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UNITED STATES COPYRIGHT OFFICE



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

Please submit a separate comment for each proposed class.

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

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

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

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

ITEM A. COMMENTER INFORMATION

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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.

Philips is well known in the healthcare industry as a trusted provider of electronic medical imaging devices for use in in-patient and outpatient hospital care throughout the United States. Philips' high quality products include ultrasound systems, computed tomography ("CT") scanners, positron emission tomography ("PET") scanners, X-ray machines, magnetic resonance ("MR") scanners, and nuclear medicine scanners. Importantly for this process, Philips supports, maintains, repairs and services these medical imaging devices using authorized repair technicians who know the devices and are regulated by statute, through oversight provided by the Food and Drug Administration ("FDA"). Building on years of innovation, Philips' medical devices are highly sophisticated and relied upon by medical professionals for diagnosis, treatment, and life-saving support of patient lives.

Given their complexity and the necessity that they operate precisely as designed, the FDA's regulations extend to every aspect of the medical devices, including their maintenance and repair, to protect the public health and safety. Philips' supervision of its authorized repair technicians complies with and furthers these paramount regulatory goals. For purposes of device repair, access to Philips' copyrighted software on medical devices is protected so that the functionality and integrity of the devices is maintained.

The Proponents of proposed exemption Class 12 fit into two categories. The first group is comprised of multiple organizations – such as the Electronic Frontier Foundation – that petition for new or expanded exemptions relating to diagnosis, repair, and modification of software-enabled devices, generally, or types of software-enabled devices that bear no relation to medical devices. The second group is comprised of two organizations – Summit Imaging, Inc. and Transtate Equipment Co., Inc. – that separately petition for an exemption allowing circumvention of technological protection measures ("TPMs") for purposes of diagnosis, modification, and repair of *medical devices*, specifically.

While the former category of Proponents seek an overbroad exemption of almost limitless scope, the latter category of Proponents have purely commercial motivations. They seek to circumvent Philips' and other medical device manufacturers' access controls in order to obtain copyrighted materials far in excess of that which is necessary to perform basic repair or maintenance. The granting of the exemption they seek would improperly allow them to circumvent Philips' security measures to access Philips' copyright-protected software installed on its medical devices. It also would threaten the functionality, integrity, safety and security of Philips' and other OEMs' medical devices by compromising the devices and making them susceptible to hacking by cybercriminals and other threat actors (i.e., a result antithetical to the longstanding efforts of OEMs and a host of federal agencies that work aggressively to reduce the threat of cybersecurity to medical devices).

With respect to the medical devices involved here, the proposed exemptions do not build off prior exemptions in any colorable respect. No prior exemptions have involved FDA-regulated devices implicating public health and safety. No prior exemptions have been sought for commercial purposes or facilitated the copying of protected software and information unnecessary to equipment repair. None of these results, moreover, align with the purpose or goals of the exemption process.

Finally, there is no demonstrable non-commercial need for the proposed exemptions. Philips does not prevent access to any of its devices for purposes of basic repairs with copyright assertions. There likewise is no real, or even imagined, repair market crisis for the devices. Rather, as the FDA has concluded, the repair market, on analysis, appears to be adequately served by independent and licensed repair personnel.

Philips accordingly submits the following comments in opposition to proposed exemption Class 12.

ITEM B. PROPOSED CLASS ADDRESSED

Proposed Class 12: Computer Programs – Repair

Philips' comments in opposition are specifically made with respect to the petitions for an exemption that would allow circumvention of technological protection measures ("TPMs") for purposes of diagnosis, modification, and repair of medical devices.

ITEM C. OVERVIEW

Philips is a well-known leader in the business of developing, manufacturing, selling, supporting, maintaining, and servicing medical imaging systems used at hospitals and medical centers. Philips medical imaging systems include Philips' proprietary hardware and software, encompassing Philips' trade secrets, which are necessary to operate, service, and repair Philips' systems. Philips' proprietary software enables certain functions on Philips medical imaging systems, which can only be modified by Philips, thereby allowing Philips to control, update, and track the use of its medical device software in the marketplace. Philips' high quality products and proprietary software have made Philips a trusted producer, manufacturer, and supplier of medical imaging systems worldwide.

In particular, Philips medical imaging systems include Philips' copyrighted software that Philips technicians can use to service the equipment. Philips includes access controls – described in greater detail below – on its medical imaging systems to protect its copyright-protected software and to restrict access to its proprietary software to authorized personnel. Its proprietary Philips' Integrated Security Tool is a suite of applications designed to secure Philips' Customer Service Intellectual Property—including Philips' copyrighted documents, service software, and other proprietary information created for the purpose of servicing Philips' products—from unauthorized access or use. The Proponents seek to circumvent these access controls.

As noted above, the Proponents fit into two categories. The first group is comprised of several organizations – such as the Electronic Frontier Foundation – that petition for new or expanded exemptions relating to diagnosis, repair, and modification of software-enabled devices, generally. Such a request is facially impermissible, as it is overly broad and fails to account for any of the unique characteristics of medical devices. The Registrar previously has declined to consider broad categories of devices grouped together, and has instead considered each class of device on an incremental, case-by-case basis.¹ Since the breadth of device categories

¹ See Section 1201 Rulemaking: Seventh Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation Of The Register Of Copyrights (Oct. 2018) ("2018 Recommendation") 191-92.

encompassed by proposed exemption Class 12 is exceedingly broad, and the circumvention of access controls on certain devices (such as medical devices) carry significant ramifications, Philips strongly believes that the Copyright Office should decline any invitation to consider software-enabled devices as a general class.

The second group is comprised of two organizations – Summit Imaging, Inc. and Transtate Equipment Co., Inc. – who separately seek an exemption allowing circumvention of TPMs for purposes of diagnosis, modification, and repair of medical devices, specifically. But their motivations are commercially driven and their request should have no place in the Triennial Rulemaking Process. Summit and Transtate (and other ISOs) already have access to extensive documentation and software sufficient to perform basic servicing of Philips medical imaging systems.² They simply want *more* access; and they have a track record of circumventing Philips' access controls – without an exemption – for their own commercial gain. Summit and Transtate, as they admit, are defendants in ongoing litigation in which Philips has alleged DMCA violations against both companies due to their having modified files on Philips' systems to gain unauthorized access to Philips' copyrighted software and files that they cannot access with their legitimate repair and maintenance accounts.³ Since Summit and Transtate seek to use the exemption process to achieve their purely commercial ends and facilitate their unlawful conduct, their request for an exemption should be rejected summarily.

Finally, as explained below, proponents of a petitioned exemption carry a significant evidentiary burden. To establish a case for an exemption, “proponents must show *at a minimum* (1) that uses affected by the prohibition on circumvention *are or are likely to be noninfringing*; and (2) that as a result of a technological measure controlling access to a copyrighted work, the prohibition is causing, or in the next three years is likely to cause, an *adverse impact* on those uses.”⁴ As the following sections demonstrate, Proponents have not met that burden, and their requested exemptions should be denied for this independent reason.

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

Describe the technological protection measure(s) that control access to the work and the relevant method(s) of circumvention. It would be most helpful to the Office if sufficient information is provided to allow the Office to understand the nature and basic operation of the relevant technologies, as well as how they are disabled or bypassed.

