



UNITED STATES COPYRIGHT OFFICE

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

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

ITEM A. PETITIONER INFORMATION

Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging
1040 Derita Rd.
Suite A
Concord, NC 28027
Robert Andrew Wheeler, President
Telephone: 800-710-9996

Of counsel:
Dentons US LLP
233 South Wacker Drive, Suite 5900
Chicago, IL 60606
Telephone: 312-867-2578
david.metzger@dentons.com
taaj.reaves@dentons.com

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) which are necessary for servicing

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).

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 Web site and use by Copyright Office staff for purposes of the rulemaking proceeding conducted under 17 U.S.C. § 1201(a)(1). NOTE: No other advisory statement will be given in connection with this submission. Please keep this statement and refer to it if we communicate with you regarding this submission.

(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 a TPM. 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. OVERVIEW

Petitioner Transtate Equipment Company (d/b/a Avante Diagnostic Imaging) (“Petitioner”) is a member of the Avante Health Solutions group of companies (<https://avantehs.com>) that, among other things, (a) provide high quality refurbished medical devices and systems (also referred to herein as “**medical equipment**” or “**equipment**”); (b) provide post warranty repair, diagnosis, and maintenance of medical systems and devices (“**servicing activities**”); and (c) sells new and used parts, all manufactured by Original Equipment Manufacturers (“**OEMs**” or “**manufacturers**”). Petitioner focuses on ionizing radiation emitter medical imaging systems, namely catheterization and angioplasty X-ray systems and computed tomography systems. Petitioner has several sister companies, including Dre Medical, Inc. d/b/a Avante Medical Surgical, Pacific Medical, Inc. d/b/a Avante Patient Monitoring, Global Medical Imaging, Inc. d/b/a Avante Ultrasound, and Oncology Services International, Inc. d/b/a Avante Oncology Services.² Petitioner and its sister companies are independent service organizations (“**ISOs**”).³

Petitioner’s sister company, Avante Medical Surgical, focuses on surgical equipment including C-Arm fluoroscopy devices, anesthesia machines, and electrosurgical units.⁴ Sister company Avante Patient Monitoring focuses on monitoring systems including patient monitors, telemetry systems, gas analyzers, and fetal monitors. Sister company Avante Ultrasound focuses on ultrasound machines. Sister company Avante Oncology Services focuses on linear accelerators and CT simulators.⁵

Exemplary medical equipment are shown below.

² See Wheeler Declaration, attached hereto as Exhibit 1, at ¶ 5; see also (<https://avantehs.com/>), attached hereto as Exhibit 2.

³ ISOs are entities, other than the manufacturer or healthcare establishments, that, among other things, maintain, restore, refurbish, or repair a finished device after distribution, for purposes of returning it to the safety and performance specifications established by the manufacturer and to meet its original intended use; see also Wheeler Decl. at ¶ 5.

⁴ See Spencer Declaration, attached hereto as Exhibit 3, at ¶ 1.

⁵ Wheeler Decl. at ¶ 5.



GE Innova 3100 Cath/Angio System



Philips Intellivue MP70 Patient Monitor



Puritan Bennett 840 Ventilator



Siemens SOMATOM Perspective CT Scanner

Petitioner realizes that it likely will be the only ISO or one of very few ISOs to provide comments with respect to the medical device servicing issues. However, the limited number of ISO Petitioners should not be taken as a lack of interest in this exemption or the desire of others for the requested exemption. On the contrary, this issue is of widespread concern among medical technicians.⁶ The ISOs in the medical equipment servicing market are small compared to the OEMs, and operate under the fear of retaliation in the form of access restrictions and slow deliveries of, or refusal to deliver parts, in addition to the ongoing threat imposed by the DMCA. In addition, two of the larger ISOs enjoy a high level of cooperation from the OEMs, and, presumably, do not want that relationship jeopardized, and thus are not getting involved. These unique circumstances should be better understood by way of the following explanation.

In the past, medical devices and systems were composed only of mechanical and electrical parts, *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, film was replaced by digital image capturing devices, making the X-ray machines digital rather than analog. 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 the manuals, as well as with the relevant mechanical and electrical knowledge, experience, and tools.⁷

However, hardware components have since been replaced by computing processors and software. As computers developed, computerized functions have become incorporated into the medical equipment. For example, stand-alone computers were used to control the digital image capturing devices in X-ray systems. Subsequently, more and more functions have become controlled or performed by computers, and the computers have become integrated into the devices such that the devices and the computers (*i.e.*, the “hardware”) and the software are inseparable. Now large sophisticated systems such as MRI and catheterization and angioplasty X-ray systems (often referred to as “cath lab” systems) are completely controlled by specially programmed computers integrated into the systems.⁸

As a result, 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 also include software specific to the medical devices, that is to say, the software from one OEM for one type of device likely cannot be used on the similar device from another OEM. Further, the devices are integrated to such a degree that the devices will not function without the software, and servicing of the devices often is not possible without use of the installed software and data files. Indeed, to properly diagnose faults and errors in the operation of a device, it is often necessary to access error logs to decipher the causes of errors, and this requires access to certain software.⁹

⁶ See, *e.g.* Exhibit 4 (Add final exhibit to Letters for Right to Repair).

⁷ Wheeler Decl. at ¶ 9.

⁸ Wheeler Decl. at ¶ 10.

⁹ Wheeler Decl. at ¶¶ 14, 33; *see also* Melvin Declaration, attached hereto as Exhibit 5, at ¶ 5; *see also* Kahler Declaration, attached hereto as Exhibit 6, at ¶¶ 6-14; *see also* Lane-Savage Declaration, attached hereto as Exhibit 7, at ¶ 5; *see also* Grogan Declaration attached hereto as Exhibit 8, at ¶ 6.

