

EXHIBIT A

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
3:20-cv-21-MOC-DSC

PHILIPS MEDICAL SYSTEMS)	
NEDERLAND B.V., ET AL.,)	
)	
Plaintiffs,)	
)	
vs.)	<u>ORDER</u>
)	
TEC HOLDINGS, INC.,)	
)	
)	
Defendant.)	
_____)	

THIS MATTER is before the Court on a Motion for Partial Summary Judgment, (Doc. No. 379), filed by Plaintiff Philips Medical Systems (“Plaintiff” or “Philips”), and on a Motion for Summary Judgment, filed by Defendants TEC Holdings, Inc., Transtate Equipment Company, Inc., and Robert A. Wheeler, (Doc. No. 383). For the following reasons the motions are granted in part and denied in part.

Plaintiff Philips North America LLC¹ develops and sells medical imaging systems to hospitals and other medical facilities and provides after-market service. Medical facilities may also hire independent service organizations (“ISOs”) to provide maintenance and support services necessary to maintain Philips’ systems, such as assembly, installation, adjustment, and testing (“AIAT”) procedures.

¹ Plaintiff Phillips refers to six named Plaintiff entities in this matter, all of which are collectively in the business of inter alia developing, manufacturing, selling, supporting, maintaining, and servicing medical imaging systems, including the proprietary hardware and software and related trade secrets necessary to operate, service, and repair such systems.

Plaintiff has named the following as Defendants in the Second Amended Complaint: TEC Holdings, Inc., formerly known as Transtate Equipment Company, Inc. (“Transtate I”), Transtate Equipment Company, Inc., formerly known as Transtate Holdings, Inc. (“Transtate II”) (collectively, “Transtate”), and Robert A. (“Andy”) Wheeler, individually and in his capacity as executor and personal representative of the Estate of Daniel Wheeler (“the Estate”) (Andy Wheeler and the Estate are referred to collectively as “the Wheelers”).

According to the Second Amended Complaint, as ISOs, Transtate I provided and Transtate II provides maintenance and support services for Plaintiff’s medical systems. Several current Transtate II employees in service specialists, service technicians, or similar positions, were previously employed by Transtate I, and before that employed by Philips North America LLC. According to Plaintiff, Plaintiff’s medical imaging systems include Plaintiff’s copyrighted and proprietary intellectual property, and proprietary trade secrets, in the form of, among other things, proprietary software that Plaintiff’s technicians use to service the medical imaging systems. Plaintiff restricts access to its proprietary software to authorized individuals by installing proprietary access controls on the medical imaging systems.

Plaintiff alleges that: Transtate I has used, and Transtate II continues to use, misappropriated trade secret information from Plaintiff to circumvent the access controls on Plaintiff’s medical imaging systems to gain unauthorized access to proprietary and copyrighted software; Transtate has also made unauthorized copies of Plaintiff’s standalone service software, circumvented access controls on the standalone software, and made unauthorized use of such software; Transtate has decrypted and made unauthorized copies of Plaintiff’s copyrighted service documentation; and Transtate has used their unauthorized access to make copies of Plaintiff’s proprietary software and copyrighted documents to unfairly compete against Plaintiff.

Plaintiff brings the following claims against the Defendant ISOs and their employees: violations of the Computer Fraud and Abuse Act, (“CFAA”), 18 U.S.C. § 1030; violations of the Digital Millennium Copyright Act (“DMCA”), 17 U.S.C. § 1201; violations of the Defend Trade Secrets Act (“DTSA”), 18 U.S.C. § 1836; Misappropriation of Trade Secrets and violation of the Georgia Trade Secrets Act (“GTSA”), O.C.G.A. § 10-1-760 et seq.; copyright infringement under the Copyright Act, 17 U.S.C. § 101 et seq.; and tortious interference with contractual relations.²

In its own motion for partial summary judgment, Plaintiff Philips seeks summary judgment on its claims under the Digital Millennium Copyright Act (“DMCA”) and Computer Fraud and Abuse Act (“CFAA”); on the 27th and 28th defenses of Defendants TEC and Transtate, and the 6th and 15th defenses of Defendant Robert A. Wheeler (collectively, the “AIAT Defenses”); on Defendants’ antitrust counterclaims for monopolization, attempted monopolization violations, and violation of the North Carolina Unfair and Deceptive Trade Practices Act (“NCUDTPA”) (collectively, the “Antitrust Counterclaims”); and on Defendants’ claims for tortious interference with contractual relations and prospective economic advantage.

Defendants have brought the following counterclaims against Philips: violations of anti-trust provisions under the Sherman Act, violation of the North Carolina Unfair and Deceptive

² To the extent the Court has dismissed portions of Plaintiff’s Copyright Act and other claims, those claims are no longer before the Court. See (Doc. No. 42). Moreover, on September 24, 2021, the parties stipulated and agreed that (1) Plaintiffs’ claims for violations of 17 U.S.C. § 1202 of the Digital Millennium Copyright Act (“DMCA”) and for violations of 18 U.S.C. § 1030(a)(6) of the Computer Fraud and Abuse Act (“CFAA”), as set forth in Plaintiffs’ Second Amended Complaint (Doc. No. 139), and (2) Defendant TEC Holdings, Inc.’s claims for Tortious Interference with Contract, as set forth in TEC Holdings, Inc.’s Answer, Defenses, and Counterclaims to Plaintiffs’ Second Amended Complaint (Doc. No. 275), were voluntarily dismissed without prejudice pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii), with each side to bear its own fees and costs. (Doc. No. 405).

Trade Practices Act, N.C. GEN. STAT. § 75.1.1 et seq., and a claim for tortious interference under North Carolina common law. In support of its counterclaims, Defendants contend, among other things, that Plaintiff takes anti-competitive measures against Defendants and other ISOs which ultimately hurt consumers, specifically medical patients. According to Defendants, Plaintiff's anti-competitive measures include charging service prices that are significantly higher than those charged by ISOs, controlling the parts market, interfering with third-party repairs, preventing ISOs such as Defendants from accessing certain security levels necessary to properly service Plaintiff's machines, and disparaging Defendants and other ISOs to the public. According to Defendants, this conduct in the aggregate amounts to "anticompetitive intent." In their summary judgment motion, Defendants moved for summary judgment on all of Plaintiff's claims.

The Court held a hearing on the motions on November 15, 2021. Thereafter, this action and all related actions were stayed on December 10, 2021, pending the FDA's ruling on an FDA Trade Complaint filed by Defendant Transtate. (Doc. No. 595). On March 10, 2022, the parties filed a joint status report, indicating that there had been no change in the status of Defendant's FDA Trade Complaint, and the parties agreed that the cases should proceed. The Court therefore lifted the stay on until June 15, 2022. (Doc. No. 618). On August 15, 2022, the Court held a status on conference, in which the parties discussed, in part, a pending motion to withdraw as counsel, filed by the law firm of Faegre, Drinker, Biddler & Reath, LLP. On September 13, 2022, the Court granted the motion to withdraw. (Doc. No. 631).

For the following reasons, considering the applicable statutes, and the facts as articulated by both parties, the Court finds that Plaintiff is entitled to summary judgment as to its DMCA and CFAA claims. However, genuine disputes of material fact prevent this Court from granting

summary judgment as to any other claims at this time. Furthermore, the issue of damages as to the DMCA and CFAA claims is also an issue for trial.

I. Plaintiff's Facts and Evidence Presented on Summary Judgment

Plaintiff Philips North America LLC³ makes and sells various medical imaging systems purchased by medical providers and healthcare facilities and provides after-market service.⁴ These include interventional X-ray systems (a.k.a. “cath labs”), such as Philips’ Allura and Azurion series.⁵ These complex medical systems comprise combinations of hardware and software.⁶ The healthcare facilities also hire independent service organizations (“ISOs”) to provide maintenance and support services necessary to maintain the systems, such as assembly, installation, adjustment, and testing (“AIAT”) procedures. Defendant Transtate is one of those ISOs.

Philips services its systems during the warranty period, which is typically one year.⁷ After that, the provider can maintain its medical systems in several ways: contracting with Philips, using its own in-house employees (“biomed”), or hiring ISOs such as Defendants Transtate and TEC.⁸ Regardless of their employer, technicians who service Philips systems often must use software installed on the medical device itself and reference service manuals and other documents published by Philips to diagnose and service these systems.

³ Plaintiff Phillips refers to six named Plaintiff entities in this matter, all of which are collectively in the business of inter alia developing, manufacturing, selling, supporting, maintaining, and servicing medical imaging systems, including the proprietary hardware and software and related trade secrets necessary to operate, service, and repair such systems.

⁴ Ex. A (Riley Rpt.) ¶¶ 21–23; Doc. No. 384 (Def. MSJ), at 2 ¶ 1.

⁵ Doc. No. 274 ¶ 160; Doc. No. 384 (Def. MSJ), at 2 ¶ 1.

⁶ Ex. C (Fenn Rpt.) ¶ 38; Ex. D (Dickson 12/31 Tr.), at 29:8–30:25, 194:7–195:17; Ex. E (Suijs Tr.), at 27:2–28:8, 12:7–16; Ex. F (McAlpin Tr.) at 45:12–46:13.