² Letter from Mary S. Pastel, Sc.D., Deputy Director for Radiological Health, Food & Drug Administration, to Gail M. Rodriguez Ph.D., Executive Director, Medical Imaging & Technology Alliance 2 (Jan. 30, 2014), <https://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM385149.pdf> (“[T]here are limits on the information that 21 CFR 1020.30(g) and 21 CFR 1020.30(h) require the manufacturer of the original system to provide. The manufacturer of the original system is not required to disclose trade secrets or confidential information. Also, the manufacturer of the original system may provide the user or its own service personnel with additional documentation or enhanced software programs, with privileged access codes. This additional documentation or enhanced software programs may operate in conjunction with other proprietary accessories or functions.”)

³ See, e.g., *Philips Med Sys. Nederland B.V. et al. v. TEC Holdings, Inc. et al.*, No. 3:20-cv-00021-MOC-DCK (W.D.N.C.) and *Philips N. Am. LLC et al. v. Summit Imaging Inc. et al.*, No. 2:19-cv-01745-JLR (W.D. Wash.).

⁴ Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 83 Fed. Reg. 54,010, 54,011 (Oct. 26, 2018).

Philips' Integrated Security Tool ("IST") is a suite of applications designed to secure Philips' Customer Service Intellectual Property ("CSIP"), including documents, service software, and other proprietary information created by Philips for servicing Philips Healthcare products, from unauthorized access or use.⁵ Philips' IST solution provides a mechanism to manage user entitlements to access CSIP. Individual users may register with Philips to open an IST account. A Philips IST administrator then assigns entitlements to the user's account specifying the CSIP materials the user can access. Users may then install Philips IST client on their personal computer and request Philips to issue an encrypted IST certificate to enable the user to access Philips' proprietary CSIP information. Upon receiving such a request, Philips' IST system generates a user-specific and computer-specific encrypted IST certificate with information including the user's entitlements and sends the certificate to the user.⁶ The user can then use his or her IST certificate and password to access CSIP materials Philips authorizes the user to access.

In the United States, Philips provides an account with CSIP Level 0 entitlements at cost to anyone who requests such an account. CSIP Level 0 entitlements provides access to materials that Philips makes available upon request to comply with regulatory requirements as well as other basic service documentation and software.⁷ Philips provides CSIP Level 1 entitlements to customers who have a current contract that provides CSIP Level 1 access and have received any requisite training.⁸ Philips provides CSIP Level 2 entitlements to its employees and to certain trade partners under contract.⁹

Philips' IST solution uses multi-factor authentication to confirm that only authorized users can access Philips' proprietary CSIP materials. For example, to access Philips' proprietary CSIP materials on a medical imaging system, a user must present his or her IST certificate and password to the system.¹⁰ If the user has the correct password, the system will decrypt the certificate and provide the user with access to software and files according to the entitlements in the user's certificate.¹¹ Thus, engineers employed by independent service providers may log into Philips' medical imaging systems with their IST certificates and have complete access to Philips' CSIP Level 0 materials. They cannot, however, access the software and files that Philips reserves for its licensees or its own employees. Licensees with CSIP Level 1 access can log into Philips medical imaging systems with their IST certificates and they will receive access to additional CSIP materials, but not materials that Philips reserves for only its employees or trade partners. Philips employees and trade partners with CSIP Level 2 access receive even greater access to specialized service tools and files.¹²

Through their Philips-issued accounts, the vast majority of the thousands of ISOs in the U.S. have sufficient access to service Philips' medical imaging systems. Philips provides ISOs with access to the CSIP Level 0 materials that allow them to setup and service Philips' medical

⁵ Declaration of Jacqueline Dickson, attached hereto as Exhibit A, at ¶ 6.

⁶ *Id.*

⁷ *Id.* at ¶ 3.

⁸ *Id.* at ¶¶ 4, 8.

⁹ *Id.* at ¶¶ 5, 9.

¹⁰ *Id.* at ¶ 10.

¹¹ *Id.*

¹² *See id.*

imaging systems, but restricts them from accessing more advanced unlicensed features and service functionalities.¹³

Nevertheless, through its policing efforts, Philips has learned of a few ISOs that use methods to circumvent Philips' IST multi-factor authentication security to gain unauthorized access to Philips' copyrighted CSIP materials. The specific methods used by those ISOs vary, but their circumvention methods achieve a common result of providing the ISOs with unlicensed access to Philips' copyrighted software. The ISOs use that unlicensed access to sell advanced services for Philips' medical imaging systems. Philips has pending lawsuits against several ISOs that circumvent Philips' access controls to gain unauthorized access to its copyrighted CSIP. For example, Robert A. Wheeler, the CEO of Transtate Equipment Company, developed exploit software that Transtate uses to modify files within Philips medical imaging systems to effectively disable their access controls and allow Transtate employees to gain access unlicensed access to Philips' copyrighted materials.¹⁴ Summit Imaging developed a different software program designed to circumvent Philips' access controls and provide unauthorized access to Philips' proprietary copyright protected software within Philips medical imaging systems.¹⁵

ITEM E. ASSERTED ADVERSE EFFECTS ON NONINFRINGEMENT USES

I. No Exemption is Permissible Because The Uses Are Not Noninfringing

A. Legal Standards

Section 1201(a)(1)(A) of the Digital Millennium Copyright Act provides that “No person shall circumvent a technological measure that effectively controls access to a work protected under this rule.” The Register will recommend granting an exemption *only when* the “preponderance of the evidence in the record shows that the conditions for granting an exemption have been met.”¹⁶ Such evidence must show that it is “*more likely than not* that users of a copyrighted work will, in the succeeding three-year period, be adversely affected by the prohibition on circumvention in their ability to make *noninfringing uses* of a particular class of copyrighted works.” *Id.* at 112 (emphasis added).

To establish a case for an exemption, “proponents must show *at a minimum* (1) that uses affected by the prohibition on circumvention *are or are likely to be noninfringing*; and (2) that as a result of a technological measure controlling access to a copyrighted work, the prohibition is causing, or in the next three years is likely to cause, an *adverse impact* on those uses.”¹⁷ More particularly, “[i]t is not enough that a particular use *could be* noninfringing. Rather, the Register

¹³ *Id.* at ¶ 7.

¹⁴ Second Amended Complaint at ¶¶ 59-65, *Philips Med. Sys. Nederland B.V.*, No. 3:20-cv-00021-MOC-DCK (May 23, 2019), ECF No. 139.

¹⁵ Third Amended Complaint at ¶¶ 6, 40-44, *Philips N. Am. LLC*, No. 2:19-cv-01745-JLR (Dec. 28, 2020), ECF No. 99.

¹⁶ U.S. Copyright Office, Section 1201 of Title 17 at 111 (June 2017), <https://www.copyright.gov/policy/1201/section-1201-full-report.pdf>.

¹⁷ Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 83 Fed. Reg. at 54,011.

will assess whether the use is *likely to be* noninfringing based on current law.”¹⁸ “There is no ‘rule of doubt’ favoring an exemption when it is unclear that a particular use is noninfringing.” *Id.*

B. The Requested Uses Do Not Satisfy the “Fair Use” Test of 17 U.S.C. § 107

Proponents of proposed exemption Class 12 argue—by conclusion only—that the petitioned uses are likely to be noninfringing under 17 U.S.C. § 107 (fair use). These conclusory contentions are, however, unsubstantiated and flawed.

