

**Comments by Philips North America, LLC In Response To
Petitions To Renew DMCA Exemption Relating To Medical Devices**

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I. INTRODUCTION

Proponents’ request for renewal of the 2021 DMCA exemption regarding medical devices is based on the false premise that they are making transformative, fair and benevolent uses of other OEMs’ proprietary software. To the contrary, Proponents are engaged in purely commercial conduct that seeks an unfair advantage through widespread unauthorized use of OEMs’ advanced servicing software, so they can make repairs faster and more profitably. Recent Supreme Court jurisprudence clarifies that the activities supposedly justifying the exemption do not qualify as “fair use.” Accordingly, Philips hereby opposes the petitions to renew the 2021 exemption governing “Computer programs that control medical devices or systems, and related data files, for diagnosis, maintenance, or repair of the device or system.” 37 C.F.R. § 201.40(b)(15).

Specifically, the Supreme Court recently issued its ruling in *Andy Warhol Found. for the Visual Arts, Inc. v. Goldsmith*, 143 S. Ct. 1258 (2023), where it further clarified “fair use” jurisprudence under copyright law. There, the Court confirmed that commercial use of a copyrighted work for the same or highly similar purpose is non-transformative. Here, commercial service organizations seek to use copyrighted service software authored by Original Equipment Manufacturers (“OEMs”) for the *exact same* purpose as it was created by OEMs – to service medical imaging systems. The *Warhol* decision clarifies that such use infringes; it is non-transformative and not fair use under the Copyright Act.

The non-transformative nature of Proponents’ commercial conduct is underscored by the factual record in a federal lawsuit brought by Philips North America, LLC (“Philips”) against one of the Proponents, Transtate Equipment Company, Inc. dba Avante Diagnostic Imaging (“Transtate”). There, after a four-week trial, the jury found that Transtate made millions of dollars in profits through its illegal and unauthorized use of Philips’ copyrighted materials for servicing medical imaging devices, reinforcing the commercial nature of Proponents’ use. Numerous witnesses also testified about the serious patient safety risks caused by Proponents’ unauthorized and untrained use of OEM advanced servicing software – and explained the importance of restricting access to such advanced software to prevent such risks. Notably, the court in that case

had earlier ruled at summary judgment that the very uses at issue in Transtate’s petition violate not only the DMCA¹, but also the Computer Fraud and Abuse Act (“CFAA”).

Allowing service organizations to profit through unauthorized use of OEMs’ proprietary software for the service organizations’ own (and very same) commercial servicing activities undermines the goal of copyright. The exemption has been and will continue to be used solely for commercial and non-transformative purposes, and therefore is outside the bounds of fair use as clarified by the Supreme Court. The Librarian should therefore reject Proponents’ renewal requests.

II. BACKGROUND

Philips is a well-known leader in the business of developing, manufacturing, selling, supporting, maintaining, and servicing medical imaging systems. Philips’ proprietary software enables certain functions on these systems that can be modified only by Philips, thereby allowing Philips to control, update, and track the use of its medical device software in the marketplace in accordance with FDA guidance. Philips’ high-quality products and proprietary software have made Philips a trusted producer, manufacturer, and supplier of medical imaging systems worldwide.

Philips includes access controls on its medical imaging systems to protect its copyright-protected software and to restrict access to its software to authorized personnel. This includes software designed for use by Philips engineers to diagnose and service the systems. 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.

Philips restricts access to its proprietary software not only to protect its intellectual property rights, but for important patient safety reasons as well.² The devices at issue are life-saving medical imaging systems, such as diagnostic X-ray systems (“cath labs”) used in cardiac procedures. Some of the advanced tools enable a service engineer to modify radiation settings on the devices, and thus can create severe safety risks if misused. Restricting access to such tools is not only a matter of patient safety and common sense, but comports with the FDA’s own guidance for reducing cybersecurity risks and other safety concerns.

¹ The court ruled that Transtate violated the DMCA pre-exemption. *Philips Med. Sys. Nederland B.V. v. TEC Holdings, Inc.*, 2023 U.S. Dist. LEXIS 7319, at *38 (W.D.N.C. Jan. 17, 2023). While it found that Transtate’s method of bypassing security modified the systems, *Id.* at *15-16, it did not specifically rule on whether Transtate violated the DMCA after the 2021 exemption went into effect.

² Proponents argue that they should be permitted to bypass the security that protects access OEMs’ copyrighted software because they claim to need the software to service medical devices, and that OEMs improperly protect that software to thwart such servicing. Those arguments cannot support renewal of the exemption, because the DMCA statutorily authorizes exemptions only if users are “adversely affected by” the anticircumvention rule “in their ability to make *noninfringing* uses,” 17 U.S.C. § 1201(a)(1)(C) (emphasis added), not to advance other policy considerations. Proponents’ purported policy reasons for renewing the exemption are thus simply irrelevant. It is nonetheless important to point out that they are also factually incorrect, and that Philips properly restricts access to its copyrighted works for compelling safety, cybersecurity, and other reasons.

When two independent service organizations, including Transtate, first sought an exemption to the DMCA for access to device software and data files stored on medical devices and systems, Philips objected, arguing that the proposed exemption was for infringing, commercial purposes and not fair use and would cause risks to patient safety, among other reasons.³ Notwithstanding Philips’ and others’ extensive comments, the Register of Copyrights recommended granting an exemption covering “[c]omputer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files.”⁴ On fair use, the Register stated that “[c]ommericality is not fatal to a fair use determination” and that the petitioners’ “proposed use is likely transformative and so the first factor favors fair use.”⁵ In reaching that conclusion, however, the Register offered no explanation and did not attempt to square her transformative-use finding with her own prior acknowledgement that the petitioners themselves had not claimed transformative use and thus did “not seek an exemption to modify medical devices or systems, or their software.”⁶ The recommendation also specifically excluded from the exemption uses that modify medical devices (including modifications to software).⁷ The Librarian, without elaboration, adopted the Exemption “based upon the Register’s Recommendation” and without further response to comments.⁸ Two industry groups sued the Librarian over enactment of the exemption, and that lawsuit is currently on appeal before the U.S. Court of Appeals for the District of Columbia Circuit.⁹

The current Proponents – all profit-motivated service organizations¹⁰ – seek renewal of the exemption allowing circumvention of TPMs for purposes of diagnosis, modification, and repair of medical devices. Two of the Proponents – Transtate and GMI¹¹ – are defendants in ongoing litigation in which Philips has alleged DMCA and CFAA violations against both companies for their modification of files on Philips medical imaging systems to gain unauthorized access to Philips’ copyrighted software.¹²

In the lawsuit against Transtate, the court granted summary judgment to Philips on its claim for violation of the DMCA, holding that “[b]ecause [Transtate] ha[s] admitted to using software [it] developed to bypass [Philips’] security, there can be no dispute that [Transtate] ha[s]

³ See Long Comment Regarding a Proposed Exemption Under 17 U.S.C. § 1201 by Philips North America, LLC (Feb. 8, 2021), available at

https://www.copyright.gov/1201/2021/comments/opposition/Class_12_Opp'n_Philips%20North%20America.pdf.