⁷ Sec. Am. Compl. ¶ 49; Defs.’ Ans. ¶ 49; Ex. 2, 75:13–76:1.

⁸ Sec. Am. Compl. ¶ 49; Defs.’ Ans. ¶ 49; Ex. 2, 19:9–18.

A. Philips And Its Valuable Intellectual Property

Philips has developed various Customer Service Intellectual Property (“CSIP”) software tools and documents to service and maintain its Allura systems.⁹ These software programs and other materials provide advanced software tools and information for servicing, troubleshooting, and configuring Philips medical imaging systems.¹⁰ Philips’ service software is solely for use by Philips and its authorized agents, and accordingly Philips’ restricts access to its service software.¹¹

Philips authorizes individuals to have “levels” of CSIP access based on their role and contract terms.¹² Philips places greater restrictions on Level 1 CSIP materials, which are available only to Philips’ employees and customers under contract (but not ISOs).¹³ Level 2 CSIP includes more advanced proprietary materials, such as higher-level service tools, Philips’ specialized knowledgebase of servicing know-how (“KNOVA”), and other proprietary materials reserved for Philips’ employees and specific trade partners under contract.¹⁴

⁹ Ex. C (Fenn Rpt.) ¶ 38; Ex. D (Dickson 12/31 Tr.), at 29:8–30:25, 194:7–195:17; Ex. E (Suijs Tr.), at 27:2–28:8, 12:7–16; Ex. F (McAlpin Tr.) at 45:12–46:13.

¹⁰ Ex. G (3d Rsp. Wheel. 1st Rog), at 5–6; Ex. D (Dickson 12/31 Tr.), at 30:5–34:23, 37:11–40:6.

¹¹ Ex. H (Philips Std. Terms), § 10.

¹² Ex. I (Froman Tr.) 51:20–52:7; 53:11–54:7; Ex. J (Wheeler 5/13 Tr.), 17:17–20:2, 20:19–20:22, 21:24–25; Ex. D (Dickson 12/31 Tr.), 29:8–34:23, 37:11–40:6, 176:1–10); (Ex. I (Froman Tr.), 53:11–16, 79:3–18, 91:11–25; Ex. J (Wheeler 5/13 Tr.) at 23:23–24:5; Ex. D (Dickson 12/31 Tr.), 31:12–16, 37:11–19). Level 0 CSIP materials are available generally upon request. Upon request, Philips sends a local FSE to apply a service organization ID (SOID) to a device to enable such Level 0 access free of charge. (Ex. D (Dickson 5/31 Tr.) at 87:4–89:13.

¹³ Ex. I (Froman Tr.), 53:17–25; Ex. F (McAlpin Tr.), 172:7–174:20; Ex. K (Astrachan Tr.), 32:9–19, 66:14–25, 82:5–13; Ex. D (Dickson 12/31 Tr.), 31:12–24, 37:11–39:15).

¹⁴ These partners include the U.S. military and DOD, which are provided such access to allow servicing in war zones where Philips cannot go. (Ex. M (Philips Corp. Tr.), at 290:12–291:10, 305:6–309:15). (Ex. I (Froman Tr.) 54:1–7; Ex. D (Dickson 12/31 Tr.), 33:18–34:12, 61:23–62:2; Ex. L (Orso Rpt.), ¶¶ 50–52, 279, 289.

Philips asserts that it owns the following nine trade secrets relating to its CSIP and other proprietary information, including: (1) secret information about protected security files on Philips Allura systems used to create Defendants' FD Service program; (2) Philips' Level 1 and higher CSIP software tools; (3) Philips' Remote Services information and documents; (4) Philips' Level 2 CSIP information and documents; (5) Philips' KNOVA information and documents; (6) protected log files on Philips medical imaging systems; (7) Philips' Common Analyzer Tool (CAT); (8) Philips' Xper Management Tool (Xper Editor); and (9) detailed Philips' customer information.¹⁵

Philips developed and owns copyrights for its CSIP software and has registered numerous versions.¹⁶ Those registrations include the major and semi-major versions of Allura software from 7.0 onward.¹⁷ Philips asserts that it has spent massive amounts of time, money, and effort to develop its CSIP.¹⁸ Philips maintains that a competitor that obtained Philips' CSIP and related materials without incurring the costs to develop them would obtain a huge and unfair competitive advantage.¹⁹

B. Philips' Extensive Measures to Protect Its Confidential CSIP and other Materials

Philips asserts that it takes numerous measures to protect the secrecy of its CSIP and other asserted trade secrets. These measures include: confidentiality agreements with employees, customers, and trade partners; limiting employee access on a need-to-know basis and requiring

¹⁵ Ex. G (Rsp. Wheel. Rog), at 2–17; Ex. L (Orso Rpt.), ¶¶ 266–321; Ex. D (Dickson 12/31 Tr.), at 61:23–62:2; Ex. M (Philips Tr.), at 286:19–287:18.

¹⁶ Ex. N (2nd Resp. Trans. 1st Rog), at 9–11; Ex. L (Orso Rpt.), ¶¶ 353–56, 380–83.

¹⁷ Doc. No. 139 (SAC), Ex. A; Ex. M (Philips Tr.) 125:11–126:16; Ex. O (Fenn Tr.) 205:20–206:6.

¹⁸ Ex. G (Rsp. Wheel. Rog), at 5–6). Philips estimates spending over \$113 million to develop the CSIP software and tools just for Allura products. (Ex. P (Kennedy Rpt.), ¶¶ 167–82.

¹⁹ Ex. G (Rsp. Wheel. Rog), 3–17; Ex. P (Kennedy Rpt.), ¶¶ 169–70.

return of confidential materials at termination; including confidential markings on documents; restricting customer access to proprietary software tools on the imaging systems to those with written confidentiality agreements; using technological security measures such as its Integrated Security Tool (“IST”); and maintaining secure physical premises.²⁰

According to Plaintiff, its IST tool, developed as a digital rights management solution for preventing unauthorized access to Philips’ CSIP, is particularly important.²¹ Philips generates and encrypts a user-specific and password protected IST certificate, which users load onto physical IST keys that are encoded with the user’s authorized service software.²² Philips’ CSIP functions are assigned specific IST levels, and each user is provided or denied access to service software based on the IST level on the user’s IST key.²³ In short, Philips locks down its CSIP materials via a specific user’s IST key and password, such that only users with appropriate entitlements can gain access.²⁴

C. Philips’ Contends that Defendants Hired Philips’ Employees and Misappropriated Its Trade Secrets

²⁰ Ex. G (Rsp. Wheel. Rog), 2–17, 31–38; Ex. N (2nd Resp. Trans. 1st Rog), 14–25; Ex. D (Dickson 12/31 Tr.), 29:6–34:16, 70:5–71:8, 87:4–88:19, 94:4–95:16, 102:7–13; Ex. M (Philips Tr.), 254:4–256:16, 273:2–275:8; Ex. L (Orso Rpt.), ¶¶ 303–21, 53–114; Ex. Q (Rios Rpt.), ¶¶ 37–54; Ex. R (Regard Rpt.), ¶¶ 25–28; Ex. S (Regard Tr.), 72:6–12, 82:8–83:16, 93:7–94:10, 96:10–97:10, 98:16–101:4, 115:4–9, 119:7–21; Ex. T, at 5, 11–12, 16, 18, 24, 83, 86, 88, 129; Ex. U; Ex. V; Ex. W, at 4–11; Ex. X, slides 8–13 (CSIP Policy Updates); Ex. Y (Assist Agt.), at 1, 3–4, 6.

²¹ Ex. L (Orso Rpt.), ¶¶ 53–84; Ex. M (Philips Tr.) at 11:4–13:19, 25:20–27:2, 114:14–115:3, 254:21–256:16; Ex. Z (Ray Tr.) at 56:22–57:1, 58:19–59:10, 79:10–80:1, 81:10–82:12, 86:3–88:2, 92:13–95:6; Ex. B (Kullolli Rpt.) ¶¶ 96–97; Ex. C (Fenn Rpt.) ¶ 38; Ex. O (Fenn Tr.) 83:21–85:8.

²² Ex. L (Orso Rpt.), ¶¶ 54–63, 66–80, 97, 99, 101–14; Ex. AA (Griswold Tr.) 39:24–42:24; Ex. I (Froman Tr.) at 92:10–14.

²³ Ex. L (Orso Rpt.), ¶¶ 78–80, 100–14, 131–52, 327, 371; Ex. J (Wheeler 5/13 Tr.) 17:17–20:2; 22:16–24:25; Ex. AA (Griswold Tr.) 25:4–26:1, 26:17–27:14, 37:14–38:18, 39:24–42:24.