In determining whether the use of a copyrighted work is likely to be a noninfringing “fair use” under 17 U.S.C. § 1201, the Register considers: (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. On balance, these factors weigh conclusively against the proposed Class 12 exemption for medical devices.

i. The Purpose and Character of the Requested Use Weighs Against an Exemption

The first factor in the fair use analysis – the purpose and character of the use – evaluates whether the use is of a commercial nature or is for nonprofit educational purposes, and examines “to what extent the new work is transformative” and does not simply “supplant” the original work.¹⁹ “Commercial use of copyrighted material is *presumptively* an *unfair* exploitation of the monopoly privilege that belongs to the owner of the copyright.”²⁰ This factor unquestionably weighs against Proponents.

Here, the requested uses under Class 12 with respect to medical devices are purely commercial and are thus “presumptively . . . unfair.”²¹ Both Transtate Equipment Company, Inc. d/b/a/ Avante Diagnostic Imaging (“Transtate”) and Summit Imaging, Inc. (“Summit”) are independent service providers (“ISOs”) who seek to circumvent the access controls installed on Philips’ medical devices for purely commercial (i.e., business) purposes. That is, Transtate’s and Summit’s motivations are financial, plain and simple. Their businesses stand to profit from an exemption that would allow them to circumvent Philips’ and other medical device manufacturers’ access controls that protect the integrity and security of their medical devices. But the Triennial Rulemaking Process is not a means of regulating competitive markets or promoting commercial outcomes. Nor should the Triennial Rulemaking Process

¹⁸ U.S. Copyright Office, “The Triennial Rulemaking Process for Section 1201,” at 6, https://cdn.loc.gov/copyright/1201/1201_rulemaking_slides.pdf (last visited Feb. 5, 2021) (emphasis added).

¹⁹ *Mattel Inc. v. Walking Mountain Prods.*, 353 F.3d 792, 800 (9th Cir. 2003) (quoting *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 579 (1994)).

²⁰ *Disney Enters., Inc. v. VidAngel, Inc.*, 224 F.Supp.3d 957, 972 (C.D. Cal. 2016) (quoting *Leadsinger, Inc. v. BMG Music Publ’g*, 512 F.3d 522, 530 (9th Cir. 2008) (citing *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 451 (1984)) (emphasis added).

²¹ See *Leadsinger*, 512 F.3d at 530 (quoting *Sony Corp.*, 464 U.S. at 451).

be used as a means of promoting unlawful conduct or avoiding liability for past unlawful conduct – the other motivations underlying Transtate’s and Summit’s unfair use.

Transtate indicates in its comments in support of proposed exemption Class 12 “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.”²² But there is more to the story of what motivated Transtate’s and Summit’s petitions for an exemption: both companies – along with several others – are defendants in ongoing federal litigation in which they have been accused of violating the anti-circumvention provisions of the DMCA.²³ Because the requested uses of copyrighted material are commercial – and thus, presumptively *unfair* – and because the requested uses would not transform the copyrighted material, the first “fair use” factor weighs conclusively against Proponents.²⁴

ii. The Nature of the Original Work Weighs Against an Exemption

The second factor in the fair use analysis – the nature of the copyrighted work – evaluates the “value of the materials used.”²⁵ In relation to the other fair use factors, some federal courts have recognized that this second factor is relatively insignificant in the overall balancing analysis.²⁶ In the specific context of medical devices, however, this factor weighs just as heavily against Proponents.

Philips’ IST – i.e., the access controls installed on Philips’ medical devices – is designed to secure Philips’ CSIP, including documents, service software, and other proprietary information created by Philips for servicing Philips Healthcare products from unauthorized access or use. Philips’ copyrighted service software is complex, highly expressive content designed to protect the integrity and efficacy of Philips’ life-saving medical devices.

Although the Copyright Office has previously found access controls on video games to be primarily functional, and some aspects of telematics software on motorized land vehicles to

²² Transtate Class 12 Comments at 4.

²³ See, e.g., *Philips Med Sys. Nederland B.V.* No. 3:20-cv-00021-MOC-DCK; *Philips Med. Sys. Puerto Rico, Inc., et al v. Alpha Biomedical and Diagnostic Corp.*, No. 3:19-cv-01488-BJM (D.P.R.); *Philips N. Am. LLC et al. v. 626 Holdings, LLC et al.*, No. 9:19-cv-81263 RS (S.D. Fla.); *Philips Med. Sys. (Cleveland), Inc., et al. v. Zetta Med. Techs. LLC, et al.*, No. 1:17-cv-03425 (N.D. Ill.); *Philips N. Am. LLC v. KPI Healthcare Inc.*, No. 8:19-cv-01765-JVS-JDE (C.D. Cal.), and *Philips N. Am. LLC* No. 2:19-cv-01745-JLR.

²⁴ See *Campbell.*, 510 U.S. at 569, 579 (recognizing that in addressing the first factor of the “fair use” test, one considers “whether the new work merely ‘supersedes the objects’ of the original creation, . . . or instead adds something new, with a further purpose or different character . . . [;] in other words, whether and to what extent the new work is ‘transformative.’” (brackets and citations omitted)).

²⁵ *Campbell*, 510 U.S. at 586 (quoting *Folsom v. Marsh*, 9 F.Cas. 342, 348 (C.C.D. Mass. 1841)).

²⁶ *Oracle Am., Inc. v. Google LLC*, 886 F.3d 1179, 1205 (Fed. Cir. 2018) (Federal Circuit noting that the “Ninth Circuit has recognized . . . that this second factor ‘typically has not been terribly significant in the overall fair use balancing.’”) (quoting *Dr. Seuss Enters., L.P. v. Penguin Books USA, Inc.*, 109 F.3d 1394, 1402 (9th Cir. 1997)); see also *Fox News Network, LLC v. TVEyes, Inc.*, 883 F.3d 169, 178 (2d Cir. 2018) (“This factor ‘has rarely played a significant role in the determination of a fair use dispute,’ and it plays no significant role here.”) (quoting *Authors Guild v. Google, Inc.*, 804 F.3d 202, 220 (2d Cir. 2015)).

be functional, the service software designed by OEMs and installed on medical devices are of comparatively much higher value and complexity and invoke patient safety and information security concerns. That is because with their medical devices, OEMs make every decision about service software – from the types to create, to the functions it will perform, to its design and implementation.

Controls restricting access to such proprietary software are essential to preserving the functionality, integrity, safety and security of those devices. Without them, the sophisticated and complex medical devices involved are unsecure, susceptible to alteration, a loss of data, or availability, and vulnerable to hacking and misuse. In the specific context of health care, in which patient lives often depend upon the safety and efficacy of medical devices – some of which are designed for implantation in the human body – the OEM developed software on a device is fundamental and inextricably tied to the value of the device itself.

iii. The Amount and Substantiality of the Portion Used in Relation to the Copyrighted Work as a Whole Weighs Against an Exemption

The third factor in the fair use analysis – the amount and substantiality of the portion used in relation to the copyrighted work as a whole – evaluates “both the quantity of the work taken and the quality and importance of the portion taken.”²⁷ “[T]his factor calls for thought not only about the quantity of the materials used, but about their quality and importance, too.”²⁸ This factor also weighs decidedly against Proponents.

First, Philips uses multiple layers of technological controls to protect its copyright-protected works from unauthorized access. These controls include user specific access codes and hardware keys, which enable the software access and control features for a particular user. These user-specific access controls permit access to enabled Philips tools and features based on a user’s registered access authorization level. Philips provides ISOs with access to Philips’ copyrighted software and information necessary for basic repair and maintenance of medical imaging systems. By circumventing Philips’ access controls, ISOs gain unauthorized access to Philips’ copyrighted advanced service software. ISOs then copy and use those *entire copyrighted* works to service Philips systems more efficiently or modify Philips systems for commercial gain.