⁴ Section 1201 Rulemaking: Eighth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention (Oct. 2021), available at

https://cdn.loc.gov/copyright/1201/2021/2021_Section_1201_Registers_Recommendation.pdf.

⁵ *Id.* at 209.

⁶ *Id.* at 208.

⁷ *Id.* at 208, 229.

⁸ See 86 Fed. Reg. at 59,627.

⁹ *Medical Imaging & Technology Alliance, et al. v. Library of Congress, et al.*, No. 23-5067 (Fed. Cir.).

¹⁰ The Proponents are Jordan Health Products, LLC, Transtate Equipment Co., Inc., Global Medical Imaging, LLC (“GMI”), TTG Imaging Solutions, LLC, TriMedx Holdings, LLC, Metropolis International, and Crothall Facilities Management, Inc.

¹¹ Transtate and GMI are portfolio companies of Jordan Health Products, LLC d/b/a Avante Health Solutions, which is backed by private investment company Jordan Industries International, LLC and billionaire Jay Jordan. See Exhibit A, excerpts from the Philips v. TEC Holdings Trial Transcript, (“Trial Tr.”) at 3381:18-25; 3546:6-23.

¹² See *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.); *Philips Med Sys. Nederland B.V. et al. v. Global Medical Imaging, LLC et al.*, No. 1:21-cv-3615 (N.D. Ill.).

circumvented [Philips'] technological measures under the plain terms of the DMCA.”¹³ The court specifically found that “Defendants modified files on Plaintiff’s Allura systems to bypass Plaintiff’s security and permit access to Level 1 and higher CSIP without a Level 1 or higher IST key and password.”¹⁴ Although Transtate’s conduct falls outside of the scope of the exemption – including because Transtate accessed and used more of Philips’ software than necessary for repair activities and because its hacking modified Philips’ software – the court did not reach that issue, given that Transtate’s conduct at issue occurred before the exemption was enacted. The court also concluded that Transtate violated the CFAA: “By running FD_Service to bypass the security on Philips Allura system and then using Philips Level 1 and higher tools, [Transtate] intentionally accessed a protected computer and exceeded [its] authorized level of access.”¹⁵

The jury awarded Philips \$3.6 million on its DMCA claim based on the profits Transtate reaped through its modification and circumvention of Philips’ security to access to Philips’ copyrighted software.¹⁶ The evidence at trial established that Transtate bypasses Philips’ security for commercial access and use of Philips’ software.^{17,18} Testimony from Transtate showed that it uses the software for the same purpose as it was created by Philips, namely to service and modify medical imaging systems.¹⁹ In addition, multiple witnesses testified at trial that Transtate’s access method created patient safety issues by causing reliability problems on several medical imaging systems.²⁰

Notably, in both the Transtate case and the later case brought against GMI, Transtate and GMI sought to use the DMCA exemption as a defense for their illegal conduct. For example, in the Transtate litigation, Transtate repeatedly invoked the DMCA exemption, both at summary judgment and at trial, as a defense to liability on Philips’ DMCA claim and as a purported mitigating factor for damages purposes.²¹ In the GMI litigation, GMI moved to dismiss Philips’ complaint based on the DMCA exemption.²² The court denied GMI’s motion, recognizing that the exemption did not cover modifications to Philips’ medical devices, as Philips had alleged in its complaint.²³

III. The Exemption Should Not Be Renewed.

¹³ *Philips Med. Sys. Nederland B.V. v. TEC Holdings, Inc.*, 2023 U.S. Dist. LEXIS 7319, at *35 (W.D.N.C. Jan. 17, 2023).

¹⁴ *Id.* at *35.

¹⁵ *Id.* at *42.

¹⁶ Dkt. 776 at 4, *Philips Med Sys. Nederland B.V. v. TEC Holdings, Inc.*, No. 3:20-cv-00021-MOC-DCK (April 28, 2023 W.D.N.C.).

¹⁷ Trial Tr. at 723:23-724:20; 1654:22-1655:1; 1744:-4-21; 1755:9-20.

¹⁸ Testimony also revealed that Transtate has hacked the software of other OEMs like Siemens by generating counterfeit Siemens service keys that allowed for access to higher levels of service tools than permitted to non-Siemens engineers. *See* Trial Tr. 3313:4-12; 3326:16-25.

¹⁹ Trial Tr. at 2177:18-2180:6; 2182:24-2183:4.

²⁰ Trial Tr. at 1737:5-22; 3916:20-3917:7.

²¹ *See, e.g., Philips Med. Sys. Nederland B.V. v. TEC Holdings, Inc.*, 2023 U.S. Dist. LEXIS 7319, at *38 (W.D.N.C. Jan. 17, 2023).

²² *Philips N. Am. LLC v. Glob. Med. Imaging, LLC*, 2022 U.S. Dist. LEXIS 138796, at *23-24 (N.D. Ill. Aug. 4, 2022).

²³ *Id.* at *24.

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.”²⁴ 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.

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.”²⁵ More particularly, “[i]t is not enough that a particular use could be noninfringing. Rather, the Register will assess whether the use is likely to be noninfringing based on current law.”²⁶ “There is no ‘rule of doubt’ favoring an exemption when it is unclear that a particular use is noninfringing.” *Id.*

B. Since Enactment, Further Supreme Court Precedent and Factual Developments Show that Proponents’ Use is Infringing and Not Fair Use.

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. In Philips’ comment to Proponents’ initial request for the DMCA exemption, Philips demonstrated why each factor weighed against granting the Proponents’ exemption. That analysis holds true. In fact, further legal and factual developments have confirmed that Proponents’ use of Philips’ copyrighted material is not fair use. Proponents’ requests for renewal largely ignore these factors and controlling precedent.

After enactment of the current exemption, the U.S. Supreme Court issued its *Warhol* ruling, which clarified that commercial use of a copyrighted work for the same purpose as the original work weighs against a finding of fair use. There, the Court held that the “purpose and character” factor of the fair use test focuses on “whether an allegedly infringing use has a further purpose or different character, which is a matter of degree, and the degree of difference must be weighed against other considerations, like commercialism.”²⁷ The Court further clarified that “[i]f an original work and a secondary use share the same or highly similar purposes, and the secondary use is of a commercial nature, the first factor is likely to weigh against fair use, absent some other

²⁴ U.S. Copyright Office, Section 1201 of Title 17 at 111 (June 2017), <https://www.copyright.gov/policy/1201/section-1201-full-report.pdf>.

²⁵ Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 83 Fed. Reg. at 54,011.

²⁶ U.S. Copyright Office, “The Triennial Rulemaking Process for Section 1201,” at 6, https://cdn.loc.gov/copyright/1201/1201_rulemaking_slides.pdf.