²⁴ See *id.*

Defendant TEC Holdings (“TEC”) is an independent service organization (“ISO”) that serviced various medical equipment, including Allura systems.²⁵ On March 31, 2017, TEC sold all its assets to Transtate Holdings, which then changed its name to Transtate Equipment Co., Inc. (“Transtate II”).²⁶ The business of TEC and Transtate II (collectively, “Transtate”) includes servicing, part sales, and sales of refurbished equipment for X-ray and other medical imaging systems.²⁷

According to Plaintiff, as early as 2013, Transtate embarked on a scheme to hire key Philips employees and steal Philips’ trade secrets. Specifically, Transtate’s owners, Daniel and Robert (Andy) Wheeler, met in early 2013 with William Griswold, a Philips specialist who was contractually obligated not to use or disclose his extensive access to Philips’ trade secrets.²⁸ Mr. Griswold got a job offer from Transtate in July 2013 (including responsibility for developing Transtate’s remote servicing program), but kept working for Philips for nearly two more months, despite his extensive access to Philips’ confidential and proprietary materials.²⁹ According to Philips, he arrived at Transtate with an illegally retained backup of the hard drive from his Philips laptop, and he quickly began providing Transtate employees with confidential Philips materials, including secret information about Philips’ Remote Services he acquired from a Philips training course days before his job offer (enabling Transtate to have unauthorized remote

²⁵ Doc. No. 384, at 3.

²⁶ Id.; Ex. AB (D. Wheeler Tr.), at 34:7–24.

²⁷ See id.; Ex. AC; Ex. AD.

²⁸ Id., Ex. AA (Griswold Tr.), at 94:21–99:23; Ex. AE (Griswold IP Agt).

²⁹ Ex. AA (Griswold Tr.), at 103:21–104:19, 112:11–15; Ex. AF (Offer Ltr).

access to Philips' protected materials), Level 1 and 2 CSIP information and documents, and KNOVA materials.³⁰

It is undisputed that, in connection with Transtate's servicing, Philips provides Transtate with IST accounts with only Level 0 CSIP access.³¹ Philips contends that, along with other secret materials, Griswold provided Andy Wheeler at TEC with information about specific changes that could be made to the [REDACTED] and [REDACTED] files to provide unauthorized access to Philips' CSIP on Allura systems.³² Mr. Griswold repeatedly sent Wheeler [REDACTED] files—one of two files that Transtate modifies (out of tens of thousands of files on Allura systems) to gain unauthorized access.³³

According to Philips, Wheeler used the misappropriated trade secret information to build the "FD Service" software program that modifies those same [REDACTED] and [REDACTED] files on Philips Allura systems to provide access to Level 1 and higher CSIP.³⁴ Philips contends that Transtate's employees admitted that FD Service provides access to Level 1 and higher CSIP tools that Philips restricts them from using.³⁵

³⁰ Ex. G (Rsp. Wheel. Rog), at 20–24; Ex. L (Orso Rpt.), ¶¶ 323–25, 330–31, 338; Ex. AA (Griswold Tr.), at 124:19–127:5, 128:19–130:16, 140:4–12, 149:23–152:11; Ex. AG, at 26; e.g., Ex. AH (RSN Info) at '71, 99, 110.

³¹ Ex. J (Wheeler 5/13 Tr.), 17:24–18:10, 52:10–20; Ex. I (Froman Tr.) 79:10–13.

³² Ex. G (Rsp. Wheel. Rog), at 21; Ex. L (Orso Rpt.) ¶¶ 153–164.

³³ Ex. AI; Ex. AJ; Ex. AK; Ex. AL.

³⁴ Ex. G (Rsp. Wheel. Rog), at 22; Ex. AV; Ex. L (Orso Rpt.), ¶¶ 120–25, 149–165, 272–73, 326–27, 361–364; Ex. J (Wheeler 5/13 Tr.) 35:19–36:1, 38:2–39:8, 52:22–55:21. According to Philips, Defendants' assertion that FD Service merely uses Microsoft Windows Explorer to access Allura cath labs "through legal methods" is wrong. (See Doc. No. 384 at 8 ¶ 28).

³⁵ Ex. AA (Griswold Tr.) 43:11–44:19 (FD Service provides access to service tools that are unavailable with the IST key from Philips); Ex. I (Froman Tr.) 69:23–70:1 (it allows access to Level 2 tools), 74:19–75:11 (FD Service "circumvents Philips' security measures"). Philips contends that Defendants' own admissions refute any assertion that they were only accessing Level 0 CSIP materials (which Philips makes available generally to comply with AIAT Regulations). Philips argues that, contrary to Defendants' assertions, FD Service does not enable

In deposition, Defendants’ technical experts explained how FD Service changes files on Allura systems to bypass Philips’ security. Professor Astrachan acknowledged that Philips designs its Allura software to prevent users with Level 0 access from accessing Level 1 or higher software.³⁶ He explained that Defendants run FD Service to “unlock” access to Level 1 and higher CSIP tools.³⁷ Defendants’ other technical expert, Mr. Fenn, also testified Defendants modify Allura software to access Level 1 (IST Level 2) and higher CSIP commands without an IST key.³⁸ According to Philips, Defendants thus unquestionably modify files on Allura systems to bypass Philips’ security and permit access to Level 1 and higher CSIP without a Level 1 or higher IST key and password.

According to Philips, after obtaining Philips’ secret information to develop FD Service, Defendants continued to build their business upon Philips’ stolen intellectual property. In 2016, Defendants hired Dale Dorow, another Philips employee with extensive access to Philips’ trade secrets and proprietary materials.³⁹ According to Philips, on January 2016, Dorow received a job offer from Transtate with an anticipated start date of August 1, 2016—providing more than six months during which Mr. Dorow hid from Philips that he would be going to a competitor and stockpiled copies of Philips’ confidential materials.⁴⁰ Philips has presented evidence showing

“AIAT” functions: it enables all CSIP functions. (Ex. K (Astrachan Tr.) 108:16–109:21 (FD Service gives access to all Level 1 through 8 service tools)).

³⁶ Ex. K (Astrachan Tr.), 66:14-23; 82:5–13, 83:14–22.

³⁷ *Id.* at 89:13–23 (once FD service is run “you could access the system to perform services no matter what level they might otherwise have required”), 90:13–91:10, 94:11-20, 106:15–107:25, 108:16–109:21, 185:12–186:7, 198:3–199:8.

³⁸ Ex. O (Fenn Tr.), 83:21–84:25, 92:10–22, 94:16–22.

³⁹ Ex. G (Rsp. Wheel. Rog), at 27; Ex. AM (Dorow 5/7 Tr.), at 115:3–123:2; Ex. V (Dorow IP Agt).

⁴⁰ Ex. AM (Dorow 5/7 Tr.), at 115:3–123:2; Ex. AN; Ex. R (Regard Rpt.), ¶¶ 56–59, 121–27, 174–75 & Ex. O. Philip asserts that the job offer document contains an obvious typo of January 15, 2015, given the new calendar year.

that Dorow secretly retained a hard drive containing over 200,000 files of Philips materials (55,000 of which were then accessed during his first week at Transtate), including Philips' Level 2 CSIP and KNOVA documents, Philips' CAT and Xper Editor Tools, and Philips' confidential customer information.⁴¹ Plaintiff asserts that with the misappropriated materials, Dorow established a "library" of Philips' information for Transtate employees, and also emailed Philips' Level 1 and 2 CSIP materials, KNOVA information, and CAT presets to Wheeler and other Transtate employees.⁴²

D. Philips Contends Widespread Use of Philips' Trade Secrets in Transtate's Business

Philips contends that Defendants have made widespread use of Philips' trade secrets through Transtate's entire business. Transtate began using FD Service as early as November 19, 2013.⁴³ Philips contends that Transtate employees have admitted to using FD Service to access software on Philips machines they cannot access using their Philips-provided access keys.⁴⁴

Philips has presented evidence showing that Defendants' FD Service has been used to circumvent Philips' IST security measures more than 75,000 times with Defendants' customers—

⁴¹ Ex. R (Regard Rpt.), ¶¶ 56–59, 101, 116, 121–27, 130–34, 174–75; Ex. AM (Dorow 5/7 Tr.), at 184:7–188:17, 191:23–192:24; Ex. G (Resp. Wheel. Rog), at 27)

⁴² Ex. G (Resp. Wheel. Rog), at 27–28; e.g., Ex. AO; Ex. AP, at '951-57; Ex. AQ; Ex. AR at 9; Ex. AS at '118; Ex. AT at '324–25; Ex. AU at '168–69)). According to Philips, Defendants also acquired Philips' secret information from other employees, such as Dustin Zimmerman, who brought to Transtate Philips' secret information that Philips licenses to the U.S. Military and Mr. Zimmerman improperly retained from his prior military service (Ex. G (Resp. Wheel. Rog), at 25–26; Ex. BA (Zimmerman Tr.) 353:18–354:24, 356:22–357:17) and a fake IST certificate, which Defendants used to gain unauthorized access to Philips' protected CSIP. (Ex. BB (Kalish Decl.), ¶ 10; Ex. L (Orso Rpt.), ¶¶ 185–192, 222–38; Ex. G (Resp. Wheel. Rog), at 25.

⁴³ Ex. L (Orso Rpt.), ¶ 324; Ex. AV, at 15.