Second, Philips’ ability to control access to its copyrighted software not only provides Philips with a means of protecting its valuable intellectual property, but it also protects the public from the dangers associated with modification or alteration of Philips’ medical devices by unauthorized or insufficiently trained users. Unlimited access to Philips’ copyrighted software would allow untrained—and unregulated—individuals to make unauthorized changes to Philips’ medical devices, potentially rendering the devices ineffective or unavailable for clinical use or dangerous when used. That is, the requested exemption not only would open attempts to repair or modify medical devices without device-specific training, but circumvention of the access controls would essentially give such ISOs unfettered access Philips’ *entire copyrighted* works, as well as other proprietary information within the medical devices.

²⁷ *Disney Enters.*, 224 F.Supp.3d at 973 (citing *Campbell*, 510 U.S. at 586).

²⁸ *Campbell*, 510 U.S. at 587.

Third, as discussed more fully in Section E(I)(B)(iii) below, Philips already provides domestic ISOs with extensive documentation and software that enables them to perform basic servicing of Philips' medical imaging systems, including documentation and software required by relevant FDA regulations.²⁹ This information enables ISOs, including Transtate and Summit, to perform repair and maintenance on Philips' medical devices. Neither Transtate nor Summit have explained – much less provided evidence – showing why it would be necessary to circumvent Philips' security access controls in order to perform repair and maintenance on Philips' devices. By comparison, allowing them unfettered access to enhance their business objectives would defeat the lawful copyright protection properly afforded to Philips' operating software and create safety and security risks that are avoided without the exemption.

Given that the requested exemption would give ISOs access to information that goes well beyond that which would be necessary for repair and maintenance, and would effectively grant ISOs access to the medical device manufacturers' entire copyrighted works and other proprietary information and trade secrets contained in the medical devices for purely commercial use, the third "fair use" factor weighs just as heavily against an exemption as the first two.

iv. The Effect of the Requested Use Upon the Potential Market for or Value of the Copyrighted Work Weighs Against an Exemption

The fourth factor in the fair use analysis – the effect of the use upon the potential market for or value of the copyrighted work – requires the Office to consider "not only the extent of market harm caused by the particular actions of the alleged infringer, but also 'whether unrestricted and widespread conduct of the sort engaged in by the [user] . . . would result in a substantially adverse impact on the potential market. . . .'"³⁰ At least one federal circuit court of appeals has held that when "the intended use is for commercial gain," the likelihood of market harm "may be presumed."³¹ Here, as to Transtate and Summit, there is no question that the requested exemption as applied to medical devices is sought for commercial purposes, and thus, market harm will result.

Circumvention of access controls on Philips' and other medical devices is of significant commercial value because it permits ISOs to modify such medical devices, and to attempt to provide maintenance and support services (without appropriate training or regulatory oversight) on such devices. Moreover, allowing untrained and unregulated third parties unfettered access to make modifications to such devices could result in improper operation, lack of reliability, or potentially even safety or hacking risks, all of which would create market harm for the medical devices, including their copyrighted software.

v. Fair Use Summary

On analysis, each fair use factor plainly tips against granting the proposed Class 12 exemption and, when taken together, an analysis of those factors compels that the proposed exemption should be rejected. The factorial analysis must weigh strongly in favor for an

²⁹ See, e.g., 21 C.F.R. § 1020.30.

³⁰ *Campbell*, 510 U.S. at 590 (citation omitted).

³¹ *Leadsinger*, 512 F.3d at 531 (quoting *Sony*, 464 U.S. at 451).

exemption to be granted. Whatever else might be said, that is not the case for proposed Class 12 as related to the medical devices addressed by these comments.

C. The Uses Do Not Fall Under the Exception for Essential Steps in the Utilization of a Computer Program

Proponents assert, in a conclusory manner, that their intended uses are protected by 17 U.S.C. § 117(a)(1). That provision permits “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 the 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.” *Id.* Proponents cannot meet the requirements set forth in this provision.

First, it is well established that Section 117(a)(1) shelters only those who *own* the copy of the computer program—not mere licensees of the copy. Federal courts have explained that one is a licensee rather than a user—and thus unprotected by Section 117(a)(1)—if the copyright owner “(1) specifies that the user is granted a license; (2) significantly restricts the user’s ability to transfer the software; and (3) imposes notable use’ restrictions.”³² In that regard, courts have held that facts demonstrating that a customer is a licensee include (1) the copyright owner’s retention of title in the software and grant of a non-exclusive license,³³ (2) the imposition of transfer restrictions on the licensed software,³⁴ (3) the imposition of use restrictions specifying ways in which the software must (or cannot) be used,³⁵ (4) the ability of the copyright owner to terminate the license,³⁶ and (5) the requirement that the customer destroy or relinquish copies of the software upon termination.³⁷ All of these factors are present here, and demonstrate that Philips’ customers are licensees, not owners, of the software Proponents seek to access.

Specifically, Philips’ standard terms and conditions of sale for all medical imaging products makes explicit that: (1) Philips grants only a “nonexclusive and non-transferable right and license to use the computer software” and that Philips retains “exclusive ownership” of the software;³⁸ (2) the Customer is restricted in its ability to transfer the software and give access to the software;³⁹ (3) the Customer is restricted in how it may use the software, including being prohibited from using the software on any devices other than the device it comes with or for any purposes other than the operation of that device;⁴⁰ (4) Philips retains the ability to terminate the

³² *MDY Indus., LLC v. Blizzard Entm’t, Inc.*, 629 F.3d 928, 938 (9th Cir. 2010) (quoting *Vernor v. Autodesk, Inc.*, 621 F.3d 1102, 1111 (9th Cir. 2010)); *see also Vernor*, 621 F.3d at 1110-11; *Universal Instruments Corp. v. Micro Sys. Eng’g, Inc.*, 924 F.3d 32, 44-45 (2d Cir. 2019).

³³ *MDY Indus.*, 629 F.3d at 938; *Vernor*, 621 F.3d at 1111.

³⁴ *MDY Indus.*, 629 F.3d at 938; *Vernor*, 621 F.3d at 1111.

³⁵ *MDY Indus.*, 629 F.3d at 938-39; *Vernor*, 621 F.3d at 1111.

³⁶ *MDY Indus.*, 629 F.3d at 939; *Vernor*, 621 F.3d at 1112.

³⁷ *MDY Indus.*, 629 F.3d at 939; *Universal Instruments*, 924 F.3d at 45.

³⁸ Philips Standard Terms and Conditions of Sale (Nov. 2020), Licensed Software, §§ 1.1, 1.3, <https://www.usa.philips.com/c-dam/b2bhc/us/terms-conditions/philips-standard-terms-and-conditions-of-sale-all-products-112420.pdf>.

³⁹ *Id.* §§ 1.2, 1.4; *see also id.*, Philips Proprietary Service Materials, § 9.1.

⁴⁰ *Id.*, Licensed Software, §§ 1.2, 1.5; *see also id.* § 2.2 (requiring the Customer to maintain the configuration of the device as it was originally designed and manufactured).

license if the Customer does not comply with the terms and conditions of sale;⁴¹ and (5) the Customer must “return the Licensed Software and any authorized copies thereof to Philips immediately upon expiration or termination of this License.”⁴² As a result, controlling law dictates that Section 117(a)(1) is unavailable to Proponents, and their efforts to amend what Section 117 otherwise requires through this process should be rejected.