²⁷ 143 S. Ct. at 1273.

justification for copying.”²⁸ The Court ultimately found that the use at issue was infringing, emphasizing that the “commercial nature of the use, on the other hand, looms larger.”²⁹ District courts have followed *Warhol* and emphasized commerciality in considering fair use.³⁰

Here, like *Warhol*, the non-transformative and commercial character of Proponents’ use both “point in the same direction.”³¹ There is no dispute that Proponents do not transform Philips’ copyrighted material. Transtate expressly disclaimed transformative use, explaining in its petition that “[m]odifying the software would likely lead to the system being considered remanufactured, which is not the purpose of diagnose, repair, or maintenance. Indeed, remanufacturing is to be avoided.”³² Rather than incur the significant costs necessary to develop their own software, and risk falling within the scope of FDA regulations on remanufacturing, Proponents instead copied the software OEMs labored to create and used it as OEMs designed it to be used.³³ *Warhol* clarified that this falls far outside the bounds of fair use.³⁴

As to commercialism, each Proponent seeking renewal of the exemption is a commercial entity that stands to profit from their unlicensed use of OEM copyrighted software. Evidence at trial in the Transtate litigation established that Transtate continues to bypass the security measures on Philips imaging systems for commercial use of Philips’ proprietary software.³⁵ Indeed, the jury found that Transtate made millions of dollars from its illegal access to Philips’ copyrighted materials.³⁶ Proponents have also attempted to use the exemption to shield activity clearly beyond the exemption’s scope and that has been found to violate federal law. For example, GMI moved to dismiss the lawsuit Philips brought against it on the grounds that the exemption barred Philips’ claims, even though the exemption expressly does not cover modifications to software.³⁷ The court denied GMI’s motion on that basis.³⁸ Transtate too invoked the DMCA exemption as a defense at every stage in litigation, even though the court had already found that Transtate’s conduct violated both the DMCA and CFAA, that Transtate modified files on medical devices to bypass their security,³⁹ and that the exemption did not apply retroactively to Transtate’s conduct.⁴⁰

²⁸ *Id.* at 1277.

²⁹ *Id.* at 1285.

³⁰ *See, e.g., Oracle Int’l Corp. v. Rimini St., Inc.*, 2023 U.S. Dist. LEXIS 126766, at *259 (D. Nev. July 24, 2023) (holding that fair use did not apply where defendant’s copying of software “was for a commercial purpose” “to save significant time, money, and effort”).

³¹ 143 S. Ct. at 1280.

³² Transtate Petition at 8.

³³ *See* FDA Center for Devices and Radiological Health, *Remanufacturing of Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff*, perma.cc/M3Q9-WF8C (June 21, 2021).

³⁴ *Warhol’s* holding that transformativeness depends on “whether an allegedly infringing use has a further purpose or different character” also vitiates the Register’s prior conclusion that the petitioners’ “proposed use is likely transformative,” since there is no dispute that Proponents intend to use OEM software for the same purpose as it was designed.

³⁵ Trial Tr. at 2444:4-16.

³⁶ Dkt. 776 at 4, *Philips Med Sys. Nederland B.V. v. TEC Holdings, Inc.*, No. 3:20-cv-00021-MOC-DCK (April 28, 2023 W.D.N.C.).

³⁷ *Philips N. Am. LLC v. Glob. Med. Imaging, LLC*, 2022 U.S. Dist. LEXIS 138796, at *23-24 (N.D. Ill. Aug. 4, 2022).

³⁸ *Id.* at *24.

³⁹ *Philips Med. Sys. Nederland B.V. v. TEC Holdings, Inc.*, 2023 U.S. Dist. LEXIS 7319, at *35 (W.D.N.C. Jan. 17, 2023).

⁴⁰ Dkt. 490, *Philips Med Sys. Nederland B.V. v. TEC Holdings, Inc.*, No. 3:20-cv-00021-MOC-DCK (April 28, 2023 W.D.N.C.); Trial Tr. at 3435:20-3436:8.

Transtate argues that “transformative use is not absolutely necessary for a finding of fair use.”⁴¹ While that is true, the cases are clear that when uses are both commercial and non-transformative, they do not amount to fair use. Indeed, the very cases Transtate cites establish that pure commercial use of OEM software – such as Proponents’ admitted use of OEM software to generate revenues from Proponents’ own servicing of medical systems – is not fair use.

In *Sony*, the Supreme Court analyzed whether at-home video recording constituted fair use. It observed that if “Betamax were used to make copies for commercial or profit-making purpose, such use would presumptively be unfair,” but that “time-shifting for private home use” was non-commercial.⁴² The footnote Transtate cites recognized that a fair use analysis calls for a sensitive balancing of interests and that transformative use is not always required, such as in the context of non-commercial use. But *Sony* hardly stands for the proposition that exact copying for commercial gain could somehow constitute fair use. It says the opposite: the copying in that case was fair use because it was *non-commercial*.

In *Campbell*, the Supreme Court noted that transformative use is not absolutely necessary for a finding of fair use, but in the same sentence noted that “the goal of copyright, to promote science and the arts, is generally furthered by the creation of transformative works.”⁴³ The Court went on to find 2 Live Crew’s song to be a parody commenting on the original or criticizing it, and therefore the type of transformative use that would traditionally have a claim to fair use protection.⁴⁴ The Court found that the Court of Appeals erred by concluding that the commercial nature of the parody rendered it presumptively unfair and reversed.⁴⁵ But the scenario in *Campbell* simply does not apply here, where Proponents’ use is both purely commercial and non-transformative.

Proponents’ explanation that they only want to make unlicensed use of OEM software to diagnose, repair, or maintain the systems for which the software was designed, and not modify it or create derivative works, further hurts their cause.⁴⁶ This distinguishes the Proponents’ copying from the copying at issue in *Google*.⁴⁷ While Google’s use of Sun Microsystem’s code was commercial in nature, it copied Sun’s code, “which was created for use in desktop and laptop computers,” “only insofar as needed to create tasks that would be useful in smartphone[s].”⁴⁸ Google then put Sun’s code to use in the “distinct and different computing environment” of its own Android platform, which the Court found to be transformative.⁴⁹ In contrast, Proponents desire to make unlicensed use of OEM software for its intended purpose in its intended environment, on medical devices. They are simply using the software for the same purposes in their own business, without paying for it. If this were the standard, then virtually any illegal copying could be characterized as “fair.”

⁴¹ Transtate Petition at 8, citing *Campbell v. Acuff Rose Music, Inc.*, 510 U.S. 569, 579 (1994), citing *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 455, n. 40 (1984).

⁴² 464 U.S. at 448.

⁴³ 10 U.S. 579.

⁴⁴ *Id.* at 583.

⁴⁵ *Id.* at 594.

⁴⁶ Transtate Petition at 8.

⁴⁷ *Google LLC v. Oracle America, Inc.*, 141 S. Ct. 1183 (2021).

⁴⁸ *Id.* at 1203.

⁴⁹ *Id.* at 1203-1204.

Supreme Court precedent thus leaves no room for Proponents' attempts to twist the law to argue that its hacking of medical devices to make commercial and non-transformative use of OEM software is somehow fair use. It is not.

In sum, Proponents' conduct following enactment of the exemption has confirmed that its use of protected software is not fair use. These for-profit service organizations have made millions of dollars hacking medical devices to sell services using unauthorized access to OEM copyrighted software. The Librarian should follow the Supreme Court's holding in *Warhol* emphasizing that such commercial uses are not fair and decline to renew the exemption.

C. The DMCA Exemption Permits Conduct that Risks Patient Safety.

The Librarian need not look further than the above analysis regarding Proponents' infringing, commercial use in declining to renew the DMCA exemption.⁵⁰ But it is also important to note that Proponents' requested exemption creates patient safety risks.