⁴⁴ Ex. AW (Dorow 6/3 Tr.), at 16:5–19:3, 43:20–46:1; Ex. AX (C. Peterson Tr.), at 100:15–101:12; Ex. AA (Griswold Tr.) 39:24–44:19; Ex. I (Froman Tr.) 69:23-70:1, 74:19-75:11.

and that is just based on records of the systems that happen to report log files to Philips.⁴⁵

According to Philips, such extensive use of FD Service gives Transtate unfettered unauthorized access to Philips' entire suite of advanced servicing software, allowing Transtate to provide servicing more efficiently and profitably.⁴⁶

According to Philips, the fake IST credentials provide Transtate with another means to circumvent Philips' access controls, decrypt Philips' encrypted files, and acquire and use Philips' advanced CSIP.⁴⁷ Defendants dispute having a fake IST certificate, but Philips asserts that customer log files show the use of fake IST certificates over 2,000 times to access Philips' CSIP at Transtate customer sites.⁴⁸

According to Philips, Defendants' use of fake IST certificates also enabled them to decrypt Philips' documents, as shown by internal Transtate communications funneling requests for decryption of Philips' documents and files to Messrs. Wheeler and Zimmerman.⁴⁹ Philips further argues that Defendants have used Philips' proprietary materials in other aspects of their business. For example, Transtate circumvented Philips' security on its internal "test bays" to use Level 1 and higher CSIP to test and diagnose parts that Philips sells to customers.⁵⁰ Philips further asserts that Transtate also used secret information about Philips' Remote Services to provide remote diagnostic services to Transtate's customers, including by remotely downloading and analyzing log files from Allura systems, enabling Transtate to increase its efficiency and

⁴⁵ Ex. L (Orso Rpt.), ¶¶ 165–172; Ex. P (Kennedy Rpt.), ¶¶ 91–97.

⁴⁶ Ex. P (Kennedy Rpt.), ¶¶ 168–70.

⁴⁷ Ex. L (Orso Rpt.), ¶¶ 185–92, 222–38, 245, 284.

⁴⁸ Ex. L (Orso Rpt.), ¶¶ 222–38; Ex. P (Kennedy Rpt.), ¶¶ 102–05.

⁴⁹ Ex. L (Orso Rpt.), ¶¶ 245, 284; Ex. G (Rsp. Wheel. Rog), 26–27; Ex. AY (email attaching encrypted files); Ex. S (Regard Tr.), 76:20–78:16; Ex. AZ; Ex. CI).

⁵⁰ Ex. AW (Dorow 6/3 Tr.), 43:20–46:1; Ex. L (Orso Rpt.), ¶¶ 173–84.

profitability by evaluating problems before technicians arrive on site.⁵¹ Philips asserts that Transtate also uses Philips' Level 2 CSIP documents, KNOVA trade secrets, CAT software, and Xper Editor tool in connection with its business, including via a "document library" Dorow created containing numerous Philips proprietary materials.⁵² Finally, Philips has presented evidence to show that Transtate's business has used the CAT (to interpret log files) and Xper Editor tools (to adjust irradiation levels).⁵³

E. FDA Regulation of Medical Imaging Systems

The U.S. Food and Drug Administration ("FDA") comprehensively regulates medical imaging systems, including through the federal Food, Drug, and Cosmetic Act ("FDCA").⁵⁴ Subsection (g) of the "AIAT Regulation," codified at 21 C.F.R. § 1020.30, requires a manufacturer of a diagnostic X-ray system to provide to assemblers (and, upon request, to others) "instructions for assembly, installation, adjustment, and testing" of certain certified components of the X-ray system that are adequate to assure that the product will comply with

⁵¹ Ex. G (Rsp. Wheel. Rog), at 23; Ex. BC, at 34, 40; Ex. BD at 1–2; Ex. BE (Wheeler 6/3 Tr.), at 24:11–25:1, 29:6–12; Ex. AX (Peterson Tr.), at 115:2–117:9; Ex. AA (Griswold Tr.), at 155:15–157:3). Philips designed both the log files and its Allura software that creates the log files, which contain Philips' proprietary data. (Ex. E (Suijs 1/23 Tr.) 155:5–159:7). Philips Allura software generates the log files. (Ex. K (Astrachan Tr.) 190:4–15). Philips implements closed profile security that locks users with Level 0 CSIP access into a closed software environment, which prevents their unauthorized access to Philips' copyrighted log files. (Ex. L (Orso Rpt.) ¶¶ 102, 111–12, 294.

⁵² Ex. L (Orso Rpt.), ¶¶ 336–44, 347–50; Ex. AM (Dorow 5/7 Tr.), 169:12–174:22, 183:20–188:17, 191:23–192:24; Ex. R (Regard Rpt.), ¶¶ 96, 121–27, 130–35, 141–46, 182–97, 198–206, 216–35, 239–44 & Ex. O (drive idx.)). Transtate employees also would share Philips' KNOVA information. (Ex. R (Regard Rpt.), ¶¶ 37, 225–26, 323–28; Ex. BF (Dancy Tr.), 287:12–291:2; Ex. F (McAlpin Tr.), at 160:10–161:23.

⁵³ Ex. I (Froman Tr.), 153:5–10, 188:10–190:8, 195:20–197:13, 203:11–204:8, 227:6–228:7; Ex. BE (Wheeler 6/3 Tr.), at 27:21–28:11; Ex. AA (Griswold Tr.), 223:1–234:15).

⁵⁴ (Ex. BG (Stade Rpt.) ¶¶ 14, 21, 23–25, 29–42.

applicable performance standards set by the FDA when the component is assembled, installed, adjusted, and tested as directed by the manufacturer.⁵⁵

It is undisputed the AIAT Regulation applies to the certified components of Philips Allura systems. According to Philips, Philips complies with it by providing the required instructions and related materials as part of its Level 0 CSIP access.⁵⁶ As noted previously, this Court temporarily stayed this and all related cases pending a complaint made by Defendants to the FDA, and the FDA complaint has not changed anything.

Philips asserts that it submitted its AIAT documentation to the FDA during the 510k premarket clearance process for its Allura systems and the FDA has not found these disclosures to be inadequate.⁵⁷ According to Philips, the FDA confirmed in writing, during this litigation, that there were no “unresolved compliance issues associated with Philips’ disclosure obligations as set forth in 21 C.F.R. 1020.30(g) and 1020.30(h).”⁵⁸

II. Defendants’ Facts and Evidence Presented on Summary Judgment

In response to Plaintiff’s summary judgment motion, and in support of its own summary judgment motion, Defendants have presented the following evidence:

I. Philips Views ISOs As a Competitive Threat

Defendants asserts that during the COVID-19 pandemic, Philips’ systems have been critical to diagnoses and treatment of COVID-19.⁵⁹ Defendants repair those systems and sell

⁵⁵ 21 C.F.R. § 1020.30(g).

⁵⁶ See Ex. BH, at 7; Ex. BI, at ‘878; Ex. W (2017 CSIP Policy), at ‘606–607; Ex. D (Dickson 12/31 Tr.), at 31:12–16, 37:11–19). Philips asserts that it thoroughly vets its compliance with FDA regulations, including the AIAT Regulation. (Ex. BJ (compl. record).

⁵⁷ Ex. BK (Gutierrez Rpt.) ¶ 97; Ex. BL (Pre-Sub Ltr) at ‘819, ¶ 4.

⁵⁸ Ex. BM (FDA Resp.) at ‘95–96; Ex. BK (Gutierrez Rpt.) ¶¶ 98–102).

⁵⁹ (Ex. 1; Ex. 4).

refurbished and new parts for these systems.⁶⁰ As an original equipment manufacturer (“OEM”), Philips competes with ISOs including Transtate to service Philips’ systems after the warranty expires.⁶¹ ISOs provide lower-priced, 24/7 services that increase access to vital healthcare.⁶² The annual cost of a Philips service contract is over \$187,000.⁶³

II. Philips’ Conduct Has Injured Defendants, Market Competition, and Patients

Defendants assert that while Philips’ service prices are significantly higher than ISOs, Philips’ service levels, including response times, are well-below its competitors, sometimes intentionally.⁶⁴ Defendants assert that Philips deliberately delays service to non-contract customers to make them “suffer” and “feel some pain,” as a North Carolina field service engineer was told by his superiors.⁶⁵

Defendants contend that Philips delayed “critical” repairs while a patient was on the table because the hospital didn’t have a contract.⁶⁶ This coerces hospitals into entering Philips’ expensive service contracts—at the cost of patient safety—while excluding ISO competition.⁶⁷ Additionally, Philips artificially shortens its systems’ useful life. For example, in 2017, Philips restricted its systems’ end of life (“EOL”) to 8 years, despite data showing an EOL of 10 years or more, “to be mindful of the impact to our tube & component supplier’s (GTC) margins” and to prevent newer used parts from “de-installed machines” entering the “grey market,” which allowed third parties to obtain lightly used parts. Philips feared third parties’ access to lightly

⁶⁰ (Ex. 3, 102:10–108:10; 116:1–9).

⁶¹ In 2017, Philips identified Transtate as successfully competing against Philips to service Philips’ systems. (Ex. 5).

⁶² Defs. Br. at 2 ¶ 2.

⁶³ Pl. Br., at Ex. H.

⁶⁴ See Ex. 6, ¶ 4; Ex. 7, at 4; Ex. 8, ¶ 16.

⁶⁵ Ex. 9, 142:18–151:04; Ex. 10, 96:01–96:16.