By the same token, the Registrar previously has applied these principles in rejecting proposed exemptions. For instance, the Registrar has concluded that motor vehicle telematics and entertainment system software was licensed rather than owned by the vehicle owner, thus failing to qualify for Section 117(a)(1).⁴³ And the Registrar has emphasized that the question of ownership is a fact-intensive one requiring consideration on a case-by-case basis—yet another reason the generalized, overbroad exemption sought by proponents like EFF should be rejected.⁴⁴

Second, section 117(a)(1) is applicable only if the copy of the computer program “is created as an essential step in the utilization of the computer program in conjunction with a machine.” Proponents cannot satisfy this requirement either. There is, of course, clinical software installed on the devices and licensed by Philips that is necessary to use the device.⁴⁵ But it is not that software that proponents seek an exemption to access. Rather, proponents seek to go *beyond* that software and instead access additional, unlicensed software—or unlicensed service functionalities—that has not been purchased by the device purchaser.⁴⁶ Because none of *that* software is necessary to use the devices in their standard configurations, section 117(a)(1) does not shelter Proponents.

D. The Uses Do Not Fall Under The Exception for Machine Maintenance and Repair

Proponents claim protection under 17 U.S.C. § 117(c), which provides that “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.” The copy must be used in no other manner and destroyed immediately after the completion of the maintenance or repair, and any portion of the program not necessary for the activation of the machine cannot be accessed or used.⁴⁷ Contrary to Proponents’ arguments, this exception has no application here.

Congress’ purpose in passing Section 117(c) was to ensure that servicers “do not inadvertently become liable for copyright infringement merely because they have turned on a machine in order to service its hardware components.”⁴⁸ And Congress was clear that this

⁴¹ *Id.* § 1.1.

⁴² *Id.*

⁴³ 2018 Recommendation at 201.

⁴⁴ 2018 Recommendation at 200, 209.

⁴⁵ Declaration of Jacqueline Dickson, Ex. A, at ¶ 11.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Storage Tech. Corp. v. Custom Hardware Eng’g & Consulting, Inc.*, 421 F.3d 1307, 1311-12 (Fed. Cir. 2005) (quoting H.R. Rep. No. 105-551, pt. 1, at 27 (1998)).

exception is narrow; only software actually “necessary for the machine to be activated”—that is, software that “needs to be so loaded in order for the machine to be turned on”—qualifies for the exception.⁴⁹ For this reason, the Federal Circuit has held that “[a]ccessing software programs, such as freestanding diagnosis and utility programs, that are not needed to boot up the [machine]... , goes too far because access to those programs is not strictly necessary to verify that the [machine] is ‘working in accordance with its original specifications.’”⁵⁰ Proponents, however, seek to do exactly that.

The software that Summit and Transtate seek to copy are additional, unlicensed software and unlicensed service functionalities. But as explained in Part I(C), *supra*, none of this software is necessary to activate the machine, and thus by definition cannot be copied “solely by virtue of the activation of a machine.”⁵¹ To the contrary, this software consists of “freestanding...programs, that are not needed to boot up the [machine]”—precisely the sort of software that the Federal Circuit has squarely held to be outside the scope of section 117(c).⁵²

Indeed, Proponents essentially concede the point. Transtate, in making a perfunctory argument that section 117(c) applies, argues only that accessing Philips’ diagnostic and testing software is necessary “[t]o perform the servicing activities.”⁵³ Summit similarly—and also perfunctorily—argues that diagnostic software and data files must be accessed to “perform[] service.”⁵⁴ But the question under section 117(c) is not whether the software is necessary *to perform servicing of the machine*; rather, the only question is whether the software “needs to be so loaded in order for the machine to be turned on.” Proponents do not dispute that the answer to this question is “no.” And that answer is dispositive; section 117(c) does not apply.

II. The Adverse Impact Factors Do Not Support An Exemption Here

The Librarian of Congress, on recommendation of the Register, must determine whether “persons who are users of a copyrighted work are, or are likely to be in the succeeding 3-year period, adversely affected by the prohibition [against circumventing a TPM] in their ability *to make noninfringing uses* ... of a particular class of copyrighted works.” 17 U.S.C. § 1201(1)(C) (emphasis added). As explained above, because Proponents seek to use Philips’ copyrighted works for *infringing* uses, they are barred categorically from using this Triennial Rulemaking Process to obtain an exemption for their conduct.

Apart from that, Section 1201(1)(C) sets out five factors for the Librarian to consider in determining whether to grant an exemption: (1) “the availability for use of copyrighted works”; (2) “the availability for use of works for nonprofit archival, preservation, and educational purposes;” (3) “the impact that the prohibition on the circumvention of technological measures applied to copyrighted works has on criticism, comment, news reporting, teaching, scholarship, or research”; (4) “the effect of circumvention of technological measures on the market for or

⁴⁹ *Id.* at 1314 (quoting H.R. Rep. No. 105-551, pt. 1, at 28) (brackets omitted).

⁵⁰ *Id.* (quoting 17 U.S.C. § 117(d)).

⁵¹ 17 U.S.C. § 117(c).

⁵² *Storage Tech.*, 421 F.3d at 1314.

⁵³ Transtate Class 12 Comments at 20.

⁵⁴ Summit Class 12 Comments at 8.

value of copyrighted works”; and (5) “such other factors as the Librarian considers appropriate.” *Id.* All five of these factors demonstrate that the proposed exemption should be rejected.

A. The Availability for Use of Copyrighted Works

Proponents argue that owners of medical devices are currently unable to obtain timely repair and servicing of the devices, necessitating an exemption permitting independent repairers to access copyrighted material to service such devices. But Proponents offer no credible evidence that the market for servicing and repair of medical devices is not adequately served by existing resources. A close look at the issue shows why.

To start with, the 2018 FDA Servicing Report evaluation involving all stakeholders declined to conclude that there was a prevalent health or safety concern presented by the servicing in the medical device market.⁵⁵ That same report noted that there is a robust market for independent servicing of medical devices, with an estimated number of medical device servicing firms numbering between 16,520 and 20,830.⁵⁶ And these independent servicing firms are organized and participate in trade associations such as the International Association of Medical Equipment Remarketers and Servicers (IAMERS).⁵⁷ The COVID crisis has not generated any credible evidence that this has changed so that equipment repairs are not being made or that public health and safety is threatened with respect to lack of servicing of lifesaving or life-enhancing healthcare devices. That lack of evidence is conclusive here.⁵⁸

Going beyond the FDA requirements, Philips provides independent servicers with extensive documentation, software, and instructions sufficient to perform basic servicing of Philips medical imaging systems.⁵⁹ Many of these instructions refer to CSIP Level 0 service software that independent servicers can access with their Philips-issued certificates. The CSIP Level 0 documentation and software—which Philips provides to independent servicers at cost—allows for basic servicing of the systems. Proponents are fully aware of this; indeed, Transtate has an account with Philips to receive and use these materials.⁶⁰ Therefore, the argument that independent servicers are cut off from the repair market is fiction.

The companion argument that the proposed exemption is necessary for independent servicers to perform repair and servicing of medical devices is just as flawed. No exemption is

⁵⁵ U.S. Food and Drug Administration, FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices (May 2018), at i.

⁵⁶ *Id.* at 19.