As Philips demonstrated in its comment to Proponents' initial request for an exemption, permitting independent servicers, which are not subject to the same extensive FDA regulation as OEMs,⁵¹ unauthorized access to complex, life-saving medical equipment endangers the reliability of those machines.⁵² These risks are very real and have already caused safety incidents. At trial in the Transtate litigation, the jury heard testimony regarding an incident where a medical imaging system crashed while a patient was being prepared for a procedure.⁵³ Philips' months-long investigation revealed that the system at issue had been modified by Transtate to bypass security and that the reliability issues plaguing the system were traced to Transtate's unauthorized access methods.⁵⁴ Such instances are likely to increase given the rise in the number of service organizations seeking renewal of the exemption. Indeed, Philips' continues to investigate other systems that appear to have crashed due to hacking by independent servicers. The FDA has also voiced concern over cybersecurity risks caused by hacking of medical devices.⁵⁵

The risks to patient and clinician safety are precisely why even those advancing "right to repair" legislation exempt medical devices. For example, legislation recently passed in New York and Minnesota specifically excludes medical devices from the acts' requirements regarding repair.⁵⁶ As these states have recognized, medical devices are not the same as cell phones, for

⁵⁰ 17 U.S.C. § 1201(a)(1)(C).

⁵¹ See, e.g., 21 C.F.R. §§ 801 (labeling), 803 (incident reporting), 807 (registration, listing, and premarket notification), 814 (premarket approval), 820 (quality system regulation).

⁵² Proponents cite to an FDA Report that addresses the availability of third-party entities to service and repair medical devices. See Transtate Petition at 3. That report does not sanction hacking of medical devices.

⁵³ Trial Tr. at 1737:5-22; 3916:20-3917:7.

⁵⁴ *Id.* at 1738:17-1741:1.

⁵⁵ See FDA, Strengthening Cybersecurity Practices Associated with Servicing of Medical Devices: Challenges and Opportunities (June 2021), available at <https://www.fda.gov/media/150144/download>.

⁵⁶ See New York Digital Fair Repair Act, S. B. S4104A ("Nothing in this section shall apply to...a medical device...or a digital electronic product found in a medical setting including diagnostic, monitoring, or control equipment[.]"); Minnesota Digital Fair Repair Act, 325E.72, Subd. 6. Exclusions ("Nothing in this section applies to manufacturers or distributors of medical devices ... or a digital electronic product or software manufactured for use in a medical setting including diagnostic, monitoring, or control equipment...").

example, and maintenance of those medical devices should not be left to unregulated independent service organizations that hack into proprietary software.

D. The Grounds for Renewal in Proponents' Petitions Are Baseless.

In their petitions for renewal, Proponents' justifications for renewing the exemption are either scant or based on mischaracterizations of law. For example, Crothall's petition requests an extension merely on the basis that its ability to "service a device without using the installed software and data files can be impacted by software access." This vague assertion provides no meaningful justification for an exemption for liability for hacking copyrighted software, much less the safety risks caused by such hacking.

Transtate's petition, while more detailed, relies repeatedly on misstatements of fact and law. For example, Transtate contends that the court in the Transtate litigation was wrong to find Transtate liable for violating the CFAA because the "loss" requirement under the CFAA requires technological harm to the system at issue. But the CFAA requires no such thing. "Loss" broadly encompasses "costs incurred as a part of the response to a CFAA violation, including the investigation of an offense," *A.V. ex rel. Vanderhuyse v. iParadigms, LLC*, 562 F.3d 630, 646 (4th Cir. 2009), and the Supreme Court's *Van Buren* holding does not say otherwise.⁵⁷ In any event, Transtate's access method caused technological harm to Philips' medical imaging systems.⁵⁸ Thus, even under its own (incorrect) view of the CFAA, Transtate's hacking of medical devices violated the CFAA, as the court ruled in the Transtate litigation.

As to the DMCA, Transtate's reliance on cases involving the unauthorized use of passwords is misguided.⁵⁹ Transtate has been found liable for *modifying files on medical devices* to bypass their security,⁶⁰ which has nothing to do with the cases analyzing whether unauthorized use of legitimate passwords violates the DMCA. Transtate's additional use of fake certificates to gain access to Philips' protected CSIP is also nothing like the DMCA cases analyzing unauthorized password use. Transtate's use of fake IST certificates is not a legitimate, but unauthorized, access method. Instead, it involves specially-developed software to create fraudulent certificates that bypass the security controls in Philips' IST solution.

Setting aside these misstatements of relevant authority, Proponents fail to analyze the factors as set forth in § 1201(a) to be weighed when considering whether to renew the DMCA

⁵⁷ *Van Buren v. United States*, 141 S. Ct. 1648 (2021). In *Van Buren*, the Court rejected the "improper purpose" distinction and clarified that that one "exceeds authorized access" when accessing a computer with authorization but then obtaining information located in areas of the computer that are off limits—as Transtate was found to have done. *Id.* at 1662.

⁵⁸ Trial Tr. at 1737:5-22; 3916:20-3917:7.

⁵⁹ Courts are also split as to whether such use constitutes circumvention under the DMCA. *See, e.g., Actuate Corp. v. Int'l Bus. Machines Corp.*, 2010 U.S. Dist. LEXIS 33095, *25 (N.D. Cal. Apr. 5, 2010) (holding that "unauthorized distribution of passwords and usernames avoids and bypasses a technological measure"); *321 Studios v. MGM Studios, Inc.*, 307 F. Supp. 2d 1085, 1098 (N.D. Cal. 2004) ("However, while [defendant's] software does use the authorized key to access the DVD, it does not have authority to use this key, as licensed DVD players do, and it therefore avoids and bypasses [the technological measure].").

⁶⁰ *Philips Med. Sys. Nederland B.V. v. TEC Holdings, Inc.*, 2023 U.S. Dist. LEXIS 7319, at *35 (W.D.N.C. Jan. 17, 2023).

exemption. For these reasons, the Librarian should afford little weight to the arguments in Proponents' renewal petitions.

IV. CONCLUSION

Following enactment of the DMCA exemption, for-profit commercial entities have made millions of dollars from bypassing security and copying OEMs' copyrighted software for servicing medical imaging systems. This commercial, non-transformative use is not fair use and does not warrant an exemption for DMCA liability. Indeed, far from protecting legitimate behavior, the exemption has instead emboldened independent service organizations to engage in hacking that has compromised patient safety. Accordingly, Philips respectfully urges the Librarian to take this opportunity to rectify this situation and decline to renew the exemption.

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

PHILIPS MEDICAL SYSTEMS
NEDERLAND B.V., et al.,

Plaintiffs,

vs.

TEC HOLDINGS, INC., ET AL.,

Defendants.

DOCKET NO. 3:20-CV-21

TRANSCRIPT OF JURY TRIAL VOLUME I
BEFORE THE HONORABLE MAX O. COGBURN, JR.
UNITED STATES DISTRICT COURT JUDGE
MONDAY, APRIL 3, 2023 AT 9 A.M.

APPEARANCES:

On Behalf of the Plaintiff Philips Medical Systems Dederland:

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1 they have a flaw in their security design?