⁶⁶ Ex. 81; see also Ex. 6; Ex. 8, ¶ 16.

⁶⁷ Exs. 11–13; Ex. 14, 58:21–59:24; Ex. 9, 142:18–151:04; Ex. 10, 98:24–99:01.

used parts “will put more pressure on [Philips] to be more competitive in the deinstallation space.”⁶⁸ According to Defendants, Philips has continued to prey on its own customers to extract profits and prevent competition.⁶⁹ Defendants contend that Philips also raised its rivals’ costs by increasing the trade-in value of used Philips’ systems and parts, which effectively became the cost of the used part.⁷⁰ Philips also mandated only new parts could be used in Philips’ non-EOL machines even though it refuses to use new parts in EOL or EOS machines.⁷¹

Additionally, Philips told customers that they needed Philips-trained engineers to service their machines before receiving the access to service tools and information for which they paid.⁷² But per an “ongoing policy,” Philips refuses essential service training to Defendants and other ISOs, despite Defendants’ offers to pay or to enter service contracts.⁷³ Philips provides training only by non-disclosure agreements, and only to specifically designated in-house biomedics employed by purchasers of Philips’ “first-look” service contracts.⁷⁴

A. Philips Defense that Customers Can Easily Switch OEM Imaging Systems is False

According to Defendants, while Philips argues that customers who are dissatisfied with its poor service can simply switch to a different OEM’s imaging systems, the reality is that

⁶⁸ For example, Exs. 15–16; Ex. 17 at 10; Ex. 18.

⁶⁹ Exs. 15, 18–19; see also Ex. 79–80.

⁷⁰ See Ex. 20, 165:7–20 (“Do I think there’s behavior by Philips to try to restrict and raise costs to firms that recondition parts? Yes. . . .if you want to raise cost to rivals to reconditioning, what you do is you raise the trade-in value because that becomes the cost of the used part. The arithmetic is pretty straightforward.”).

⁷¹ Ex. 92 (“Azurion Catalyst Upgrades have restrictions on re-use items.”).

⁷² Ex. 69, 139:5-140:3 and at Ex. 35; Ex. 70, 155:3-22; Ex. 71, at Ex. 12, at Philips_TEC0108971-Philips_TEC0108972.

⁷³ Transtate Ans. to Sec. Am. Compl. [Doc. No. 274] ¶ 167; Ex. 69, 38:21–40:5, 115:16–116:20, and at Ex. 24.

⁷⁴ Ex. 32, 88:6–9 (explaining 626 engineers received training from Philips’ subsidiary AllParts.

purchasers of these capital-intensive, long-lived systems are “locked in” to Philips’ services, despite Philips’ high prices, slow service, and information restrictions.⁷⁵ Defendants note that a new system can cost \$1.2 million plus significant installation, renovation, and training costs.⁷⁶

Moreover, new systems require specially-configured secured rooms—which are unique to each OEM—and complex system integration.⁷⁷ Defendants maintain further that regulatory barriers also exist: for example, North Carolina medical facilities must obtain State approval to replace or upgrade their systems.⁷⁸ Defendants’ economic expert interviewed customers who affirmed that due to the “absurdly high” cost, no customer would respond to dissatisfaction with Philips’ services by removing a Philips system before its end-of-life to replace it with another OEM system; and no one had ever heard of this.⁷⁹

B. Philips Controls the Parts Market

Defendant has also presented evidence to show that Philips controls the parts market. Philips makes 100% of the parts for its imaging systems.⁸⁰ Because Philips’ new parts are expensive, Transtate and other ISOs utilize used parts derived from buying, cannibalizing, or reconditioning equipment.⁸¹ Philips also buys, reconditions, and sells used parts for a premium.⁸² Starting in 2012, Philips began a campaign to buy up the available supply of used parts and remove them from the market.⁸³ Defendants maintain that this campaign resulted in increased

⁷⁵ Ex. 21; Ex. 20, 111:23–114:9.

⁷⁶ Ex. 22, ¶¶ 9–10 (\$200,000 to \$300,000 to renovate; \$20,000–\$30,000 per trainee).

⁷⁷ Ex. 22, ¶¶ 9–10.

⁷⁸ See (Ex. 25).

⁷⁹ Ex. 20, 111:23–114:9.

⁸⁰ Ex. 26, 155:12–155:16.

⁸¹ Ex. 20, 168:23–25 to 169:5; Ex. 68, 38:1–39:7, 42:3–43:11; Ex. 90, ¶ 6; see Ex. 77.

⁸² See generally Ex. 77.

⁸³ Ex. 27; see also Ex. 28, at 9; Ex. 17 (“Commitment to take all professional equipment back by 2020”); Ex. 29; Ex. 77 ¶¶ 4–7.

control over prices of new and used parts for Philips, and increased costs for used parts for competitors. First, Philips “continue[d] to buy back used [X-Ray] CV MRC tubes from deinstalled systems. This should significantly cut supply to the 3rd parties and raise their prices. . . . We expect to command at least a 10-15% premium over 3rd Party used tubes.”⁸⁴ Second, as the OEM, Philips applied a “certified service parts” mark to its used parts so that “if a customer is looking into purchasing a used tube from a 3rd party, then this should not be an issue since NO used tubes on the market have a renewed CSA mark”, so “if a customer insists on a CURRENT CSA Mark, then the only solution in the marketplace is a NEW MRC tube.”⁸⁵

Third, Philips seized an anticipated “\$15M USD Opportunity” to crush “competing 3rd party de-installers” in the “Philips IGT Systems/Parts only” market: “increase control of parts resale market by keeping more parts/systems in-house”, giving its subsidiary AllParts “Right of First Refusal”; recycling parts not selected for refurbishing; and using Philips’ engineers for deinstallation jobs rather than third parties.⁸⁶ According to Defendant, Philips’ board chairman noted in 2018: “Closing the loop is good business because I don’t want our medical equipment to fall in the hands of third parties who then cannibalize the systems and destroy my spare parts business. So it is actually—it makes eminent sense to do this and close that loop for 100%, which we have committed to do.”⁸⁷ Defendants contend that Philips augmented this removal of used equipment and reduction in available used parts by increasing trade-in value for used

⁸⁴ Ex. 27; see also Ex. 77, ¶¶ 4–7.

⁸⁵ Ex. 27; see also Ex. 22, ¶ 20.

⁸⁶ Ex. 29.

⁸⁷ Pl. Br., Ex. A, at 24 n.147; see Ex. 20, 169:9–18.

Philips machines, raising third-party costs.⁸⁸ In March 2020, Philips refused to sell used parts to ISOs.⁸⁹

Defendants contend that Philips also refuses to install any part from a non-Philips source, even if it is a Philips-branded used part from a third-party. Defendants maintain that this drives up costs and delays repairs because Philips only sells brand-new parts at a premium, for far more than used parts sold by reputable third parties.⁹⁰ Defendants note that, additionally, Philips appointed its subsidiary AllParts as the sole seller of its parts: but AllParts does not keep a full inventory of new parts (for ISOs and customers' purchase) or of used parts (for customers).⁹¹ For both new and used parts, this increased prices and slowed fulfillment of orders (and thus repairs).⁹²

III. Philips Limits Availability of and Access to Philips' CSIP Materials

As noted, Philips is required by law to provide “adequate” access to information for the assembly, installation, adjustment, and testing (“AIAT”) of its cath lab systems and other radiation emitting devices, to third parties, including ISOs that perform essential services on the machines, in order to meet federal performance and compatibility standards.⁹³ Philips designates its service software, documentation, training materials, and other materials as “CSIP” and assigns “Levels” corresponding to access.⁹⁴ Philips designates “Level 0,” or what it unilaterally

⁸⁸ Ex. 30, at 9; Ex. 77 ¶ 7.

⁸⁹ Transtate Ans. to Sec. Am. Compl. [Doc. No. 274] ¶ 159; see Ex. 22, ¶ 20; Ex. 77, ¶¶ 4–7, 9–12.

⁹⁰ Ex. 22, ¶ 20 (third parties charge “a fraction of the price” of new parts).

⁹¹ Ex. 77, ¶¶ 4–7 (Philips/AllParts policy change increased parts costs), ¶¶ 9–12 (Philips/AllParts policy changes prevent Defendants from purchasing parts); Ex. 26, 194:1–12.

⁹² Ex. 21, at 22; Ex. 26, 141:13–21 (more supply of used parts would lead to lower prices); see generally Ex. 77).

⁹³ Defs. Br. 3, at ¶ 4; Pl. Br. 8.