Also, manuals and other service information documents often are provided by OEMs via electronic media, sometimes as data files installed on the medical systems or devices. Hence, servicing activities require 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**”).¹⁰

While this switch to reliance on software conceptually does not pose an issue, 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 from repairing, diagnosing, and maintaining the medical systems and devices they own or lease by restricting or denying access to necessary electronic service materials installed in the medical equipment or otherwise provided via electronic media.¹¹

Additionally, electronic servicing materials, although not stored within the medical systems or devices, may be stored on other electronic media where access is prevented or hindered by TPMs, *e.g.*, encryption.¹²

The OEMs use the TPMs and the anti-circumvention provision of the DMCA to deter owners, lessee, and their ISO agents from accessing the necessary software by threatening and filing lawsuits. The TPMs are alleged to be “technological measures,” the circumvention of which is allegedly prohibited by the DMCA. While ISOs deny these allegations, the owner and lessee medical centers and ISOs are attuned to these threats. Indeed, as detailed below, the owners and lessees, while wanting to hire ISOs to service their medical equipment, refrain from doing so.

What makes the DMCA anti-circumvention provision so atrocious is its application to the mere “access” to protected works regardless whether the works are actually used or are comingled with unprotectable works.¹³ Wily, OEMs place data files, including error logs, configuration files, and other unprotected works, behind the same TPMs.¹⁴ This results in unprotected works being inaccessible because, in order to access the unprotected works, one must also access protected works (as defined in the DMCA) and therefore risk violating or being accused of violating the DMCA. Thus, by co-mingling protected and unprotected works, OEMs are able to prevent access to unprotected works as well and thwart even the most basic servicing of the medical equipment.¹⁵

The anti-circumvention restrictions of the DMCA have been aggressively invoked by OEMs in various assertions and lawsuits to prevent access to such computer software and data files, with Philips being particularly aggressive. *See, e.g., 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)¹⁶;

¹⁰ Wheeler Decl. at ¶ 17; *see also* Melvin Decl. at ¶ 3.

¹¹ Wheeler Decl. at ¶ 33; *see also* Spencer Decl. at 5; *see also* Melvin Decl. at ¶ 5; *see also* Lane-Savage Decl. at ¶ 10.

¹² Melvin Decl. at ¶ 11; *see also* Kahler Decl. at ¶ 7.

¹³ 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.

¹⁴ Wheeler Decl. at ¶ 20; *see also* Grogan Decl. at ¶ 6; *see also* Lane-Savage Decl. at ¶ 5.

¹⁵ Wheeler Decl. at ¶ 20; *see also* Lane-Savage Decl. at ¶ 3; *see also* Melvin Decl. at ¶ 4.

¹⁶ Exhibit 9

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)¹⁷; *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)¹⁸; *Philips, et al. v. Zetta Med. Techs. LLC, et al*, C.A. No. 17-3425 (N.D. Ill.) (Count III at 18-19)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)²⁰, and *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).²¹ Such frequent invocations of the anti-circumvention provisions of the DMCA show just how acute the issue presented by this petition is. Without the exemption, the OEMs will continue to prevent or unduly hinder lawful servicing activities by owners, lessees, and their ISO agents on medical systems and devices by threatening or taking legal action.

As noted below, servicing activities can legitimately be performed by owners (including refurbishers such as Petitioner), lessees, and their ISO agents, and do not need to be performed by OEMs. But, again, to perform these activities, it is necessary to access the computer software, data files, and electronic service materials necessary for performing these servicing activities.²²

Additionally, many owners have older equipment that OEMs no longer support because the OEMs have deemed the equipment to have reached end of commercial life, and hence the equipment is considered obsolete. As a result, the OEMs do not provide renewed access codes and keys; or the access codes and keys are obsolete, damaged, or malfunctioning, so that they cannot be disabled and, therefore, owners are prevented from accessing the computer software and data files needed for servicing activities. However, with proper servicing by owners or ISOs, such systems can still function well and continue to be used, thus saving healthcare providers significant sums of money.²³

In order to ensure that the critical servicing activities required for medical equipment continues, an exemption from the anti-circumvention provision of the DMCA is needed to eliminate an unintended impediment to the servicing of medical equipment. This will allow owners, lessees and ISOs hired by owners and lessees, to diagnose, repair, and maintain medical systems and devices that employ TPMs to deny or restrict access to the computer software, or modules thereof,²⁴ data files, and manuals used for controlling operation or functions of the medical equipment, or which store information pertaining to the medical equipment, but which are necessary for conducting servicing activities.²⁵ The proposed exemption will enable timely and

¹⁷ Exhibit 10

¹⁸ Exhibit 11

¹⁹ Exhibit 12

²⁰ Exhibit 13

²¹ Exhibit 14

²² Melvin Decl. at ¶ 8; *see also* Kahler Decl. at ¶ 7; *see also* Grogan Decl. at ¶ 5.

²³ Wheeler Decl. at ¶ 30; *see also* Kahler Decl. at ¶ 16; *see also* Melvin Decl. at ¶ 8; *see also* Lane-Savage Decl. at ¶ 15.

²⁴ Some medical systems, such as medical imaging systems, are controlled by software packages only a portion of which are necessary for performing servicing activities. This portion can comprise one or more discrete applications or one or more modules of a larger integrated computer program. The one or more modules may be invocable by a larger already running computer program, or as branches within an already running integrated program.

²⁵ That the computer software and data files used for servicing activities are copyright protected works currently is in dispute in various courts. *See, e.g., Philips Medical Systems Nederland B.V. et al. v. TEC Holdings, Inc. et al.*,

efficient diagnosis and maintenance of medical systems and devices to improve their functionality, and to ensure compliance with manufacturer and regulatory specifications.