2 A. No.

3 Q. And why is that?

4 A. If you look at the way the system is hacked, first you
5 need to bypass open profile. And I believe in some ways you
6 can do that, but the modifications made to the system, we
7 investigated with a team how this can be done. Our
8 conclusion is without inside design knowledge, you would not
9 be able to make these changes and know what file to modify.

10 Q. How did you reach that conclusion?

11 A. When you look at changes that need to be made, there are
12 2,000 remote files, and both file names contain no reference
13 to anything that's either IST [indiscernible] service. One
14 of the files is long. It's 68,000 lines. It is in a
15 unireadable format also, an XML file which is very complex to
16 read for normal IT specialists. You have to know exactly
17 what you're looking for. And after that, you also have
18 [indiscernible] to make sure the file reads from modify file.

19 Q. I'm sorry. I missed a word you said. You have to know
20 something that you're looking for?

21 A. The key words you have to look for, yes.

22 Q. The key words.

23 And from your investigation, do you have an
24 understanding of how defendants modified Allura systems to
25 bypass Philips' security?

1 A. Yes, I do.

2 Q. And how did they modify the systems?

3 A. Well, we have two files that are in play here. One file
4 is on the system that's called, the file is called
5 Celebration. And that's a large file, contains 68,000 lines
6 with all kind of configurations testings for the system. So
7 it will tell you where to connect to IT systems at the
8 hospital, like medical records, where you archive images.
9 But also contains a section that lists all the field service
10 tools and that are required of the [indiscernible] that
11 matches with the IST.

12 So that file, if you modify that, you can get access to
13 the tools without an IST key. But you can't modify it in
14 place. You have to first move that to a different directory.
15 When you move that to a different folder, the system doesn't
16 automatically open the file. You first need to tell the
17 system to look at that folder. And in order to do that, they
18 modified another file which contained all the file parts.
19 And that second file, it modified one file path to point to
20 the modified file itself, the regular file [indiscernible].

21 MR. OVEREND: Your Honor, may I approach for a
22 second?

23 THE COURT: Sidebar?

24 MR. OVEREND: Yes. I have a quick question.

25 THE COURT: All right.

1 events tab showing bypassing Philips' security?

2 A. It is.

3 Q. And how many entries are in this first tab?

4 A. If you can go down to the bottom of -- select everything
5 so that we can get the number, I could give you the exact
6 number.

7 Q. So it would be -- is that 202? Because there was a --

8 A. Yes. 202, yeah. Because I think there is a header.
9 Yeah.

10 Q. So 202 circumventions using a fake IST certificate by
11 whoever is using this; right?

12 A. By whoever is using it.

13 Q. Okay. And then --

14 A. All you can tell from this data because of the 12345 and
15 that's a fake certificate. But, you know, that's also the
16 user. So I cannot tell you about that, who the user is.

17 Q. And that's because, is it right, that when you use a
18 fake certificate, that's hiding the true identity of the
19 person who's using it?

20 A. You are using a fake ID. And so I don't know, you know,
21 who the -- the actual person using this is.

22 Q. And then if we go to the next tab, the Command Events
23 tab, can you explain what this shows?

24 A. This shows, again, the entry in the log filtered by
25 12345 and further filtered so as to consider only commands.

1 Basically, execution-specific commands in the system.

2 Q. And so back when we saw the video of the field service
3 running and you could navigate through the commands, these
4 are the instances where someone was then going and running a
5 command after using a fake certificate; is that right?

6 A. That's correct.

7 Q. And so would each of these circumvent Philips' security?

8 A. Each of these will circumvent Philips' security because
9 I wouldn't be able to run those commands unless I had a fake
10 certificate on that system.

11 Q. And how many rows are in this tab?

12 A. Again, if you can -- if you don't mind scrolling to the
13 bottom, we can view the number. Is 1913. So, 1,913.

14 Q. And then the third tab here, it says "Combined
15 Circumvention Events." Is that just the combined data from
16 the first two tabs?

17 A. Yeah, it's just the -- yeah, the combined data.

18 Q. And what's the total number of events in this tab?

19 A. And these are sum of the other two. And again, without
20 doing the math, it would be 2,115.

21 Q. Okay. And so this is the total from looking at the use
22 of fake certificates on Allura systems, in your opinion,
23 2,115 circumventions occurred?

24 A. That is correct.

25 Q. And are -- you're not able to tell, if I understand

1 A. I was.

2 Q. And when did you first become involved in that
3 investigation?

4 A. December 2020.

5 Q. So you talked about, I believe, reliability and
6 crashing. Are there -- what kind of safety issues could that
7 raise if there is a crash or reliability issues in the midst
8 of an actual procedure?

9 A. Well, during a procedure, you lose X-ray functionality.
10 And depending upon the point in the procedure, if you have a
11 catheter in somebody's heart or a vessel and it's occluding,
12 something is going -- calcification is breaking loose that
13 you don't have visibility of, a blockage that occurs, you
14 lose that visibility during that time frame.

15 The geometry is also reset, so the brakes and motors are
16 not working, the tabletop floats. If something goes bad and
17 you need to do CPR on the patient, it's problematic because
18 the table's floating. And then also, you know, depending
19 upon how they're positioned, it's also a fall risk off the
20 table.

21 Q. So it's a dangerous situation?

22 A. Absolutely.

23 Q. Did Philips have any initial assessment as to what might
24 be causing these crashes?

25 A. Initially, what we saw from logging we received was that

1 the systems were being left on for prolonged periods of time,
2 which is outside of our recommendations. So we asked them to
3 follow our recommendations for regular daily reboots of the
4 systems.

5 Q. And what happened? What happened after the customers
6 did that?

7 A. After they did that, it was reported by the customer
8 that the crashes seemed to stop. And the local market and
9 the customer agreed to close the escalations.

10 Q. And did they -- did the things remain that way? Did
11 they stay stopped?

12 A. No. A few weeks later, about a month later, late
13 January 2021, the sites were re-escalated with a couple extra
14 ones escalated at this point, also.

15 Q. And so was there further investigation?

16 A. Yes, there was.

17 Q. What was done initially as part of this further
18 investigation?

19 A. Initially, we had the local team, local service team,
20 save data for PR, which is very invasive. Large mod file.
21 Takes a snapshot of everything in the system. And collect
22 those. Also take pictures of what was connected to the
23 network switch in the system. And then verify the hardware
24 connections in the room.

25 Q. And did Philips have any initial findings as a result of

1 those steps?

2 A. We did.

3 Q. Could you describe them, please.

4 A. Yeah. We found some interesting registry changes.
5 Whitelisting, which is software hardening tool that prevents
6 changes to the software being disabled or bypassed. And we
7 saw programs, non-Philips, loaded onto the systems.

8 Q. Could you tell us more about the programs that were the
9 non-Philips programs.

10 A. Yes. There were two programs, one was called
11 FD_Service.exe. It was FD_temp. They were both being
12 permissioned into the systems from a removable drive. And
13 they had a path name of Transtate.

14 Q. You also mentioned whitelisting being turned off and
15 that registry changes had been made. What did that mean to
16 you?