⁹⁴ Defs. Br. 4, at ¶ 11–12.

deems “AIAT,” access for information that it claims it is required to disclose by the FDA, and limits ISOs, including Defendants, only to Level 0 CSIP access.⁹⁵

According to Defendants, Philips refuses to provide access to or license necessary servicing information. Defendants assert that while Philips claims that Level 0 CSIP materials are available to anyone who requests access, including Transtate and all other ISOs, customers and ISOs must request access to even Level 0 CSIP information from Philips and do not receive it in a timely, unhindered manner, or in some cases, at all.⁹⁶ Defendants further contend that Philips regularly denies access to Level 0 CSIP materials, including but not limited to: (i) revoking access to useful manuals and tools that third parties relied on for years, claiming they were shared “in error” or were “proprietary IP”; (ii) providing outdated information; (iii) giving updated information only to Contract Customers; (iv) effectively making access unavailable to competitors; (v) arbitrarily changing ISOs’ access levels.⁹⁷

According to Defendants, Philips’ Level 0 CSIP materials also do not include access to all materials the law authorizes Defendants to access and use, including those identified in Philips’ own AIAT manuals.⁹⁸⁹⁹ Even to set up Level 0 access, Philips reaps millions of dollars in fees and labor for “no regulatory reason.”¹⁰⁰ Defendants contend that this exceeded Philips’

⁹⁵ Defs. Br. 3, at ¶ 12 & 5 at ¶ 15.

⁹⁶ Ex. 32, 59:4–9; Ex. 3, 112:6–113:10; Ex. 70, 90:21–92:15, 147:20–149:12, and at Exs. 1, 6; Ex. 71 161:17–163:2, and at Ex. 16.

⁹⁷ Ex. 33; Ex. 34, Ex. 35, Ex. 36, Ex. 37, Ex. 39, ¶¶ 10–11; Ex. 40–41; Ex. 43 ¶ 9; Transtate Ans. to Sec. Am. Compl. [Doc. No. 274] ¶ 87; TEC Ans. to Sec. Am. Compl. [Doc. No. No. 275] ¶ 88; Ex. 51 (from ISO Frontier Imaging Services); Ex. 59, 160:20–161:18, 162:21–163:24; Ex. 78, 77:16–79:08 (actual access may not correspond to access level on document’s face); Ex. 91, 81:7–82:6; 82:11–82:22; 279:21–280:11.

⁹⁸ Ex. 46; Ex. 47 (\$2,000 smartcard and \$200 access dongle).

⁹⁹ Defs. Br. 5, ¶ 16; Ex. 91 ¶ 6.

¹⁰⁰ Ex. 42; *see, e.g.*, Ex. 82 (Philips employee stating “there is no regulatory reason for Philips to require sending an FSE onsite to activate the service”); Ex. 43 1–5; Ex. 44 ¶ 9 (must pay for \$2,000 service call simply to populate an IP address); Ex. 84 ¶ 6.

costs of providing access, violating its obligations under 21 C.F.R. § 1020.30(g) and (h).¹⁰¹ Philips also derived “substantial fees” of at least \$7.5 million from “licensing” Level 0 information. Philips’ CSIP denials are calculated business decisions that often create delays and compromise patient safety.¹⁰² For example, without warning, Philips removed an ISO’s access to all instructions for all cardiovascular systems.¹⁰³

Defendants contend that, facing revenue pressures from servicing rivals, Philips wields its CSIP in an attempt to justify technological lockouts to life saving equipment they do not own.¹⁰⁴ Philips explicitly recognizes the anticompetitive nature of its CSIP access denials; its CSIP access guidelines even list elements of a competition law claim.¹⁰⁵

IV. Philips also Uses TPMs to Hinder ISOs’ Ability to Properly Service Its Machines

Philips’ attempted use of restrictive technological protective measures (“TPMs”) to deny access to data files—including error logs, configuration files, and event logs—hinders biomed’s and ISOs’ ability to diagnose faults and errors in the operation of a system.¹⁰⁶ This prevents them from accessing Level 0 or other functions that are undisputedly essential for servicing the machines.¹⁰⁷

V. Defendants’ Access to and Service of Philips’ Products Is Authorized

Philips claims to use its “IST” technology to control a user’s access level to Philips’ CSIP

¹⁰¹ Ex. 43, ¶¶ 4–8.

¹⁰² Ex. 48–50.

¹⁰³ Ex. 51 (from ISO Frontier Imaging Services).

¹⁰⁴ Ex. 52, at 5; *id.* at 9.

¹⁰⁵ Ex. 53, at Philips_TEC0108969, Philips_TEC0108974.

¹⁰⁶ Ex. 57, 307:2–13 (explaining that for Transtate engineers to determine what part is needed they must service the machine which sometimes includes “reviewing the customer’s inner logs”).

¹⁰⁷ Ex. 39, ¶¶ 1011; Ex. 44, ¶ 9.

and that it sometimes prevents customers and ISOs from accessing menu options above their CSIP levels.¹⁰⁸ Defendants contend that access to the actual system files, however, is not protected, and anyone with a rudimentary understanding of the Windows XP operating system can view the files.¹⁰⁹ Defendants further argue that, “due to pernicious issues accessing Level 0 CSIP materials (and other required AIAT information),” Andy Wheeler, President of both TEC and Transtate, developed the FD_Service software tool through proper reverse-engineering of Philips’ used equipment TEC owned.¹¹⁰ According to Defendants, the FD_Service software tool makes available the necessary service functions on Allura cath labs that Philips fails to make readily available.¹¹¹

Defendants further assert that, contrary to Philips’ contentions, FD_Service does not provide access to any Philips software code or other copyrighted work to which Defendants do not already have access.¹¹² FD_Service merely makes available for use service functions from the field service framework (“FSF”) service menus on the systems that are not otherwise visible to a user.¹¹³ Defendant argues that although Philips states that FD_Service modifies numerous files, it actually only temporarily modifies one file (a 4-line functional [REDACTED] file), which it changes to refer to a [REDACTED] file created by FD_Service.¹¹⁴

¹⁰⁸ Defs. Br. 5 ¶ 13.

¹⁰⁹ Ex. 58; Pl. Br., at Ex. L at ¶¶ 44–50.

¹¹⁰ Defs. Br. 8 ¶ 26.

¹¹¹ Defs. Br. 8 ¶ 26.

¹¹² Pl. Br. 7; Ex. 57, 37:18–21, 53:21–54:2 (Explaining that FD_Service only provides access to AIAT functions.

¹¹³ Defs. Br. 8 ¶ 26.

¹¹⁴ Ex. 58, 127:17–128:7; Pl. Br., Ex. AD at ¶¶ 32–34; Ex. 59, 55:1–17. No other file is modified. Ex. 59, 55:1–23.

Defendants argue that these changes are not made to allow access to the Allura software, which indisputably Defendants already can access, and no other file is modified.¹¹⁵

A. Philips' Interferes with Third-Party Repairs

Defendants have presented evidence that Philips monitored hospitals' equipment and ISOs' use of equipment, constituting an "unauthorized service in the field" even though it knew the hospitals' contracts allow them to grant full access to third-party servicers.¹¹⁶ According to Defendants, if Philips detects that a biomed or ISO conducted a repair, it will delay service to the hospital.¹¹⁷

Defendants further assert that Philips also monitors heavy use periods in hospitals, leveraging it to extract supra-competitive revenues on part sales.¹¹⁸ Further, Philips hinders non-contract customers by making unauthorized and unnecessary repairs to machines. For example, Philips conducted firmware upgrades on equipment owned outright by two medical facilities—for which Philips provided no warranty, no service, and no support—which allegedly prevented those medical facilities from servicing their own equipment.¹¹⁹

B. Philips Deceived Customers and Disparaged ISO Services

Finally, Defendants contend that Philips has disparaged Transtate and TEC's services, resulting in lost income and several customers.¹²⁰ Philips sabotaged its own systems to falsely

¹¹⁵ (Ex. 57, 77:22–23 (“FD Service, it’s my understanding FD Service doesn’t modify files.”)).

¹¹⁶ Ex. 60; Ex. 85, 118:22–121:1, and at Ex. 18.

¹¹⁷ Ex. 9, 142:18–150:25 (explaining that service engineers were instructed by Philips to not provide same day service for customers that did not have service contracts with Philips; “If they don't have a contract, they'd have to suffer.”); Ex. 43, ¶ 12.

¹¹⁸ See Ex. 23, at Philips_TEC1335643.

¹¹⁹ Ex. 61, ¶¶ 23, 30)

¹²⁰ Pl. Br., at Ex. A ¶¶ 80–119; Ex. 3, 39:13–58:8; Pl. Br., at Ex. AK at 41:7–12 (Renovo, Iasis, Health First, and Regional Medical Center at least partially ceased Transtate’s services after interacting with Philips representatives).

blame Transtate and interfere with its service contracts.¹²¹ Philips also disparaged ISOs generally, and deceived customers by saying only Philips-trained technicians could service its systems (while denying ISO training).

III. STANDARD OF REVIEW

Summary judgment shall be granted “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(a). A factual dispute is genuine “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A fact is material only if it might affect the outcome of the suit under governing law. Id.

The movant has the “initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact.” Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986) (internal citations omitted).

Once this initial burden is met, the burden shifts to the nonmoving party. The nonmoving party “must set forth specific facts showing that there is a genuine issue for trial.” Id. at 322 n.3. The nonmoving party may not rely upon mere allegations or denials of allegations in his pleadings to defeat a motion for summary judgment. Id. at 324. The nonmoving party must present sufficient evidence from which “a reasonable jury could return a verdict for the nonmoving party.” Anderson, 477 U.S. at 248; accord Sylvia Dev. Corp. v. Calvert Cnty., Md., 48 F.3d 810, 818 (4th Cir. 1995).