This exemption builds on the following previously-granted exemptions:

- The 2018 exemption for “*Computer programs that are contained in and control the functioning of a lawfully acquired motorized land vehicle such as a personal automobile, commercial vehicle, or mechanized agricultural vehicle, except for programs accessed through a separate subscription service, when circumvention is a necessary step to allow the diagnosis, repair, or lawful modification of a vehicle function, where such circumvention does not constitute a violation of applicable law, including without limitation regulations promulgated by the Department of Transportation or the Environmental Protection Agency, and is not accomplished for the purpose of gaining unauthorized access to other copyrighted works.*”
- The 2018 exemption for “*Computer programs that are contained in and control the functioning of a lawfully acquired smartphone or home appliance or home system, such as a refrigerator, thermostat, HVAC, or electrical system, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system, and is not accomplished for the purpose of gaining access to other copyrighted works.*”
- The 2015 exemption for “*Computer programs that are contained in and control the functioning of a motorized land vehicle such as a personal automobile, commercial motor vehicle or mechanized agricultural vehicle, except for computer programs primarily designed for the control of telematics or entertainment systems for such vehicle, when circumvention is a necessary step undertaken by the authorized owner of the vehicle to allow the diagnosis, repair or lawful modification of a vehicle function; and where such circumvention does not constitute a violation of applicable law, including without limitation regulations promulgated by the Department of Transportation or the Environmental Protection Agency; and provided, however, that such circumvention is initiated no earlier than 12 months after the effective date of this regulation.*”

ITEM D. TECHNOLOGICAL PROTECTION MEASURE(S) AND METHOD(S) OF CIRCUMVENTION²⁶

Nearly all OEMs that restrict or deny owners and ISOs access to these necessary computer software, data files and manuals use challenge-response TPMs, involving access codes, passwords, keys, digital signatures, or encryption. These TPMs are implemented under the guise that the computer software and data files contain propriety information. Below are several examples of the TPMs OEMs employ.

3:20-cv-00021-MOC-DCK (W.D.N.C.) (alleging Defendants, including Petitioner, infringed Plaintiff’s copyrighted works by servicing its X-ray systems, and violated the DMCA anti-circumvention provisions by bypassing TPMs to gain unauthorized access to Plaintiff’s alleged copyrighted works).

²⁶ Just as in fn. 1 Petitioner does not admit 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), Petitioner does admit that any particular method of circumvention discussed herein constitutes a prohibited circumvention under the DMCA.

Philips imaging systems employ a Field System Framework that provides multiple levels of access to a system. Philips imaging systems employ an access key dongle (“Access Key”), in the form of a flash drive, that attaches to a computer port and, allegedly, must be present to run software and to identify the access level of a user. The Access Key must be “recharged” through Philips every 30 days. When a user attaches his or her Access Key to a system, the software provides the user with access only to the computer software and data files that Philips, in its sole discretion, allows. Philips alone controls the active status of an Access Key and, thus, controls at will when an Access Key will work.²⁷ However, the limited subset of computer software, data files, and manuals to which Philips provides access to owners and ISOs does not allow Petitioner and other ISOs to perform the full gamut of authorized servicing activities necessary to ensure that a given medical system can operate safely and conforms to manufacturing and regulatory specifications.

Notably, even AIAT material (discussed below), which the FDA mandates must be freely available to ISOs such as Petitioner, requires access via the Field System Framework. And, to obtain a key to obtain the lowest level of access to this information, one must first register with Philips. General Electric (“GE”) also uses a dongle in the form of a flash drive on which is stored a passcode or license key.²⁸ Like the Philips dongles, a GE dongle contains a license key which is read by the servicing software to determine if access is to be permitted, and to what degree access is permitted.

Siemens provides a 256-bit passcode in the form of a hexadecimal string that is entered into the servicing software system that then determines if access is permitted, and to what level.²⁹

Other OEMs, including Nihon Kodan, Spacelabs, and Welch Allyn do not provide software access to parties who are not employees of customers, for monitors and modules.³⁰

Dräger and Penlon also manufacture certain medical equipment that require access codes in the form of passwords to access the software embedded in the machines.³¹

Several ultrasound devices from various OEMs, including GE, Philips, Siemens, Toshiba, and Samsung, restrict or limit access to embedded servicing software with the use of TPMs. Examples of the ultrasound devices that use TPMs to restrict or limit access to software include the Logiq E9, Vivid E9, Vivid E95, Logiq E10, Vivid IQ, Logiq E, Logiq I, Vivid I, Vivid E, Voluson I, Voluson E, Voluson S Series, Voluson E6/8, and Voluson E10 Series from GE; the Epiq, Affiniti, CX50, iU22, iE33, HD- Series, and Volcano IVUS models from Philips; all of the S – Series models, the SC2000, and New Sequoia models from Siemens, and the Aplio300/500 and i800 models from Toshiba.³²

These TPMs can be bypassed in several ways, some of which are discussed below.

²⁷ See, e.g., *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.), Second Amended Complaint, ¶¶ 43-47. See also Lane-Savage Decl. at ¶ 11.

²⁸ Wheeler Decl. at ¶¶ 21, 25; Spencer Decl. at ¶ 5.

²⁹ Wheeler Decl. at ¶ 21.

³⁰ See Peloso Declaration, attached hereto as Exhibit 15, at ¶ 15.

³¹ Spencer Decl. at ¶ 5.

³² Peloso Decl. at ¶ 3-4.

Presumably without implicating the anti-trafficking provisions of the DMCA, dongles can be cloned. The Internet has many sites that explain how to do so or that offer to do it for a fee.³³

Also without implicating the anti-trafficking provisions of the DMCA, as noted above, the servicing software on many, if not all large OEM machines runs in an operating system such as Microsoft Windows® or Unix. The servicing software is run under a special user account. It is possible to access the user account management of the operating system using the administrator account and simply “blank out” the password for the special user account (*i.e.*, set it to null), thereby eliminating the need for a password altogether.³⁴

Yet further without implicating the anti-trafficking provisions of the DMCA, time consuming, brute force passcode tools can be used to determine a passcode that will unlock access. Such tools are available via the Internet.³⁵

And yet further without implicating the anti-trafficking provisions of the DMCA, a dongle or passcode can be obtained from an alternative source such as borrowed either from some medical provider clients or a co-worker.