17 A. The systems were being modified in a way that was not
18 expected by Philips in their design.

19 Q. Could you tell how the FDSservice program was being used
20 based on your investigation?

21 A. Yes. We saw that every time it was being commissioned
22 in, it was preceding a log-in for service. So somebody would
23 use that to access the service tools.

24 Q. Were there any other significant developments in the
25 course of the Banner hospital site investigation?

1 A. Yes.

2 We also found evidence of very high network traffic in
3 the firewall logging, which included very strange IP address,
4 which is computer address that didn't match the IP address
5 scheme of the rest of the hospital.

6 Q. Were you ever able to determine the origins of that
7 IP address?

8 A. Yes. It came from a Google Cloud server based out of
9 South Carolina.

10 Q. And were you able to get any additional information
11 about the origins or ownership of that IP address?

12 A. Yes. We talked to the IT group at Banner and asked if
13 they were aware of this outside IP address getting into the
14 hospital. They were. And when we asked further what that
15 was for, they said that was for our support vendor who they
16 identified as Transtate for their remote access to the
17 systems.

18 Q. And were you able to determine what was happening with
19 the server, when the server with that IP address accessed the
20 hospital's network?

21 A. Yes. It was being used to access the FTP, the file
22 transfer protocol, at the Windows level on the systems.

23 Q. And what was the significance of that in terms of the
24 behavior that you were seeing on those systems?

25 A. Well, we were able to find a lot of times it was

1 happening in conjunctions with the crashes.

2 Q. So did you ever communicate with Banner about shutting
3 off the access from that particular IP address?

4 A. We did. We asked them to shut it off on a trial basis
5 through our investigation, and they agreed.

6 Q. And what happened when they shut off that access?

7 A. The system crashes stopped happening.

8 Q. Did your analysis of the access from that IP address
9 connected to Transtate reveal anything else?

10 A. Yes. The nature that they were accessing the system in
11 the FTP, that they were accessing it dozens of times a day,
12 sometimes minutes apart.

13 When we access, we access once a day. The system
14 creates a log file daily on a reboot. So there's not a whole
15 lot of reason to going in. But it was constantly showing up
16 in the FTP logs.

17 Additionally, the Windows security log showed when these
18 tunnels were open, we were getting -- the systems were being
19 port scanned. Sequentially, every port, the CDP computer
20 firewall ports were being scanned. The software was blocked
21 because it's not supposed to be open. But it was continual
22 to the point where the log file would fill up in a manner of
23 weeks where in a normal system it takes like a year.

24 Q. So are there any risks from accessing the system so many
25 times in the fashion that you observed?

1 A. Yes. The remote access that was being allowed was not
2 consistent with how our systems were designed and was causing
3 undue stress on the system, causing it to crash.

4 Q. And were there any findings as to FDSERVICE?

5 A. Yes. We found FDSERVICE software designer, and it can
6 be used to modify registry and other settings in the system,
7 bypass whitelisting and do things that were not intended as
8 we designed the system.

9 Q. So you talked about modifications. In what ways had the
10 system been modified by Transtate using FDSERVICE?

11 A. Well, we found that most of the systems in a normal use
12 mode we'll call an open profile, which is an open mode. When
13 we deliver a system for the users to use, it's in a closed
14 profile. The application we run in the cath lab is all they
15 have access to.

16 In these systems, with the basic key stroke, hot key,
17 it's control escape, which anyone with a computer at home --
18 the Windows menu that popped up had a lot more things in
19 there than we expect. There was a command prompt, which is a
20 Windows tool. There was an Internet Explorer that was
21 available. And just things that were not normal.

22 Q. And those things that were not normal, did those
23 create vulnerabilities for the system?

24 A. That one could.

25 Q. So I want to return to the issue of systems crashing.

1 Allura system's host PC.

2 Is that consistent with your findings at Banner Health?

3 A. That is.

4 Q. And the non-Philips software, is that FDSERVICE?

5 A. That's correct.

6 Q. And did you see evidence of FDSERVICE being used at
7 Prisma, as well?

8 A. We did.

9 Q. And then please look at the third bullet point here, it
10 talks about: "Bypassing the Allura system's Integrated
11 Security Tool."

12 Integrated Security Tool, that's IST the jury's heard
13 about?

14 A. Yes.

15 Q. And then there's several subpoints here. Is that an
16 accurate description of your findings at Banner Health?

17 A. That's correct.

18 Q. Had FDSERVICE enabled the bypassing of IST that's
19 described here?

20 A. Yes.

21 Q. And did Philips have concerns that the same bypassing of
22 IST security measures could be happening at Prisma, as well?

23 A. We did.

24 Q. And is that true of the different consequences that are
25 described of that bypassing that are in these three

1 Q. Do you know what level of access you had when you were
2 at Philips?

3 A. I had Level 2.

4 Q. And there's levels above you in Xper Editor; right?

5 A. I believe so.

6 Q. There were levels for the factory and for R&D; right?

7 A. I believe so.

8 Q. And a Level 0 key, that can't change radiation settings;
9 right?

10 A. No.

11 Q. You can't change the radiation dose?

12 A. No.

13 Q. You can't change an Xper Editor to frame rate?

14 A. No.

15 Q. You can't change other fluoroscopy settings?

16 A. I think the only thing you can change is some brightness
17 and contrast settings.

18 Q. Mr. Griswold, you've edited files for Xper Editor to
19 provide access to higher functions than you can access with
20 your IST Level 0 key; right?

21 A. Yes.

22 Q. The edits you make to the file Xper Editor would give
23 access to functionalities that you cannot access with your
24 Level 0 key?

25 A. Yes.

1 Q. The edits you make give you access to functions that you
2 wouldn't have been able to access with your Philips national
3 support specialist key; right?

4 A. Possibly.

5 Q. Possibly?

6 A. Yeah. Some of the functions that were enabled had to do
7 with editor presets and stuff like that. I don't know that
8 that actually enabled that or not.

9 Q. When you edited the file for Xper Editor, you gave
10 yourself access to the service tools that were reserved for
11 the EPX editor preset account; right?

12 A. I don't know if the presetting was available or not. I
13 don't know.

14 Q. Did you give yourself access to everything within Xper
15 Editor when you modified that file?

16 A. Anything for doing the doses and possibly everything.

17 Q. Possibly you gave yourself access for everything?

18 A. Yeah. It was -- I was very familiar with the tool, so
19 it wasn't -- I knew what I needed to do the job for the
20 customer.

21 Q. When you went in and modified the files for Xper Editor,
22 you went into a file on the system and you changed the access
23 levels for all of the tools to 0; right?

24 A. I believe so.

25 Q. And that gave you access to all of the tools in it;

1 right?