¹²¹ Ex. 9, 164:23–166:3; Ex. 3, 41:7-52:6; Pl. Br., at Ex. AK at 51:5-55:13 (Philips serviced system installed by Transtate and blamed Transtate when system crashed; Transtate lost the business).

When ruling on a summary judgment motion, a court must view the evidence and any inferences from the evidence in the light most favorable to the nonmoving party. Anderson, 477 U.S. at 255. “Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial.” Ricci v. DeStefano, 129 S. Ct. 2658, 2677 (2009) (quoting Matsushita v. Zenith Radio Corp., 475 U.S. 574, 587 (1986)).

IV. DISCUSSION

A. Summary of the Parties’ Arguments

Although the claims are numerous and the arguments are highly technical, the parties’ arguments are boiled down to this: Defendants contend that “Philips unjustifiably asserts alleged intellectual property rights over a broad set of materials—which is required to be, and in the past has been, readily available to independent service organizations (“ISOs”), such as Transtate—in an attempt to foreclose competition in the after-market for servicing vital medical equipment owned by healthcare providers.” Specifically, Defendants argue that Plaintiff is attempting to gain or maintain a monopoly by creating security levels on its machines to prevent ISOs from performing maintenance on the machines. Lastly, Defendants contend that they merely figured out a way to legally reverse engineer the security controls and that nothing they have done violates any of Plaintiff’s trade secrets or copyrights. Justifying their actions, Defendants emphasize that Plaintiff’s anti-competitive strategies pose risks to patients’ health and safety.

On the other hand, Plaintiff has portrayed Defendants as unscrupulous and deceitful thieves who brazenly stole Plaintiff’s highly valuable trade secrets and its copyrights, and who poached some of Plaintiff’s employees with the purpose of stealing Plaintiff’s intellectual property. In short, each party has painted the other as a despicable villain. The parties have submitted briefs amounting to hundreds of pages and thousands of additional documents attached

as exhibits. The parties have also flooded the Court with numerous discovery disputes. The Court will not recite every fact asserted and argument made in the parties' briefs in addressing their respective summary judgment motions. The Court does make the following findings on the parties' respective summary judgment motions:

B. Plaintiff is Entitled to Summary Judgment that Defendants Violated the DMCA

Section 1201(a)(1) of the DMCA provides that “[n]o person shall circumvent a technological measure that effectively controls access to a work protected under this title.” 17 U.S.C. § 1201(a)(1)(A). “A technological measure ‘effectively controls access to a work’ if the measure, in the ordinary course of its operation, requires the application of information, or a process or a treatment, with the authority of the copyright owner, to gain access to the work.” Id. § 1201(a)(3)(B). “To ‘circumvent a technological measure’ means to descramble a scrambled work, to decrypt an encrypted work, or otherwise to avoid, bypass, remove, deactivate, or impair a technological measure, without the authority of the copyright owner.” Id. § 1201(a)(3)(A).

Here, it is undisputed 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. Because Defendants have admitted to using software they developed to bypass Plaintiff's security, there can be no dispute that they have circumvented Plaintiff's technological measures under the plain terms of the DMCA. The Court therefore grants summary judgment of liability in Plaintiff's favor as to the DMCA claim. See 17 U.S.C. § 1201(a)(3)(A); see also Disney Enters. v. Vidangel, Inc., 371 F. Supp. 3d 708, 714 (C.D. Cal. 2019) (granting summary judgment to plaintiff on liability because defendant admitted to using software to decrypt plaintiff's encryption access controls). The issue remains for trial, however, what damages Plaintiff has occurred as a result.

In opposing Plaintiff's summary judgment motion, Defendants argue that the availability of and access to Plaintiff's CSIP materials is a significant problem, and that it justifies their circumvention of Plaintiff's technological measures. As Defendants note correctly, Plaintiff is required by law to provide "adequate" access to information for the assembly, installation, adjustment and testing ("AIAT") of its cath lab systems and other radiation emitting devices, to third parties, including ISOs that perform essential services on the machines, in order to meet federal performance and compatibility standards.¹²² Defendants contend, among other things, however, that Philips' Level 0 CSIP materials do not include access to all materials the law authorizes Defendants to access and use, including those identified in Philips' own AIAT manuals. Defendants further contend that Philips uses technological protective measures to hinder the ability of ISOs to properly service its machines. Defendants also contend that Philips actively interferes with third party repairs by delaying important services to hospitals.

Even assuming Defendants' assertions are true, the Court's hands are tied as to the DMCA claim. That is, DMCA claims are not preempted by the AIAT regulation, as this Court cannot usurp the FDA's authority to interpret the AIAT regulations. Moreover, there is no evidence in the record of any FDA determination that affects the elements of Philips' claims. In other words, the existence of the AIAT regulation does not prevent Plaintiff from asserting their intellectual property claims against Defendants. To the extent the AIAT regulations do not adequately protect ISOs, such as Defendants, this is a matter for the parties to take up with Congress or the FDA.

The Court does agree with Defendants, however, that this case exemplifies problems with the DMCA and the right to repair. Whereas the DMCA was originally enacted to protect

¹²² Defs. Br. 3, at ¶ 4; Pl. Br. 8.

copyright owners from digital piracy (such as illegally downloading and sharing music, video games, and movies), powerful corporations are now putting digital locks on their products as a tool to capture and retain a huge market share over the repair industry, reducing consumer choice and raising repair costs.¹²³ Issues of third-party rights to repair not only affect the medical imaging industry, but they extend further to extremely problematic areas for consumers. Indeed, under the literal and very broad language of the DMCA, car owners may be prevented from repairing their own vehicles or from sending their vehicles to third parties for repairs. Imagine the company you bought your vehicle from telling you that you may only get your vehicle repaired at the dealership. This cannot be what Congress intended when it passed the DMCA.

As the parties note, the Copyright Office does allow people to request so-called ‘Section 1201 exemptions’ of the DMCA every three years. To this end, in October 2021 the Library of Congress issued a DMCA exemption allowing ISOs to access the software medical systems to service and repair those medical systems. Specifically, in October 2021, in response to a petition filed by Defendants in this case, the Copyright Office recommended, and the Library of Congress adopted a DMCA exemption recognizing that repair and maintenance activities on medical devices and systems, such as the ones at issue in this case, meet the criteria of “fair use” as set forth in the Copyright Act and exempting “circumventions” under the DMCA. However, Plaintiff contends that the exemption is not as broad as Defendants contend, noting that rather than granting ISOs an “unfettered” right to diagnose and repair medical imaging machines, the exemption merely recognizes an exemption for medical devices where “where “circumvention is a necessary step to allow the diagnosis, maintenance, or repair of [a lawfully acquired medical

¹²³ Of course, the Court recognizes that maintaining strict controls on medical imaging machine repairs is vital since it affects patient safety.

device or system].”¹²⁴ Plaintiff further contends that the Register’s Recommendation stipulates further limits—characterized as “narrow proposed uses and additional limitations” on the exemption’s scope—that clearly exclude what Philips describes as Defendants’ “unlawful hacking.” (Doc. No. 514 at 4).

Regardless of the scope of this new exemption, both parties agree it is inapplicable here, because the exemption is not retroactive. (Doc. No. 501 at 4; Doc. No. 514 at 3). Thus, the recently recognized exemption does not help Defendants. In sum, Defendants have violated the DMCA. Therefore, Plaintiff is entitled to summary judgment on this claim. The issue of damages remains for trial. What damages, if any, including nominal damages, will be up to the jury to determine.

C. Plaintiff is Entitled to Summary Judgment that Defendants Violated the CFAA

A person violates the CFAA by “intentionally access[ing] a computer without authorization or exceed[ing] authorized access, and thereby obtain[ing] . . . information from any protected computer.” 18 U.S.C. § 1030(a)(2)(C). Here, the undisputed facts show that Defendants intentionally accessed a “protected computer,” which is defined as one used in or affecting interstate or foreign commerce or communication. See 18 U.S.C. § 1030(e)(2). A computer with Internet access generally satisfies this requirement under the CFAA. See United States v. Yucel, 97 F. Supp. 3d 413, 417–18 (S.D.N.Y. 2015); United States v. Nosal, 676 F.3d 854, 859 (9th Cir. 2012). Philips’ Allura systems are generally connected through hospital networks to the Internet, so they are protected computers.¹²⁵

¹²⁴ (Ex. B, at 59640 § 15; see also Ex. D (NTIA Letter), at 75–76 (recommending against the “unfettered” exemption requested by Transtate)).

¹²⁵ Ex. AK (Wheeler 6/3 Tr.) 24:11–25:18 (explaining that Defendants remotely collect logs from Philips systems via FTP), 34:2–6.

The undisputed evidence further shows that Defendants intended to access Philips' Level 1 and higher CSIP software on Allura systems in excess of Defendants' level of access authorized by Philips. The requisite intent is "the intent to obtain unauthorized access of a protected computer," and does not require proof that the defendant "had the intent to defraud in obtaining the information or that the information was used to any particular ends." United States v. Willis, 476 F.3d 1121, 1125 (10th Cir. 2007) (citation omitted).