Petitioner also notes that there are websites that advertise that they can generate passcodes. These sites appear to have reverse engineered the passcode generating algorithms. *See, e.g.*, www.service-password.com (offering service passwords for use with CT and MRI scanners manufactured by Siemens, Philips, GE, Toshiba, and Ultrasonix).³⁶ A purchaser’s purchase and use of such a passcode would seem to not implicate the anti-trafficking provisions of the DMCA. Petitioner does not offer an opinion herein.

And, an imperfect action that might be undertaken in the face of lack of access to the electronic service materials, is to rely on experience and device behavior.³⁷ The resulting diagnosis, while informed by experience, is of course, just a guess.

ITEM E. ASSERTED ADVERSE EFFECTS ON NONINFRINGING USES

The adverse effects of the DMCA anti-circumvention provision are varied. Those affected include medical equipment owners and lessees, ISOs, hospital patients, and taxpayers.³⁸

Without circumvention, owners and lessees are forced to pay inflated prices for OEM service calls and sufficient access. The cost for such access runs \$20,000.00 to 25,000.00 USD per year per device, or \$2,500.00 to \$5,000.00 USD per event and device. OEMs typically charge 30% to 50% more for service calls than ISOs.³⁹ Without the competition of ISOs, OEMs will see no

³³ *See, e.g.*, <https://www.donglify.net/>. *See, also*, the results of a simple search at Exhibit 16.

³⁴ *See, e.g.*, <https://www.raymond.cc/blog/change-xp-administrator-password-without-knowing-it/>; *see also*, https://answers.microsoft.com/en-us/windows/forum/windows_10-security-winpc/how-to-change-local-standard-account-password/e226df9a-f9df-4ae4-bed3-f529cfe7a7f3; *see also*, <https://www.cyberciti.biz/faq/linux-set-change-password-how-to/>; *see also*, <https://www.howtogeek.com/howto/windows-vista/change-your-forgotten-windows-password-with-the-linux-system-rescue-cd/>.

³⁵ *See, e.g.*, <https://www.softwaretestinghelp.com/password-cracker-tools/>

³⁶ Exhibit 17.

³⁷ Peloso Decl. at ¶8; Lane-Savage Decl. at ¶22.

³⁸ *See, e.g.*, Peloso Decl. at ¶¶ 9-10; *see also* Lane-Savage Decl. at ¶ 21; *see also* Kahler Decl. at ¶ 10.

³⁹ Melvin Decl. at ¶ 6 .

reason to lower their prices or provide prompter service. Further, without sufficient access by owner in-house service departments, troubleshooting or diagnosis of machine faults can take days or weeks instead of hours, preventing more rapid service.⁴⁰

Without circumvention, ISOs are being driven out of the medical equipment servicing market altogether. The OEMs enjoy a large share of the servicing market, and that share continues to grow.⁴¹ OEMs can and do refuse to provide ISOs with sufficient access to electronic service software and materials, which often are the only tools that can be used to service the equipment.

Taxpayers and patients are affected because the costs for the access keys and higher service charges by OEMs are then passed on to them as part of the overhead covered by the medical provider's fees.⁴²

Patients surely are also severely affected by delayed servicing caused by an inability of owners and ISOs to troubleshoot malfunctioning equipment.⁴³ Long service times caused by the need to wait for an OEM to send a technician with a key, lead to rescheduling of procedures and appointments. Consequently, patients' frustration with rescheduling due to unnecessary and avoidable delays are expressed in patient reporting, which is reported to the Centers for Medicare & Medicaid Services (CMS) through the Hospital Outpatient Quality Reporting Program ("Hospital OQR Program") under a mandate by the Tax Relief and Health Care Act of 2016.⁴⁴ Under the Hospital OQR Program, hospitals have a financial incentive high patient reporting.

Additionally, the TPMs are used to block access to unprotected works such as configuration files, service logs, error logs, and the like.⁴⁵ For example, as discussed below in Section 1 ("Fair Use"), purely functional materials such as service and error logs and configuration files are placed behind the TPMs.⁴⁶ Thus, the TPMs adversely prevent access to and use of unprotected works which should be freely available to the owners and lessees of medical equipment.

Patient safety also is affected. The longer necessary medical equipment remains out of service, the longer patients are denied the benefit of that equipment.⁴⁷ In facilities where there is little or no redundancy of equipment, for example a smaller rural hospital or clinic, surely that can translate into a lack of medical services dependent on that equipment. Delayed medical services in turn can lead to exasperated illness or even death. Also, rather than waiting for a delayed

⁴⁰ Melvin Decl. at ¶ 7; *see also*, Lane-Savage Decl. at ¶¶ 13-14.

⁴¹ *See, e.g.*, Medical Equipment Maintenance Market Report - Forecast to 2023 *available at* <https://www.marketsandmarkets.com/Market-Reports/medical-equipment-maintenance-market-69695102.html> (defining, describing, and forecasting the medical equipment repair market size based on device type, service type, service provider, end user, and region; stating that the medical equipment maintenance market is project to reach USD 74.49 billion by 2023 from USD 28.97 billion in 2018 and noting that OEMs are "expected to dominate market") provided herein as Exhibit 18.

⁴² Kahler Decl. at ¶ 16; *see also* Lane-Savage Decl. at ¶ 21

⁴³ Lane-Savage Decl. at ¶¶ 15-16; *see, e.g.*, Peloso Decl. at ¶ 10.

⁴⁴ *See, e.g.*, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalOutpatientQualityReportingProgram> provided hereto as Exhibit 19; *see also* Lane-Savage at ¶ 23.