⁵⁷ See International Association of Medical Equipment Remarketers and Servicers, “IAMERS Campaigning for Healthcare Providers Right to Choose,” <https://iamers.org/> (last visited Feb. 8, 2021).

⁵⁸ Proponents offer a few isolated and undocumented incidents where delays allegedly occurred in obtaining OEM servicing. Philips, for its part, has no record of any reduction in service capabilities or customer inability to obtain service during the COVID crisis. See Declaration of James Salmons, attached hereto as Exhibit B, at ¶¶ 7-8. Medical device maintenance services were not materially delayed even with customers’ reporting an overall increase in volume of service. *Id.* at ¶ 8. Notably, the handful of incidents identified by Proponents does not establish any *systemic* problem of access to OEM servicing in the marketplace – the only relevant issue for the Copyright Office. Finally, unlike Proponents, the FDA has looked at the marketplace and did not find any systemic evidence of inadequate servicing or repairs for medical devices.

⁵⁹ 21 C.F.R. § 1020.30(g).

⁶⁰ Declaration of Jacqueline Dickson, Ex. A, at ¶ 7.

needed to permit basic repair and servicing of Philips medical devices because Philips already provides independent servicers with all the information they need to conduct such servicing—and will continue to do so, as required by FDA regulations. In fact, Philips routinely acts as a third-party servicer in repairing and servicing non-Philips medical devices—and has always managed to do so perfectly well with the materials made available to all independent servicers, without the circumvention Proponents insist is necessary for third-party servicers to do their jobs.⁶¹ Accordingly, what proponents really seek through this exemption is the ability to go *beyond* essential repair and servicing of the devices and to access additional, copyright-protected options and features for commercial gain.

To that end, the pending litigation against Summit and Transtate revolves around their modification of files on Philips systems to gain unauthorized access to Philips’ proprietary service software and files that they cannot access with their legitimate CSIP Level 0 accounts. They exploit this heightened access for commercial gain by utilizing Philips’ proprietary documents and software to provide services that only Philips and its authorized licensees are permitted to provide. Proponents’ attempt to use the need for repair and servicing as a vehicle to pursue their commercial interests provides no justification for granting this exemption and should not be entertained.

In support of their position, Proponents offer a handful of declarations that existing servicing options cause increased cost and delay. But this meager showing—a handful of declarants claiming that the exemption would lower costs—cannot compete with the clear evidence described above, including FDA conclusions and regulations, that demonstrates otherwise. This is especially true given the heavy burden Proponents bear to establish the appropriateness of the exemption, *see* Part I(A), *supra*. Simply put, there is no market vacuum or crisis requiring this exemption. For these reasons, it is clear that the medical devices at issue here differ fundamentally from other categories of devices that the Registrar previously has found lack adequate servicing through manufacturer-approved channels—such as vehicle telematics systems⁶² and smartphones.⁶³ Proponents have failed to demonstrate that Philips’ copyrighted works will be unavailable to medical device owners unless proponents obtain an exemption allowing them to access Philips’ protected intellectual property. In reality, the opposite is true.

Finally, Proponents press the argument that an exemption is necessary to permit servicing of older equipment that has reached the end of its commercial life and thus does not receive servicing from OEMs.⁶⁴ But Proponents misrepresent the status of this equipment and omit the substantial risks inherent in their proposed exemption.

First of all, there is no reason why “older” and “newer” equipment should be treated differently when it comes to the need to protect proprietary software contained in the devices. As discussed above and below, Philips medical devices contain proprietary software protected by copyright, and Proponents’ attempts to gain access to that software for their own commercial gain (and to the detriment of public safety) through this exemption process is flatly

⁶¹ Declaration of James Salmons, Ex. B, at ¶¶ 3-4.

⁶² 2018 Recommendation at 213-14.

⁶³ 2018 Recommendation at 216.

⁶⁴ Summit Class 12 Comments at 2; Transtate Class 12 Comments at 6.

inappropriate. This remains just as true for “older” devices as it does for “newer” devices, and Proponents cannot show otherwise.

As for certain medical devices that have received an End of Service (EOS) designation from the OEMs, Proponents argue that an exemption is needed to permit independent servicers to repair and service these devices because OEMs will phase out their servicing. But Proponents fail to point out that servicing can be phased out for a variety of reasons, specifically including that the equipment is no longer safe and effective to operate. Apart from that prevalent safety concern, the Proponents’ hypothesized claim of purported service inadequacies related to EOS equipment certainly does not support the categorical exemption Proponents demand for all devices under all circumstances. Finally, Proponents do not provide support for any market-wide problem as related to older equipment either. Without that substantiation, there is no basis to even consider the exemption.

B. The Availability for Use of Works for Nonprofit Archival, Preservation, and Educational Purposes

Proponents advance no argument whatsoever that independent servicers must be permitted to circumvent Philips’ protective measures for purposes of nonprofit archival, preservation, or educational purposes; to the contrary, they seek to use Philips’ software in a commercial setting. Because Proponents bear the burden to establish the propriety of an exemption, their failure to do so here must weigh against them.

The Electronic Frontier Foundation does advance an argument on this factor, claiming that “tinkering is itself educational and is a common path for young people to become interested in studying science and engineering.”⁶⁵ But the Foundation’s arguments are aimed at its desired (and overbroad) exemption for virtually all software-enabled devices.⁶⁶ Whatever the persuasiveness of such arguments in the context of a “smart litterbox,”⁶⁷ they clearly have no application to Philips’ FDA-regulated medical devices. It should go without saying that the “educational” benefits of tinkering with expensive, life-sustaining medical devices cannot justify the enormous accordant risks to human life. This factor therefore does not support the proposed exemption.

C. The Impact that the Prohibition on the Circumvention of Technological Measures Applied to Copyrighted Works Has on Criticism, Comment, News Reporting, Teaching, Scholarship, or Research

Proponents do not argue that prohibiting unauthorized parties from obtaining the copyrighted software in medical devices such as Philips’ unduly hinders free speech, criticism, news reporting, teaching, or research. Again, the Electronic Frontier Foundation advances such an argument for software-enabled devices generally.⁶⁸ But no such argument is made or can

⁶⁵ Electronic Frontier Foundation Class 12 Comments at 16.

⁶⁶ *Id.* at 1-2.

⁶⁷ *Id.* at 22.

⁶⁸ *Id.* at 16.

seriously be made for medical devices. Therefore, this factor weighs against the proposed exemption as well.

D. The Effect of Circumvention of Technological Measures on the Market for or Value of Copyrighted Works

This factor does not support an exemption because the proposed exemption would severely harm the value of Philips' (and other manufacturers') copyrighted works or harm the market for those works. As explained in Part I(B)(iii), *supra*, the access requested by the Proponents is extensive. They seek to give independent servicers full access to the entire copyrighted works and other proprietary information contained within the medical devices. This wholesale invasion of intellectual property rights would destroy the value of those copyrighted works and undermine the incentive for Philips and other OEMs to produce medical devices with their related software in the first instance—an endeavor that requires substantial time and expense as OEMs develop and secure regulatory clearance for medical devices.

The fact that this access is being requested for purely commercial purposes—meaning that the likelihood of market harm “may be presumed,”⁶⁹ Part I(B)(iv), *supra*—further demonstrates that the effect (and perhaps the intention) of the exemption would be to devalue OEMs' intellectual property interests and increase the economic prospects of those seeking to exploit that intellectual property for their own gain. Once again, Proponents cannot demonstrate that this factor supports an exemption; the opposite is true.