2 A. Possibly, yes.

3 Q. With the changes you made, you were able to modify the
4 frame rate on Allura systems; right?

5 A. Yes.

6 Q. And you've done that while you were employed by
7 Transtate; right?

8 A. Many, many times. Hundreds of times.

9 Q. That's something you cannot do with a Level 0 --

10 A. Not with Transtate but Philips.

11 Q. I'm asking at Transtate. Since you've gone to
12 Transtate, you've done that; right?

13 A. Couple times, yes.

14 Q. And you've done that even though you only have a Level 0
15 key; right?

16 A. Yes.

17 Q. You've done that even though Philips doesn't give you
18 authorization to do that; right?

19 A. Not at the Level 0 key, no.

20 Q. And that changes how many times per second the patient
21 is irradiated; right?

22 A. Well, it depends on what you're actually changing or
23 working on. Sometimes that's the case, yes.

24 Q. And when you change the frame rates, that changes how
25 often the patient is irradiated; right?

1 A. If you change frame rate, yes.

2 Q. And you have changed the frame rates on Allura systems
3 while working for Transtate; right?

4 A. Yes. I was one of the ones who set up the default
5 settings for doses for the USA. I was perfectly qualified to
6 do that.

7 Q. You were perfectly qualified to do that in 2012; right?

8 A. Yes.

9 Q. When's the last time you received training from Philips
10 for modifying the Xper database?

11 A. I did it for years. I did it for -- I changed doses and
12 set doses for Philips back as far as 1995. The physics
13 hasn't changed. The equipment hasn't changed. Some of the
14 newer systems have IQ changes that allow you to lower the
15 dose, but they don't change how you set it. The physics is
16 the same. So I have more on-hands time with Transtate than I
17 ever had with Philips.

18 Q. Mr. Griswold, in 1995, Allura systems hadn't been
19 developed yet; right?

20 A. No. This was on the Integra system, the previous
21 generation.

22 Q. Right. That's a completely different medical imaging
23 device; right?

24 A. The physics is not different. It's a different system.
25 The settings were done differently. But X-ray was still

1 Q. How do you know it didn't change if you're not speaking
2 with the developers of the system?

3 A. I'm using the same system that we've used for the last
4 15 years.

5 Q. You're using it from a user perspective, not from a
6 developer's perspective; right?

7 A. No. The release 7.2 system has not changed in 15 years.
8 The release 8.1 system has not changed in 14 years or
9 13 years, or whatever it is. Things that have changed are
10 the image processing. That doesn't change the way you do
11 dose.

12 Q. And you can't know what the R&D people are changing in
13 the system; right?

14 A. If the software level didn't change, it didn't change.

15 Q. And you can't know if their training changes for how the
16 things should be serviced; right?

17 A. Like I said, what we're doing has not changed.

18 Q. You've changed the fluoro setting on Allura systems
19 since you've gone to Transtate; right?

20 A. A couple times, yes.

21 Q. And those are changes you cannot make with your Level 0
22 key; right?

23 A. That's correct.

24 Q. And you've changed settings relating to radiation dose
25 while you've been at Transtate; right?

1 A. Yes.

2 Q. And those were settings you cannot change with your
3 Level 0 key; right?

4 A. That's correct.

5 Q. Mr. Griswold, are you familiar with the de-noising
6 algorithms that are used in the image quality processing of
7 the Allura system?

8 A. On which release? They are different in each one of
9 them.

10 Q. Name one.

11 A. There's a lot of them. We use the function called XRES
12 on the older systems. On the newer systems they use
13 something called Clarity. Clarity's a new processing or a
14 higher-speed processing to reduce noise so that you can
15 reduce dose.

16 Q. And have you received training from Philips on the
17 Clarity database?

18 A. I have received some on that. But I relied on Dale for
19 that because Dale had more training on that.

20 Q. So you have secondhand training on that?

21 A. No. I did have some training on it initially when it
22 came out.

23 Q. Mr. Griswold, does the FDSservice software have
24 functionality to provide access to the Xper Editor?

25 A. It did have a link for the Xper Editor, yes.

1 Q. Well, let's see. You had issued your expert report in
2 this case in July 2021; correct?

3 A. Correct.

4 Q. And have defendants continued to use FDSservice since the
5 issuance of your report in July of 2021?

6 A. It's my understanding from updated reports that
7 FDSservice is still being used.

8 Q. And what's your basis for saying that?

9 A. There's an updated report showing those patterns
10 produced up through -- I think it's March of this year, and
11 it shows continued observations regarding use of FDSservices
12 identified by those patterns we talked about.

13 Q. And approximately how many additional instances of
14 FDSservice use were shown in that later RADAR report?

15 A. Since my June report in June '21, about
16 35,000 additional uses of FDSservice.

17 Q. And so does that continued use of FDSservice mean that
18 you needed to update the numbers from your July 2021 report?

19 A. Well, I had to update them anyway. But that gives me
20 additional support for updating the numbers through trial.

21 Q. And how did you -- could you just explain to the jury
22 how you did that.

23 A. Sure. So I don't have that mass of underlying
24 information that took literally hundreds of hours to comb
25 through to update the specifics like I had before.

1 Exactly."

2 Do you see that?

3 A. Uh-huh.

4 Q. And then Mr. Wheeler says: "Why are they trying so hard
5 not to work with us?"

6 A. Uh-huh.

7 Q. And then he says: "We freaking gave them keys."

8 Did Mr. Wheeler give you keys?

9 A. Yes.

10 Q. That's consistent with what Mr. Testa says; right?
11 Because he says: "Yes, we did"?

12 A. Yes.

13 Q. And then he says: "But not for all systems for a year."

14 And then Andy says: "Not yet."

15 THE COURT: Any questions? What are questions?

16 MR. BRENNAN: Sure. Let's go down the bottom of
17 this.

18 BY MR. BRENNAN

19 Q. There's a question about: "Did you buy them yet";
20 correct?

21 Did you buy those keys?

22 A. No, I did not.

23 MR. BRENNAN: I'm sorry, John. Could we go back
24 up. To where we were. I think we lost the page.

25

1 Q. The emails we just looked at with the Siemens' keys you
2 were being provided -- that was prior to you participating in
3 this litigation; correct?

4 A. Correct.

5 Q. It was before you spoke with Defendants' expert,
6 Warren-Boulton; correct?

7 A. Warren. I don't know Warren.

8 Q. I believe you spoke with him.

9 A. Okay. I may have. I don't recall the name.

10 Q. This was before you submitted a declaration on behalf of
11 Transtate in this case?

12 A. Oh, yes. Absolutely.

13 Q. It was before you came to testify here today; correct,
14 Mr. Kelley?

15 A. Yes. Correct.

16 Q. And just so we're clear, you got access to diagnostic
17 tools that Siemens doesn't provide to you; correct? You got
18 access to tools that Siemens didn't provide to you; correct?

19 A. I'm trying to think how to answer that. I did have
20 access to the equipment, but I didn't go through Siemens to
21 get that access, correct.

22 Q. Okay. So I think the answer to my question is correct.
23 You did not get these Siemens' diagnostic materials from
24 Siemens; correct?

25 A. That is correct.

1 Q. And when we talk about Avante Diagnostic Imaging, that's
2 basically Transtate?

3 A. That's correct.

4 Q. Okay. Now, we heard some testimony in this case about
5 Avante being a global -- a huge global conglomerate. Could
6 you actually tell us what the size of the total Avante
7 company is.

8 A. 2022 we had net revenues of a little less than
9 \$170 million.

10 Q. Okay. Is Transtate the largest part of that?

11 Let me state it a different way. Is it the largest
12 company by revenue?

13 A. It is the largest net revenue portion, yes.

14 Q. And how does that compare with the size of Philips?

15 A. I believe that in 2022 Philips' global net revenue was
16 over \$16 billion. So we would be approximately 1 percent of
17 their total net revenue.