⁴⁵ Peloso Decl. at ¶ 5; *see also*, Melvin Decl. at ¶ 5; *see also* Grogan Decl. at ¶ 6; *see also* Kahler Decl. at ¶ 6; *see also* Lane-Savage Decl. at ¶ 5.

⁴⁶ Wheeler Decl. at ¶¶ 14, 33; *see also* Melvin Decl. at ¶ 5; *see also* Kahler Decl. at ¶¶ 6-14; *see also* Lane-Savage Decl. at ¶ 5; *see also* Grogan Decl. at ¶ 6.

⁴⁷ Lane-Savage Decl. at ¶ 17.

troubleshooting of the medical equipment (when a clinical technician could instead readily access the error logs), medical personnel are prone to retry use of the equipment to confirm that the equipment is malfunctioning.⁴⁸ Thus, for example, if an error occurs partway through an X-ray scan, the patient might get rescanned, thereby being subjected to extra X-ray dosing.⁴⁹

In that regard, restrictions placed on the repair of medical devices is a risk to public safety.⁵⁰ Particularly at the height of the COVID-19 pandemic, repair and maintenance issues have increased on essential medical devices like ventilators.⁵¹ Providing access to repair medical equipment safely and efficiently is a matter of life and death.⁵²

More specifically, medical systems and devices play a pivotal role in the screening and diagnosis of COVID-19. For example, reverse-transcription polymerase chain reaction (RT-PCR), which is an essential tool for medical laboratories, and chest computerized tomography (CT) are used as diagnostic tests for COVID-19.⁵³ Additionally, chest X-ray machines are integral to the treatment of COVID-19 positive patients and the study of the long-term effects. Given the ubiquitous nature of COVID-19, there exists a need for hospitals, medical schools, and other medical providers to allow unfettered diagnosis, repair, and maintenance of these life-saving tools without having to wait for the limited resources of the OEMs.⁵⁴

In an area where properly functioning machines can literally be a matter of life and death to patients, hospital and other machine owners need as many quality options as possible to keep the machines functioning properly. Petitioner's business model as an ISO, as well as the business models of other ISOs, is dependent upon the ability to quickly and efficiently respond to service requests from these owners and lessees, which significantly enhances patient safety.⁵⁵ As noted

⁴⁸ Kahler Decl. at ¶ 13.

⁴⁹ *Id.*

⁵⁰ 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") provided herein as Exhibit 20; see also Lane-Savage Decl. at ¶ 15-18; see also Peloso Decl. at ¶ 10

⁵¹ See, e.g., Lauren Goode, Right-to-Repair Groups Fire Shots at Medical Device Manufacturers, *Wired*, available at <https://www.wired.com/story/right-to-repair-medical-equipment-ifixit/> (May 19, 2020) ("COVID-19 has exposed not only our biological vulnerabilities but also our structural, society, and political shortcomings. Producing, procuring, and distributing all kinds of medical equipment is a complicated labyrinth outside of a pandemic; within the context of a global pandemic, every move or maneuver has the potential for more dire consequences.") provided herein as Exhibit 21; see also Lane-Savage Decl. at ¶ 18.

⁵² See 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.") provided herein as Exhibit 22; see also ¶ Peloso Decl. at ¶ 16-17.

⁵³ See Tao Ai, et al., *Correlation of Chest CT and RT-PCR Testing for Coronavirus Disease 2019 (COVID-19) in China: A Report of 1014 Cases*, 296 *Radiology* E32-E40 (Aug. 2020); see also Youxin Wang, et al., *Combination of CT and RT-PCR in screening and diagnosis of COVID-19*, 10 *J. Global Health* 1-3 (June 2020) provided herein as Exhibits 23-24, respectively.

⁵⁴ Peloso Decl. at ¶¶ 16-18; see also Lane-Savage Decl. at ¶ 15; see also Melvin Decl. at ¶ 7; see also Kahler Decl. at ¶ 15.

⁵⁵ See 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> (provided herein as Exhibit 25); see also Peloso Decl. at ¶¶ 11-13.

above, without the exemption, OEMs will continue to hamper, if not outright prohibit, the legitimate service and maintenance activities of medical equipment, devices, and imaging systems by owners, lessees, and ISOs. And, even if certain limited access is provided by OEMs, it is provided at undue expense in time and money and is lacking essential information and capabilities required for proper maintenance. In short, failure to provide this exemption will continue to allow OEMs to improperly harm legitimate competition and cause unnecessary death or injury to countless patients by using TPMs to block access to portions of customer-owned medical devices needed to repair and maintain such devices in the field.

The Copyright Office’s Earlier Policy Studies

In two policy studies, the Copyright Office previously considered the core issues this petition raises. In 2016, the Copyright Office considered the issues in connection with software enabled consumer products. *See*, U.S. Copyright Office, Software-Enabled Consumer Products (2016), <https://www.copyright.gov/policy/software/software-ful-report.pdf> (“**Software Study**”). In 2017, the Registrar considered the issues in connection with its policy review of Section 1201. 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> (“**1201 Report**”).

In the Software Study, the Office considered how to allow repair of and tinkering with consumer products with software. The Office recognized that repair activities are often protected from infringement claims by multiple copyright law provisions, including the fair use doctrine and Section 117.⁵⁶

In the 1201 Report, the Office examined statutory exemptions to permit circumvention to fix obsolete, damaged, or malfunctioning TPMs, to engage in diagnosis, maintenance, and repair of a device protected by a TPM, noting that software has become central to the repair of many devices.⁵⁷ The 1201 Report noted The Repair Ass’n & iFixit comments that the “‘use of electronic locks that prevent repair’ are really ‘about protecting the competitive position of the manufacturers for repair services’ and outside the purpose of copyright.”⁵⁸ . The Office concluded that:

... a properly-tailored exemption for repair activities could alleviate concerns regarding section 1201’s effect on consumers’ ability to engage in legitimate activities that did not previously implicate copyright law, without creating a material risk of harm to the market for or value of copyrighted works. As discussed above, virtually 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.⁵⁹

⁵⁶ *See* Software Study at 33, 39-41, which is provided herein as Exhibit 26.