E. Such Other Factors as the Librarian Considers Appropriate

Proponents argue that an exemption is warranted—indeed, required—for reasons of public and health and safety. But there is reason to pause on their unsupported assertion. As explained above, *see* Part II(A), Philips already provides enough information and resources to allow independent servicers to repair and service Philips medical devices. The proposed exemption, therefore, cannot be justified by appealing to the health and safety benefits of the servicing activities Proponents are perfectly capable of conducting. Beyond that, permitting this additional access would jeopardize, not protect, health and safety.

Philips, as a manufacturer of medical imaging equipment, is acutely aware of the impact that the proper—or improper—use of sensitive medical equipment has on public health and safety. So is the FDA, which has recognized the serious ramifications for health and safety that this area poses, and which for that reason extensively regulates the medical-device arena. Medical equipment manufacturers, like Philips, are subject to an extensive array of regulations designed to ensure that medical devices consistently meet safety and quality requirements. They are, for instance, subject to registration, listing, premarket notification and approval, quality system, labeling, and reporting requirements.⁷⁰ By comparison, independent servicers are not

⁶⁹ *Leadsinger*, 512 F.3d at 531.

⁷⁰ *See* 21 C.F.R. §§ 801 (labeling), 803 (incident reporting), 807 (registration, listing, and premarket notification), 814 (premarket approval), 820 (quality system regulation). These regulations also extend to the provision of information by OEMs to customers on assembly, installation and adjustment of certain devices to protect their functionality, integrity and availability. The FDA can intervene if the information provided is inadequate. *See* 21

registered, not obligated to make reports, and not subject to regulated quality management systems or product training. Nor are they obligated to keep up with changes in equipment specifications, to use customized diagnostic tools, or to stay up to date on device history.

In addition, approved servicers are extensively regulated and must comply with a host of requirements; independent servicers are not. Approved servicers are trained to service and repair the specific medical device at issue and possess the latest diagnostic tools and device records and histories; independent servicers are not and do not. And approved servicers have up-to-date knowledge of device specifications and compatible products and parts, while independent servicers do not. Proponents' attempts to paint approved servicers—regulated, trained, and licensed to deal with the specific machinery at issue—as equivalent to independent servicers who are not subject to reporting, quality management, or other requirements, and who do not have the latest product knowledge, training, and tools, is wrong.

Beyond that, the profound difference between approved and independent servicers relates directly to the quality of the repairs and the proper functioning of the medical equipment. These concerns are magnified as one moves from the more basic repairs and servicing that independent servicers already conduct to the more advanced modifications and alterations—possible only by using Philips' proprietary tools—that Proponents seek an exemption to conduct. Permitting unapproved servicers to perform these advanced alterations on medical devices could lead to, for example, incomplete equipment records (which OEMs are required to maintain), assembly of the device without the proper tools or parts, a lack of up-to-date product calibration, a lack of ongoing market surveillance (which OEMs conduct), and a failure to report adverse events (which OEMs are required to report). There is no guarantee that the modified medical device will function as originally intended.

Finally, these potential malfunctions have serious ramifications for public health and safety. Improperly modifying life-saving medical equipment could cost human lives. Improper repair of diagnostic and treatment devices could lead to misdiagnoses of patients' conditions, ineffective or counterproductive treatment, and a host of other problems seriously jeopardizing patient health and safety. And circumvention of the access controls that Philips and other OEMs install on their medical devices also renders the devices susceptible to cybersecurity threats that OEMs and several federal agencies already work to protect against. Indeed, the FDA already “works aggressively to reduce cybersecurity risks [to medical devices],” a responsibility it shares with “device manufacturers, hospitals, health care providers, patients, security researchers, and other government agencies, including the U.S. Department of Homeland Security's Cybersecurity & Infrastructure Security Agency (CISA) and U.S. Department of Commerce.”⁷¹ These concerns, which threaten the safety and security of the medical devices upon which human

U.S.C. § 337(a); 21 C.F.R. §§ 10.30(g), (h). These regulations do not require the disclosure of trade secrets and they permit OEMs to provide their own employees with more advanced software.

⁷¹ U.S. Food and Drug Administration, “Medical Device Cybersecurity: What You Need to Know,” <https://www.fda.gov/consumers/consumer-updates/medical-device-cybersecurity-what-you-need-know> (last visited Feb. 5, 2021); *see also* U.S. Food and Drug Administration, “FDA Fact Sheet: The FDA's Role in Medical Device Cybersecurity,” <https://www.fda.gov/media/103696/download> (last visited Feb. 5, 2021).

lives depend, cannot be justified by the exemption’s alleged benefit of saving money on repairs.⁷²

This is precisely why Proponents are wrong to equate the exemptions recommended in the Registrar’s 2018 Recommendation with their proposed exemption here.⁷³ Modifying a medical imaging machine used to diagnose patients in need is not the same as repairing someone’s smartphone. These devices do not exist in the “do it yourself” space, where modification and tinkering carry no collateral consequences except to the device’s owner. The Registrar has emphasized the need to follow an incremental approach that considers each class of device on its own terms, precluding such a comparison between highly different classes of devices.⁷⁴ There is no reason to abandon that approach now. The FDA has considered and analyzed the servicing issues and will continue to do so.⁷⁵ Congress has taken up right-to-repair exemptions, and a comprehensive public debate can be held in that forum. The copyright exemption process should not be used to supplant either the regulatory oversight or broader public debate. There is no “lawful” right to modify the medical devices implicated in this analysis. By statute and under existing case law, the unlicensed copying of OEMs’ proprietary works to perform repairs as championed by Proponents is unlawful, and absent action by Congress it should stay that way.

DOCUMENTARY EVIDENCE

Commenters are encouraged to submit documentary evidence to support their arguments or illustrate pertinent points concerning the proposed exemption. Any such documentary evidence should be attached to this form and uploaded as one document through regulations.gov.

⁷² See Transtate Class 12 Comments at 9-10 (requesting the exemption because it would supposedly lower the cost of repairs and protect the income of independent servicers); Summit Class 12 Comments at 3 (urging the exemption out of concern that manufacturers may charge higher prices for servicing).

⁷³ See Transtate Class 12 Comments at 7.

⁷⁴ 2018 Recommendation at 191-92.

⁷⁵ The FDA’s regulatory oversight is pervasive where medical devices are involved. This includes with respect to Proponents’ rewriting of code (to bypass TPMs) that would be facilitated by the grant of the blanket exemption Proponents seek. The FDA does not directly regulate third-party servicers, which, as noted, creates its own set of security and safety risks in this context. But the FDA does regulate those who, like certain of the Proponents, would seek to rewrite code and place an adulterated system into the stream of commerce. See 21 C.F.R. § 820.3(o), (w) (subjecting to FDA quality-system-regulation requirements those who “significantly change[] the finished device’s performance or safety specifications, or intended use”). These considerations are ignored by Proponents in urging that the exemption purportedly is needed to promote public health and safety. The FDA is unlikely to hold that view.

