machines up and running. As the FDA has recognized in a 2018 report: "The continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system."[6]

Proposed Exemption Covers Non-Infringing Uses

Running computer software and accessing data files by owners of medical devices or those acting on behalf, such as ISOs, for the purpose of diagnosing, repairing, or maintaining their systems and devices, is non-infringing. This is for at least three independent reasons:

1. Fair use (17 U.S.C. § 107);
2. Essential step in the utilization of a computer program in connection with a machine (17 U.S.C. § 117(a)(1)); and
3. Machine maintenance and repair (17 U.S.C. § 117(c)).

Each of these reasons is discussed more fully below.

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[3] patreasury.gov/newsroom/archive/2020/04-14-Call-On-Manufacturers.html

[4] Quotation from https://www.wired.com/story/right-to-repair-medical-equipment-ifixit/.

[5] wyden.senate.gov/news/press-releases/wyden-and-clarke-introduce-bill-to-eliminate-barriers-to-fixing-critical-medical-equipment-during-the-pandemic-

[6] 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

1. Fair Use

The Copyright Act sets forth four factors to consider when determining whether a use of a copyrighted work is noninfringing fair use:

- the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
- the nature of the copyrighted work;
- the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
- the effect of the use upon the potential market for or value of the copyrighted work.

17 U.S.C. § 107.

In connection with existing exemptions, the Librarian has recognized the fair use of computer programs for the diagnosis, repair, and modification of motorized land vehicles and the fair use of computer programs for the maintenance and repair of appliances. 37 CFR § 201.40(b)(9), (10). In its 2018 Recommendation[7] in support of the latter exemption, the Registrar wrote as follows:

> In analyzing the first fair use factor, the Acting Register notes that the Copyright Office' Software Study observed that, ***because the fundamental purpose of repair is to restore the functionality of a device so that it may be used, "repair supports— rather than displaces—the purpose of the embedded programs."*** Applying similar logic, the 2015 rulemaking concluded that the first factor favored an exemption for vehicle repair because the activities were personal, noncommercial, and would "enhance the intended use" of the vehicle programs. Moreover, the Office's Section 1201 Report observed an emerging "general understanding that bona fide repair and maintenance activities are typically noninfringing." Because proponents express the same desire to engage in these bona fide repair activities with respect to other devices, the Acting Register concludes that this factor favors proponents.

2018 Report at p. 203.

The same reasoning applies to medical devices. Repair supports rather than displaces the purpose of the embedded programs. The whole point of repair is to make the devices

[7] 2018 Recommendation of the Acting Registrar of Copyrights for Rule Making: Seventh Triennial Proceeding to Determine Exemptions on the Prohibition on Circumvention (Oct. 2018).

useful for the purpose for which they are intended.

The second factor also supports fair use. The computer programs and data files at issue are functional works used to control the operation of the medical device systems and the diagnosis, repair, and maintenance of them. For example, error logs are computer files containing events that occur during the use of a medical device by its owner. As such, they are the property of the equipment owner, not the OEM. In any event, because they are functional, they are no protected by copyright. *Lexmark International, Inc. v. Static Control Components, Inc.*, 3877 F.3d 522, 536 (6th Cir. 2004) (configuration files and lock-out codes generally "fall on the functional-idea rather than the original-expression side of the copyright line"); *Sony Comput. Entm't, Inc. v. Connectix Cor*., 203 F.3d 596,603 (9th Cir. 2000) ("[T]he fair use doctrine preserves public access to the ideas and functional elements embedded in copyright computer software programs.").

The third fair use factor similarly supports fair use. It is necessary to execute the computer programs and access the data files during servicing activities to understand system or device performance and, in several instances, update the data files such as service logs. The computer programs and data files involved are but a small portion of the entire software package used to operate and service medical imaging devices and are integrated into the machine. For example, the software on a Philips ultrasound system consists of a number of different components, most of which are involved in the clinical operation of the machine. The software for diagnosing problems with the system, including error logs, comprise only a small part of the system software.

Finally, the fourth factor also supports fair use. The effect of the use upon the potential market for or value of the copyrighted work is minimal.[9] The computer programs and data files are necessary for the operation and control of the medical equipment, including the basic servicing of the equipment, and are sold together with the equipment in which they are employed. They have no other use. Thus, the OEMs must include them or make them available to enable operation, control, and servicing of new equipment. Although OEMs might sell or make available updates to their software, there is no independent market for the computer programs and data files outside of the purchase of new equipment because the software is not of any value outside of use on this equipment.