⁵⁷ *See* 1201 Study at 88.

⁵⁸ *Id.* at 89

⁵⁹ *Id.* at 92.

Other Policy Considerations

ISOs like Petitioner and OEMs are required to comply with safety or regulatory requirements set by the Food and Drug Administration (“**FDA**”).⁶⁰

The FDA’s authority to regulate the servicing of medical devices by any entity, including ISOs, is grounded in the agency’s authority to regulate medical devices and radiation-emitting electronic products under the Federal Food, Drug, and Cosmetic Act (“**FD&C**”). Notably, the FDA has concluded that third-party service providers such as Petitioner and other ISOs “provide high quality, safe, and effective servicing of medical devices.” *See*, 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>. *See also*, Conor Hale, FDA Passes On Setting New Regulations For Medical Device Servicing, Fierce Biotech, (Published May 17, 2018; Last Accessed July 20, 2020) *available at* <https://www.fiercebiotech.com/medtech/fda-passes-setting-new-regulations-for-medical-device-servicing>) (describing the FDA’s decision not to require formal regulatory action, including obligatory registration and reporting of adverse events, of third party service providers of medical devices despite the Medical Imaging and Technology Alliances’ urging Congress to pass legislation that would require the same).⁶¹

The FDA specifically recognizes and provides for third party servicing of medical imaging devices. The FDA refers to this as AIAT (assembly, installation, adjustment, and testing) servicing activities of medical imaging equipment.⁶² Per the FDA, “**assembly**” refers to fitting together the parts or pieces of a component or system; “**installation**” refers to setting up for use by verifying that proper assembly and adjustments were made to assure compliance with federal performance specification; “**adjustment**” refers to bringing various component parts up to a true or more effective relative position for performance purposes; and “**testing**” refers to critical examination, observation, or observation of such conditions and operations through procedures provided by the manufacturer that will prove the unit meets specifications.⁶³

Manufacturers of ionizing radiation emitting medical imaging systems are subject to information disclosure obligations by the FDA so that AIAT servicers or other interested parties may obtain, upon request, information regarding the assembly, installation, adjustment, and testing of a medical imaging system to ensure it meets federal performance standards. To that end, the FDA requires at 21 C.F.R. § 1020.30(g) that:

Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions

⁶⁰ The FDA is required to protect the public health from unnecessary exposure to electronic product radiation by, among other things, requiring that electronic products meet performance standards. *See* Section 532 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360ii. The standards for ionizing radiation emitting devices are set forth at 21 C.F.R. § 1020. The standards for ionizing radiation emitting medical imaging devices are set forth at 21 C.F.R. §§ 1020.30-1020.33.

⁶¹ Attached herein as Exhibit 27.

⁶² *See* 21 C.F.R. § 1020.

⁶³ *See* Guidance Document--*Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems - Guidance for Industry and FDA Staff* (September 2003), *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/information-disclosure-manufacturers-assemblers-diagnostic-x-ray-systems-guidance-industry-and-fda>. Attached herein as Exhibit 28.

for assembly, installation, adjustment, and testing of such components adequate to assure that the products will comply with applicable provisions of this section and §§ 1020.31 [Radiographic equipment], 1020.32 [Fluoroscopic equipment], and 1020.33 [Computed tomography (CT) equipment], when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible.

Bundling of AIAT information with allegedly other proprietary software does not relieve an OEM from having to readily disclose the AIAT information. The aforementioned FDA Guidelines are quite explicit on this point: “Some manufacturers bundle AIAT information covered by § 1020.30(g) with other types of proprietary software; in some instances the proprietary software cannot be deleted from the bundled information. Nothing in § 1020.30 prohibits bundling software information or programs; however, the practice does not relieve manufacturers of their responsibilities under the performance standard to provide AIAT documentation or the AIAT software at cost.” Moreover, the FDA regulations further provide that “[t]he owner of a diagnostic X-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this section or of 1020.31, 1020.32, or 1020.33.”⁶⁴ However, as noted above, the OEMs still place the unprotected AIAT material behind TPMs, thereby forcing owners, lessees, and ISOs to go through cumbersome, time consuming and unnecessarily expensive procedures to gain access to this information. Further, OEMs often fail or refuse to classify all relevant software and information as AIAT information.

The Proposed Exemption is for Noninfringing Uses⁶⁵

The execution of computer programs and access to related data files and manuals by owners of medical systems and devices, or those acting at their behest, such as ISOs, for the purpose of diagnosing, repairing, or maintaining their systems and devices, does not constitute copyright infringement for at least three reasons. First, such activities constitute fair use under 17 U.S.C. § 107. Second, such activities are exempted from infringement as an essential step in the utilization of a computer program in conjunction with a machine under 17 U.S.C. § 117 (a)(1). Third, such activities are exempted as permitted machine maintenance and repair under 17 U.S.C. § 117(c).

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.⁶⁶ :

⁶⁴ See 21 C.F.R. § 1020.30(q)(2).

⁶⁵ Petitioner is engaged in litigation with Philips and the arguments expressed herein should not be construed or interpreted as limiting arguments that may be applicable to that litigation depending on the specific facts and laws at issue in the pending action(s).