EXHIBIT A

Declaration of Jacqueline Dickson

Declaration submitted in support of Comments from:

Philips North America, LLC
2000 Minuteman Road
M/S 109
Andover, MA 01810

DECLARATION OF JACQUELINE DICKSON

I, Jacqueline Dickson, hereby declare as follows based on my personal knowledge:

1. I have held the position of Program Manager for Customer Service Intellectual Property Governance with Philips North America, LLC since 2016. In that position, I work with Philips' businesses and markets to ensure that Philips operates in compliance with its customer service intellectual property ("CSIP") policies and strategies. My work also involves CSIP enforcement, including coordinating with security groups to ensure the business takes appropriate actions to secure CSIP and supporting investigations and lawsuits when third parties breach Philips' security to gain unauthorized access to Philips' restricted CSIP materials.

2. Philips' CSIP includes service software, service documentation, training materials, and other proprietary materials that Philips creates for servicing Philips medical imaging systems. Philips assigns CSIP "levels" to these materials to specify those authorized to access the materials.

3. Philips makes its CSIP Level 0 materials available to equipment owners, Independent Service Organizations ("ISOs"), and any other individuals in the United States who request such access. These CSIP materials include materials and service tools that Philips makes available to comply with regulatory requirements (such as 21 CFR 1020.30), as well as other documentation and software for performing basic maintenance and servicing on Philips imaging systems, including manufacturer's specifications for what planned maintenance activities need to be conducted at various intervals.

4. Philips restricts access to its proprietary CSIP Level 1 materials to certain customers who contract for such access, subject to terms and conditions for the use of such materials. Those customers purchase a limited license to use Philips' CSIP materials to service their own Philips imaging systems. CSIP Level 1 materials include certain training materials as well as additional documentation and software to support planned maintenance activities and to execute common corrective maintenance activities.

5. Philips reserves its proprietary CSIP Level 2 materials and tools for only its own employees and limited trade partners, such as subcontractors and manufacturing partners,

pursuant to contractual terms. CSIP Level 2 materials include Philips' internal information about changes to medical imaging systems (some of which may be part of campaigns required by regulatory bodies), as well as advanced training materials, documents, and software for advanced troubleshooting and advanced configuration of imaging systems (such as changes that may impact x-ray dosage).

6. Philips developed its Integrated Security Tool ("IST") solution to secure its CSIP materials. Philips' IST solution provides a mechanism to manage entitlements to access CSIP materials and tools. Individual users may register with Philips to open an IST account. A Philips IST administrator then assigns to each user entitlements that specify the CSIP Materials the user can access, based on the CSIP rules as described above and subject to any pertinent contractual terms. Philips creates an encrypted IST certificate for each user containing various information, including the user's CSIP entitlements. Philips also offers, at cost, IST smartcards that can be used to access CSIP materials on its medical imaging systems in accordance with user entitlements.

7. The default CSIP access level for IST accounts in the United States is CSIP Level 0 access. This includes individuals employed by ISOs, like petitioners Summit Imaging, Inc. and Transtate Equipment Co., Inc. I searched our IST records and observed that individuals from Transtate in fact have created IST accounts with Philips that provide them with CSIP Level 0 entitlements. They can use their existing accounts to access Philips' CSIP Level 0 materials. Summit does not have IST accounts and it appears they have not requested Level 0 access.

8. Philips assigns CSIP Level 1 entitlements to accounts for employees of licensed customers once those employees have satisfied the prerequisites for such access, such as entering into confidentiality agreements and completing any training necessary to safely and effectively use the materials.

9. Philips assigns CSIP Level 2 entitlements primarily to its own employees once they complete necessary training.

10. Philips' IST solution includes an IST client application for installation on a field service engineer's computer. The IST client application requires a user to enter his or her IST certificate password. If the password is entered correctly and the individual has a valid IST certificate on their computer, IST will allow the user to access CSIP materials according to the user's entitlements in the IST certificate. A user with CSIP Level 0 access will be able to read Philips' CSIP Level 0 documents and run Philips CSIP Level 0 software, but would be restricted from accessing any CSIP Level 1 or 2 materials. A user with CSIP Level 1 access will be able to decrypt Philips' CSIP Level 1 documents and run Philips' CSIP level 1 software as well. Both the CSIP Level 0 and 1 users would be unable to decrypt or read Philips' CSIP Level 2 documents or to execute software requiring CSIP Level 2 entitlements. A Philips employee with CSIP Level 2 access would be able to access CSIP Level 0 and 1 materials.

11. Philips' IST solution also includes an IST application that runs on Philips medical imaging systems, including ultrasound systems, computed tomography scanners, positron emission tomography scanners, X-ray machines, magnetic resonance scanners, and nuclear medicine scanners. When started, Philips medical imaging systems load software for clinical use

of the system. To access Philips' field service software and information, a field service engineer may plug an IST smartcard charged with his or her IST certificate into a USB drive on the imaging system, provide his or her certificate password, and then choose to run field service software or access other field service information. The imaging system will then provide the user with access to software and information according to his or her entitlements. A CSIP Level 0 user, such as an ISO employee, would get access to various programs and information that allow them to set up and service Philips medical imaging systems, but restricts them from accessing more advanced unlicensed features and service functionalities. Philips' licensees and employees in turn receive higher levels of access based on their entitlements.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and corrected. Executed on February 5, 2021 in Northfield, Ohio.


Jacqueline Dickson

EXHIBIT B

Declaration of James Salmons

Declaration submitted in support of Comments from:

Philips North America, LLC
2000 Minuteman Road
M/S 109
Andover, MA 01810

DECLARATION OF JAMES SALMONS

I, James Salmons, hereby declare as follows based on my personal knowledge:

1. I have held the position of Head, Global Multivendor Services at Philips North America, LLC since 2019. This includes overseeing Philips' companies AllParts Medical and AGITO Medical.

2. Philips' multivendor services provide vendor-agnostic, multi-modality solutions for maintenance, lifecycle, and performance services for imaging systems and other biomedical assets. Philips multivendor services range from traditional maintenance services to comprehensive solutions that incorporate a portfolio of added capabilities, such as data driven tools to identify equipment usage and replacement opportunities.

3. Philips' multivendor group services medical imaging systems from a variety of Original Equipment Manufacturers ("OEMs"), including systems from GE and Siemens.

4. Philips' multivendor group accesses software and information on systems according to OEM specifications. OEMs typically make service specifications available to Independent Service Organizations ("ISOs"), such as Philips' multivendor group, to enable ISOs to perform authorized services. For example, Siemens makes service documentation and information available through an "Online Library." GE similarly provides a "Customer Documentation Portal" where ISOs can access service documentation and other information.

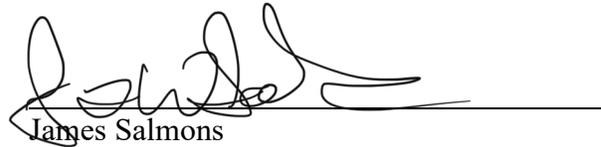
5. If a medical imaging system that Philips' multivendor group is servicing lacks necessary system software or if there is an issue that Philips cannot resolve with its level of access to the OEM's service documentation and software, the customer or Philips will contract the appropriate OEM to acquire the necessary software or access.

6. If Philips cannot acquire authorized access to OEM software or information necessary to perform a particular service on a medical imaging system, then the customer or Philips can contact the appropriate OEM to provide the necessary service.

7. Philips saw no extended reduction in service capabilities or reduction in customers' ability to access maintenance services due to COVID.

8. From the perspective of Philips' multivendor services, medical device maintenance services were not materially delayed due to the COVID crisis. Service companies that we materially supported reported an overall increase in volume of service in 2020. This includes increased activity from Siemens, GE, and major ISOs.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and corrected. Executed on February 8, 2021 in Tennessee.



James Salmons