18 Q. All right. Now, did there come a time in 2016 when
19 Avante started looking for opportunities in other medical
20 areas to expand its business?

21 A. Yes. When I joined Jordan Health Products/Avante Health
22 Solutions in May of 2016, there were already two companies in
23 the portfolio. One was Global Medical Imaging, our GMI which
24 you heard referred to earlier today which Philips has also
25 filed a lawsuit against. They were in the portfolio at the

1 time, which is an ultrasound business. And we had a
2 medical-surgical capital equipment company which was referred
3 to as DRE Medical, and now that's Avante Medical Surgical.

4 And we were very actively looking to understand how we
5 could expand into the service side of the portfolio for the
6 Avante Health Solutions business. So we were actively
7 looking at diagnostic imaging and X-ray and other areas for
8 service.

9 Q. When you say "diagnostic imaging," is that basically the
10 business Jordan Health -- sorry -- that Transtate is in?

11 A. That's correct.

12 MR. RUTHENBERG: Okay. Justin, let's bring up
13 DDX-388.

14 And, Your Honor, this is demonstrative. I would
15 move to be able to use this as a demonstrative.

16 MR. HULTQUIST: No objection as a demonstrative,
17 Your Honor.

18 THE COURT: It may be used as demonstrative.

19 BY MR. RUTHENBERG:

20 Q. And, Steve, if you could look at this timeline and look
21 at the very far left, June 2016. Does that relate to what
22 you were telling us about starting to look at diagnostic
23 imaging?

24 A. That's correct. Our business development team had a --
25 I'm going to call it a list of companies that were in the

1 A. It is.

2 Q. And did you understand the distinction between
3 remanufacturing and servicing?

4 A. Correct. Transtate is a servicing organization, not a
5 remanufacturing organization.

6 Q. Okay. And the fourth bullet point says: "The continued
7 availability of third-party entities to service and repair
8 medical devices is critical to the functioning of the
9 health-care system."

10 Is that something that you agree with?

11 A. It is.

12 Q. And did you review that and rely upon it at the time in
13 making your decision to continue using FDSERVICE?

14 A. It is.

15 Q. Now, did you, after this lawsuit was filed, become
16 familiar with the Digital Millennium Copyright Act?

17 A. I did.

18 Q. All right. And that's what we refer to as the DMCA?

19 A. Yes, it is.

20 Q. And are you familiar with a process sometimes called the
21 triennial process for applying for exemptions under the DMCA
22 to the Copyright Office?

23 A. Yes, I am.

24 Q. And did you do anything on behalf of Transtate to try to
25 pursue an exemption from the DMCA?

1 A. We did. In conjunction with a few other like-minded
2 organizations, we made an appeal to the Copyright Office for
3 an exemption to the DMCA, specifically to medical devices.

4 Q. All right. And do you recall what you applied -- what
5 was the nature of the exemption you applied for?

6 A. It was specific to servicing of medical devices and not
7 being prevented from doing such that the equipment could be
8 brought to its functioning order through the service.

9 MR. RUTHENBERG: All right. Let's pull up DTX-998,
10 please.

11 BY MR. RUTHENBERG:

12 Q. All right. And do you recognize DTX-998?

13 A. Yes.

14 Q. Can you describe what it is?

15 A. This is a component of our petition to the Copyright
16 Office for the exemption we're discussing.

17 MR. RUTHENBERG: All right. And I would move
18 DTX-998 into evidence, Your Honor.

19 MR. HULTQUIST: Subject to our prior discussions,
20 Your Honor, no objection.

21 THE COURT: Okay. Let it be admitted.

22 (Defendants' Exhibit Number DTX-998 was received
23 into evidence.)

24 BY MR. RUTHENBERG:

25 Q. All right. And was this a petition filed on behalf -- I

1 targeted acquisitions, Avante will provide a breadth of
2 service and product offerings to a variety of customers
3 located throughout North America and the world."

4 Did I read that right?

5 A. Yes.

6 Q. And then finally, now, Jordan Industries is an investor
7 in Avante Health Solutions; am I correct about that?

8 A. Yes.

9 Q. And they do that through -- do they do that through
10 JZ Capital Partners Limited?

11 A. I believe that they are also an owner, yes.

12 Q. And J. Jordan, who we spoke about just a minute ago, is
13 a known billionaire; isn't he, sir?

14 A. I don't know if that's known.

15 Q. Well, you wouldn't dispute that he's a billionaire;
16 would you, Mr. Inacker?

17 A. He's a billionaire.

18 Q. And Mr. Jordan has actually -- he's heavily invested in
19 the companies that we've already talked about here this
20 morning?

21 A. I don't know his level of investment.

22 Q. He certainly has an interest; doesn't he?

23 A. He has an interest.

24 Q. In fact, during 2020, he divested -- or at least the
25 entity that he is part of, divested \$65 million through the

1 sides.

2 Q. And when you say "beneficial for both sides," what do
3 you mean by that?

4 A. It's a pretty symbiotic relationship. It's a win-win.
5 You know, we are able to, for example, with a used system, we
6 are able to keep that system from going to scrap somewhere in
7 a landfill, and they are able to take the system and break it
8 down for used parts.

9 Q. Turning to another topic.

10 The jury has heard testimony, quite a bit of testimony,
11 regarding some letters that Philips sent to certain of
12 Transtate's customers.

13 Are you familiar with these letters?

14 A. I am.

15 Q. Who did Philips send them to?

16 A. We sent them to Banner Health, Lee Health in Florida,
17 Northside Hospital in Georgia, and I believe there are one or
18 two additional sites. I don't recall the names off the top
19 of my head.

20 Q. Did Philips send them to all of Transtate's customers?

21 A. No. It was just that small number of customers.

22 Q. And why did Philips select those particular sites?

23 A. Those particular sites were exhibiting unusual patterns
24 in the log. And these are patterns that go beyond the
25 pattern we see in the exploit. But unusual patterns in the

1 log that would indicate that there was a potential for these
2 systems to crash.

3 We had seen these patterns occur at Banner Health, which
4 is a customer out in the west part of the U.S. And we were
5 seeing those systems crash and in some cases with patients on
6 the table. We were seeing the same sort of problem in this
7 handful of systems, and that was concerning to us.

8 Q. Were these sites targeted because Transtate serviced
9 them?

10 A. Not at all.

11 Q. Did Philips choose the recipients of these letters based
12 on the size of their business to Transtate?

13 A. No. We chose the recipients of these letters based on
14 the patterns that we were seeing in the logs and the severity
15 of what could happen if these systems crash.

16 Q. So Philips wasn't targeting Transtate's key customers to
17 quash its business; is that fair to say?

18 A. No. This was a very small number of customers. We see
19 Transtate servicing, you know -- at my last -- the last time
20 I looked closely, it was well over 125 systems. I know the
21 number's higher than that. This was five customers that we
22 felt that there was a significant potential for the systems
23 to have a problem while a customer might be on the table.

24 Q. During the trial, Transtate has identified, I believe,
25 Crothall, GE Multi-Vendor, and Renovo as some of its key