Of course, the TPMs that restrict access to the computer programs and data files provide value to the OEMs by allowing them to control the market for repair services for their machines. But, as the Registrar recognized in its 2017 policy review of Section 1201[8] (the "1201 Report"), this is not a valid purpose of Section 1201. "[V]irtually all agree that section 1201 was not intended to facilitate manufacturers' use of TPMs to facilitate product tying or to achieve a lock-in effect under which consumers are effectively limited to repair services offered by the manufacturer." 1201 Report at 92.

[8] Section 1201 of Title 17-A Report of the Registrar of Copyrights (June 2017), https://www.copyright.gov/policy/1201/section-1201-full-report.pdf.

OEMs will argue that their investments in computer software enable them to serve customers better than ISOs. The FDA rejected this proposition in its 2018 report on the quality, safety, and effectiveness of servicing medical devices ("FDA Report").[9] Faced with OEMs requesting that the FDA impose additional regulations on ISOs, the FDA rejected the invitation concluding: "the objective evidence indicates that many OEMs and third party entities provide high quality, safe, and effective servicing of medical devices." FDA Report at i.

2. Essential Step (17 U.S.C. § 117(a)(1))

   Title 17 U.S.C. §117 (a)(1) provides:

   > (a)(1) Notwithstanding the provisions of section 106, it is not an infringement for the owner of a copy of a computer program to make or authorize the making of another copy or adaptation of that computer program provided that such a new copy or adaptation is created as an essential step in the utilization of the computer program in conjunction with a machine and that it is used in no other manner.

The access, use, and modification of computer programs and data files embedded in medical equipment is an essential step in the servicing and repair activities associated with that equipment and in maintaining its usefulness. The software is integrated into and is inseparable from the machines. Medical equipment purchases represent substantial investments by their owners. And that equipment is useless without the included software. Some OEMs attempt to only "license" the embedded software. However, there is no alternative to the software as it is tailored to the equipment, and there are no market alternatives. Regardless, the owner of the machine owns the copy of the computer programs installed on that machine. To the extent that the owners or the service companies that work on that their behalf copy or adapt that copy, they are "created as an essential step in the use of the computer program in conjunction with a machine," and "used in no other manner."[10]

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[9] 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.

[10] *See, e.g., Krause v. Titleserv, Inc*., 402 F.3d 119 (2d Cir. 2005) (holding company's modification of copyrighted computer programs created for it by former consultant, after consultant declined to turn over source code, was "essential step" in their utilization, within meaning of Copyright Act's safe harbor provision; modifications, which fixed bugs, allowed company to add new client information, adapted program so it would function on company's new system, and added new features, were necessary if company was to make use of programs on its machines); *Universal Instruments Corp. v. Micro Sys. Eng'g, Inc*., 924 F.3d 32 (2d Cir. 2019) (holding that modifications made by licensee, a medical device company, to server software customized by software developer for licensee's multi- phased test handling system project that allowed existing

3. Hardware Maintenance and Repair (17 U.S.C. § 117(c))

Title 17 U.S.C. §117 (c) provides:

> Machine Maintenance or Repair.—Notwithstanding the provisions of section 106, it is not an infringement for the owner or lessee of a machine to make or authorize the making of a copy of a computer program if such copy is made solely by virtue of the activation of a machine that lawfully contains an authorized copy of the computer program, for purposes only of maintenance or repair of that machine, if—
>
> (1) such new copy is used in no other manner and is destroyed immediately after the maintenance or repair is completed; and
>
> (2) with respect to any computer program or part thereof that is not necessary for that machine to be activated, such program or part thereof is not accessed or used other than to make such new copy by virtue of the activation of the machine.

To perform service on a medical imaging device, it is necessary to activate the device. In performing service, diagnostic software and data files such as error logs are used to diagnose the operating conditions to determine if the device and its components are performing according to their specifications. Data files may be accessed to diagnose issues, confirm operating information, or to update servicing information.

Following a servicing activity, except for any updated data reflecting the service, the computer programs and data files are left in their original condition. To the extent that any new copy is created, it is destroyed upon deactivation or reactivation of the device.

Conclusion

For the foregoing reasons, Summit requests that the Librarian determine that the non-infringing uses described above are, and are likely to be adversely affected by the anti-circumvention provisions of Section 1201(a) and therefore approve the proposed exemptions.

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server software to interact with additional systems in manner intended when source code was developed for licensee was essential step in utilization of computer programs in conjunction with machine).