⁶⁶ See 17 U.S.C. § 107

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

In prior and current exemptions, the Librarian has recognized the fair use of computer programs for the diagnosis, repair, and modification of motorized land vehicles both in 2015 and 2018 for many of the same reasons Petitioner relies upon. In 2018, the Librarian also recognized the fair use of computer programs for the maintenance and repair of appliances.⁶⁷

(9) Computer programs that are contained in and control the functioning of a lawfully acquired motorized land vehicle such as a personal automobile, commercial vehicle, or mechanized agricultural vehicle, except for programs accessed through a separate subscription service, when circumvention is a necessary step to allow the diagnosis, repair, or lawful modification of a vehicle function, where such circumvention does not constitute a violation of applicable law, including without limitation regulations promulgated by the Department of Transportation or the Environmental Protection Agency, and is not accomplished for the purpose of gaining unauthorized access to other copyrighted works.

(10) Computer programs that are contained in and control the functioning of a lawfully acquired smartphone or home appliance or home system, such as a refrigerator, thermostat, HVAC, or electrical system, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system, and is not accomplished for the purpose of gaining access to other copyrighted works. For purposes of this paragraph (b)(10):

(i) The “maintenance” of a device or system is the servicing of the device or system in order to make it work in accordance with its original specifications and any changes to those specifications authorized for that device or system; and

(ii) The “repair” of a device or system is the restoring of the device or system to the state of working in accordance with its original specifications and any changes to those specifications authorized for that device or system.

The 2015 Recommendation of the Registrar of Copyrights for Rule Making: Sixth Triennial Proceeding to Determine Exemptions on the Prohibition on Circumvention (Oct. 2015) (“**2015 Recommendation**”) and the 2018 Recommendation of the Acting Registrar of Copyrights for Rule Making: Seventh Triennial Proceeding to Determine Exemptions on the Prohibition on

⁶⁷ See 37 C.F.R. § 201.40(b)(9) & (10)

Circumvention (Oct. 2018) (“**2018 Recommendation**”)⁶⁸ contain extensive discussions of these factors in the contexts of ECUs for land motor vehicles and software for appliances and other devices.

The 2018 Recommendation is particularly instructive.

With respect to the first factor, the purpose and character of the use of the computer programs and data files by or on behalf of an owner is clear. The computer programs and data files are used to either (i) assemble and install their new systems and devices, or (ii) repair and maintain their existing systems and devices.

From page 203 of the 2018 Recommendation (footnotes omitted):

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.

With respect to medical systems and devices generally, it is equally true that “repair supports—rather than displaces—the purpose of the embedded programs.” The systems and devices continue to be useful after repair and provide the intended functions in a safe and reliable manner. Further, it ensures patient and medical personnel safety and well-being. Indeed, it can be the difference between life and death for some individuals.

With respect to diagnostic X-ray systems in particular, as noted above, those systems are subject to information disclosure obligations so that AIAT servicers or other interested parties may obtain, upon request, information regarding the assembly, installation, adjustment, and testing of an X-ray system to ensure it meets federal performance standards.⁶⁹ In its guidance for compliance with this rule, the FDA requires that when OEMs supply the AIAT information in the system software, that software must be made available to those performing AIAT servicing activities. Moreover, the federal regulations further provide that “[t]he owner of a diagnostic X-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this section or of 1020.31, 1020.32, or 1020.33.”⁷⁰ Thus, the first factor weighs in favor of fair use.

⁶⁸ Attached herein as Exhibit 29.

⁶⁹ 21 C.F.R. § 1020.30(g).

⁷⁰ 21 C.F.R. § 1020.30(q)(2).

Regarding the second factor, the nature of the computer programs and data files involved is that they are entirely functional or essentially functional works used to control operation of the systems and the diagnosis, repair, and maintenance of the systems. They are used to support operation, mechanical, and electronic processes of the medical systems. If computer programs and data files are expressive at all, the expressiveness is *de minimis*. For example, error logs are computer files containing lists of noted faults that occur during use of a medical device. Event logs are lists of other non-fault events, such as tasks computer calls and internet connections, to name two. Configuration files simply have set up the configuration of the machine at a very base level. For the sake of argument, while such files do not express any human creativity or, to the extent thin copyright protection may be warranted, the equipment owner, such as a hospital, owns these automatically generated files.⁷¹ The equipment owner requires access to such programs and files for maintenance and repair. There is no conceptual difference between these types of computer programs and data files and those used, *e.g.*, in modern-day land-based vehicles or appliances. The manuals are technical and contain data, namely information of the functions of the systems or devices and the operating specifications. These are not novels or highly creative works. The creativity, if any, is *de minimis*. Thus, the second factor weighs in favor of fair use for the same reasons the Office articulated in the 2018 Recommendation.

Regarding the third factor, it is necessary, *i.e.*, required, 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. As noted above, the machines are, for all intents and purposes, specialized computers in which the software is inseparable from the hardware and the machines cannot function without the computer programs and data files. The servicing computer programs and data files involved can be but a small portion of the entire software package used to operate and service the medical imaging system and are integrated into the machine. For instance, the software on a Philips Allura system comprises various modules used to control different portions of the system or to perform different functions, only some of which are involved in the servicing activities. In the Allura software, the Field Service Framework and associated service logs are invoked for servicing of an X-ray diagnostic system. Simply put, no “copies” of the Allura code—or even portions of the code—are ever made other than what is necessarily executed when using the particular customer-owned machine. Moreover, any “copies” of service logs should not constitute infringement.

Further, manuals are needed to understand the manufacturers specifications for the systems and devices, and to correctly identify replacement parts. With this understanding, an owner or its agent can ensure the medical system or device is operating safely and in compliance with the specifications. Thus, the third factor also weighs in favor of a finding of fair use.

Regarding the fourth factor, the effect of the use upon the potential market for or value of the copyrighted work is minimal.⁷² The computer programs and data files are necessary for the

⁷¹ See *Lexmark International, Inc. v. Static Control Components, Inc.*, 387 F.3d 522, 536 (6th Cir. 2004) (configuration files and lock-out codes generally “fall on the functional-side 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.”)

⁷² Although OEMs will argue that their investments in computer software enable them to better serve customers, this is not so. According to the FDA Report conducted in 2018, twenty-nine complaints alleged inadequate servicing by OEMs in addition to others that complained about OEMs not providing service manuals, not providing critical

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 medical 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.⁷³

The electronic manuals merely provide technical information. They too have no value or use other than to provide information for the servicing of the systems and devices. Moreover, manuals used to be provided freely by OEMs and thus have a demonstrated neutral effect on the market.

The value to OEMs is in the TPMs that restrict access to the computer programs and data files. The value is not in the computer programs or data files themselves. That is to say, the computer programs and data files must be included for anyone to operate or perform any servicing activities on the systems and devices, given the replacement of electrical and mechanical parts by software-based components. There is no need to otherwise copy or access the computer programs and data files. But, as recognized in the 1201 Study, the TPMs allow the OEMs to maintain a monopoly or near monopoly on the servicing of the systems and devices they sell because they can control the equipment even after its sale.

Because the use by ISOs does not affect the market for or value of the computer programs and data files involved, the fourth factor also weighs in favor of a finding of fair use.

2. Use is an Essential Step under 17 U.S.C. § 117(a)(1)

Congress exempted from infringement certain executions of computer programs in connection with the repair and maintenance of machines.

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.

Access, use and/or adaptation of the computer programs and data files embedded in medical equipment is undeniably an essential step in the servicing and repair activities associated with the medical equipment and in maintaining the usefulness of the systems and devices. As mentioned above, the software is integrated into and is inseparable from the machines if the machines are to operate. Owners, including refurbishers like Petitioner, pay substantial consideration in

replacement parts, providing poor technician training, knowingly falsifying service records and device serial numbers, and conducting repairs using broken replacement parts. *See* 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>.

⁷³ Wheeler Decl. at ¶ 35.

exchange for ownership of medical equipment (*i.e.*, hardware) that invariably includes—due to the complex nature of modern medical systems—software embedded within the equipment. The equipment is useless without the software embedded by the OEMs. 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. But licenses are only for the intellectual property rights. The copies of the software are included as part of the purchase of the machines. Accordingly, the equipment owners are “owners” of copies of computer programs copies of which are “created as an essential step in the use of the computer program in conjunction with a machine,” and “used in no other manner.”⁷⁴ To conduct repair and maintenance of the medical equipment they own, hospitals and other medical care providers, and ISOs like Petitioner, use the computer software embedded in the medical equipment as an essential step in the utilization of the equipment in order to repair, diagnose, and maintain the equipment. Thus, use of the servicing computer programs and data files is exempt from infringement under Section 117.

Petitioner and ISOs like it are lawful possessors of diagnostic medical equipment, and the right of possession to the hardware they own is perpetual. That some OEMs may claim they only “license” the software is not relevant.⁷⁵ Licensing is a concept relating only to intellectual property rights. Thus, the “licensing” is only relevant to how an OEM attempts to control use of the software. It does not control who owns the copy of the software on a machine, which is included in purchase of the machine. Additionally, and because use of the software is an essential step in the use of the machine, as explained above, Section 117 provides an exception as to any controls attempted by the licensing terms.

⁷⁴ See, e.g., *Krause v. Titleserv, Inc.*, 402 F.3d 119 (2nd 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 (2nd 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 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).

⁷⁵ See e.g., 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.”); Compare, e.g., *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.), Second Amended Complaint, ¶ 33 (alleging that when Philips sells medical equipment, “the agreement establishes that the presence of Proprietary Service Materials will not give the customer any right or title to such property or any license or other rights to access or use such property”).

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

Congress exempted from infringement certain executions of computer programs in connection with the repair and maintenance of machines.

Title 17 U.S.C. §117 (c) provides:

(c) 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 the servicing activities, it is necessary to activate the central controlling computer to operate the various components of the medical system or device, and simply to obtain diagnosis information. When performing the servicing activities, the diagnostic and testing modules are used to diagnose the operating conditions and to determine if the system or device is performing according to specifications. Data files such as event logs and error logs may be opened to diagnose system or device issues, confirm operating information, or to otherwise update servicing information for proper record keeping. Configuration files may be reviewed for proper configuration of the machines.

Following a servicing activity, except for any updated data reflecting servicing information, the computer programs and data files are left in their original condition. There are no copies to be destroyed. However, deactivation or reactivation of the medical imaging systems will automatically “destroy” any “new” copy of the modules and data files. Thus, use of the servicing computer programs and data files is exempt from infringement under Section 117.

ISOs Working at the Direction of the Owners and Lessees Should Not be Excluded From the Exemption

In its 2018 Recommendation for making the exemptions for land vehicles and appliances noted above, the Copyright Office specifically declined to exclude third party assistance and declined to include language that the circumvention be “undertaken by the authorized owner.”⁷⁶ The proposed exemption for servicing materials for medical devices is similarly fashioned and will enable owners and lessees who do not have the ability to service their medical equipment or skills and equipment to circumvent TPMs. This would be in concert with the Office’s 2018

⁷⁶ Section 1201 Rulemaking: Seventh Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention (“**2018 Recommendation**”) at 224-225.

position that in future rulemakings it would “seek to avoid recommending unduly narrow definitions of exemption beneficiaries.”⁷⁷ Further, the proposed exemption is easily understood that it would apply to the extent it does not implicate the anti-trafficking provisions Section 1201(a)(2) as it would be limited to circumvention where such circumvention does not constitute a violation of any other applicable law.

Conclusion

For all of the reasons set forth above, the Librarian should determine that the non-infringing uses described above are, and are likely to be, adversely affected by the anti-circumvention prohibitions of Section 1201(a), and therefore approve the proposed exemptions for the period 2021-2024.

DOCUMENTARY EVIDENCE

Copies of the Exhibits referred to in this comment, including declarations, are attached hereto.

⁷⁷ Section 1201 Report at 62.