Here, Defendants knew that Philips only authorized them to have Level 0 access to Philips' CSIP materials.¹²⁶ It is undisputed that Philips did not authorize Defendants to access Level 1 or higher CSIP.¹²⁷ Defendants acquired unauthorized access to Philips' Level 1 and higher CSIP software on Allura systems by creating and using software to bypass Philips' security software.¹²⁸

The Supreme Court recently confirmed that an individual "exceeds authorized access" under the CFAA when he accesses a computer with authorization but then obtains information located in areas of the computer "that are off limits to him." Van Buren v. United States, 141 S. Ct. 1648, 1662 (2021). Even if owners of specific Philips Allura systems authorized Defendants to access and service those systems, Defendants were not authorized to access Philips' Level 1 and higher proprietary service materials residing on those systems. Defendants' technical expert

¹²⁶ Ex. K (Wheeler 5/13 Tr.) 17:17–20:2; Ex. Q (Froman Tr.) 79:10–13.

¹²⁷ Ex. K (Wheeler 5/13 Tr.) 23:23–24:25.

¹²⁸ Ex. K (Wheeler 5/13 Tr.) 37:18–39:8, 52:22–55:21; Ex. Y (Griswold Tr.) 42:11–44:19; Ex. Q (Froman Tr.) 69:13–70:1, 74:19–75:11; Ex. R (Astrachan Tr.) 66:14–23; 81:11–83:22, 89:13–23, 198:3–199:8. Defendants' technical expert, Mr. Fenn, analyzed log files produced in this case and concluded that Defendants accessed Philips' Level 1 and higher CSIP software thousands of times (Ex. L (Fenn Rpt.) at p. 45–46 (showing Defendants issued 307 "CSIP Level 1" commands, 2,323 "Additional AIAT Commands" and 688 "Likely Additional AIAT Commands"); Ex. X (Fenn Tr.) 306:19–308:7 (explaining that "AIAT commands" in Fenn's expert report refers to IST Level 2 or higher commands that Defendants can only access by modifying Allura systems, but that Defendants contend are AIAT), 308:8–21).

even opined that Philips' security software specifically locks Defendants out of accessing Philips Level 1 and higher software.¹²⁹ By running FD_Service to bypass the security on Philips Allura system and then using Philips Level 1 and higher tools, Defendants intentionally accessed a protected computer and exceeded their authorized level of access.¹³⁰ In fact, it is because Mr. Wheeler knew that Philips did not allow him to access Level 1 and higher CSIP materials that he developed FD Service to bypass Philips' security and gain access to restricted CSIP information and tools.¹³¹

The Court further agrees with Plaintiff that Defendants' conduct satisfies the "obtained information" element of a CFAA claim. "Obtain[ing] information from a computer" has been described as "includ[ing] mere observation of the data. Actual aspiration...need not be proved in order to establish a violation[.]" United States v. Drew, 259 F.R.D. 449, 457 (C.D. Cal. 2009) (quotation omitted). Defendants' own technical expert concedes that Defendants obtained and used information from Philips' Level 1 and higher CSIP to service Allura systems thousands of times.¹³²

The CFAA permits private parties to bring a cause of action if the violation caused a loss during any one-year period aggregating at least \$5,000. A.V. ex rel. Vanderhye v. iParadigms, LLC, 562 F.3d 630, 645 (4th Cir. 2009); see also 18 U.S.C. §§ 1030(c)(4)(A)(i)(1) and 1030(g). "Loss" under the CFAA is a "broadly worded provision," and encompasses "costs incurred as a part of the response to a CFAA violation, including the investigation of an offense." Id. at 646. Here, Philips has presented sufficient evidence showing that it incurred at least \$5,000 in per-

¹²⁹ Ex. R (Astrachan Tr.) 66:14–23; 82:5–13, 83:14–22.

¹³⁰ Ex. Q (Froman Tr.), 92:10–20.

¹³¹ Ex. Q (Froman Tr.) 102:5–104:13; Ex. R (Astrachan Tr.) 198:3–199:8.

¹³² Ex. L (Fenn Rpt.) at 45–46 (showing thousands of instances where Defendants used Level 1 and higher CSIP after using FD Service to bypass security measures).

year costs investigating Defendants' breach of Philips' security.¹³³ Therefore, Plaintiff has satisfied the threshold loss requirement of its CFAA claim. The Court therefore grants summary judgment of liability in Plaintiff's favor as to the CFAA claim.

D. Remaining Claims and Counterclaims

While the Court finds that Plaintiff is entitled to summary judgment as to its DMCA and CFAA claims, the Court further concludes that there are genuine issues of disputed fact that preclude an award of summary judgment to either party on the remaining claims and counterclaims. These genuine issues of disputed facts include the following:

- The extent to which Plaintiff attempted to protect and did protect its trade secrets and whether the alleged trade secrets were already readily available (for purposes of the DTSA claim)
- The dates Plaintiff reasonably discovered or would have discovered Defendants' misappropriation of trade secrets for statute of limitations purposes (for the DTSA claim)
- Defendants' conduct related to Plaintiff's tortious interference claims (e.g., whether Defendants schemed to hire away key employees of Plaintiff to steal Plaintiff's trade secrets)
- Disputed issues of fact related to whether copying and using Philips' copyrighted materials for Defendants' own commercial gain constitutes "fair use" or is excluded from copyright infringement
- Plaintiff's alleged conduct related to Defendants' Sherman Act and North Carolina Unfair and Deceptive Trade Practices Act counterclaims

¹³³ Ex. AL (Kennedy Rpt.) ¶¶ 202-05; Ex. AM (Philips_TEC1516513).

- The parties' disputed facts regarding the relevant market for purposes of Defendants' Sherman Act counterclaim and whether Plaintiff has a monopoly or market power in the relevant market
- The parties' disputed facts as to whether Plaintiff denied essential facilities or access to essential facilities in violation of the Sherman Act

As to Plaintiff's claims against Defendants under the Georgia Trade Secrets Act, only conduct that occurred in Georgia is actionable against Defendants.

Thus, this case shall commence to trial for a liability finding on all claims and counterclaims except for Plaintiff's DMCA and CFAA claims. On these two claims, trial shall proceed as to the issue of damages only.

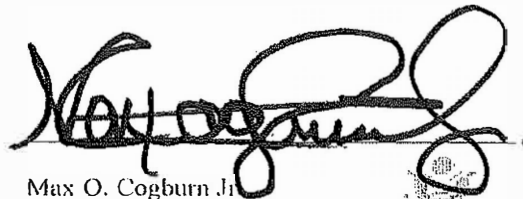
V. CONCLUSION

For those reasons, the Court **DENIES IN PART AND GRANTS IN PART** Plaintiff's summary judgment motion, and the Court **DENIES** Defendants' summary judgment motion.

ORDER

IT IS, THEREFORE, ORDERED that the Motion for Partial Summary Judgment, (Doc. No. 379), filed by Plaintiff Philips Medical Systems, is **DENIED in part and GRANTED in part**, and the Motion for Summary Judgment, filed by Defendants, (Doc. No. 383) is **DENIED**. This action shall proceed to trial.

Signed: February 16, 2023



Max O. Cogburn, Jr.
United States District Judge

EXHIBIT B

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.)	DOCKET NO. 3:20-CV-21
)	
TEC HOLDINGS, INC., ET AL.,)	
)	
Defendants.)	
)	

TRANSCRIPT OF JURY TRIAL VOLUME X
BEFORE THE HONORABLE MAX O. COGBURN, JR.
UNITED STATES DISTRICT COURT JUDGE
MONDAY, APRIL 17, 2023 AT 8:30 A.M.

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I N D E X

DEFENDANT'S CASE IN CHIEF -----

WITNESS	PAGE
Andy Wheeler	
Direct Examination by	2616
Cross-Examination by Mr. Hultquist	2798

EXHIBITS

DEFENDANT'S EXHIBITS -----

NO.	RCVD
212	2636
DTX-635	2643
DTX-636	2643
DTX-634	2673
DTX-630	2679
DTX-159	2712
42	2734
DTX-120	2741
DTX-130	2751
DTX-150	2758
DTX-489	2775
DTX-169	2777
DTX-207	2786
208	2790
DTX-210	2791
DTX-1004	2794

EXHIBITS

PLAINTIFF'S EXHIBITS -----

NO.	DESCRIPTION	MKD	RCVD
PTX-228		2777	
PTX-326		2801	
689		2841	
PTX-362		2849	
PTX-398		2850	
PTX-346		2852	
PTX-347		2855	
PTX-343		2861	

18 Q. Okay. All right.

19 Well, I think we're about to stop talking about software
20 development and script writing. But I've got a few sort of
21 followup questions on that.

22 When you developed this program, did you make all of the
23 menu items available?

24 A. I did.

25 Q. And why did you do that?

1 A. Well, I thought about not, but I determined that it was
2 important because we saw no correlation with our Level 0 key
3 to the AIAT access that we needed. We didn't have everything
4 that we needed. So I just -- basically, our engineers go
5 onsite. They work on cath labs. We trust them to use all
6 the tools they need. I mean, they're accustomed and trained
7 to use what they need when they need it and do that. They
8 don't go around fixing other parts of the cath lab that don't
9 need fixed; right?

10 Essentially I said if it's a backup tool and I need to
11 make everything available, the engineer will determine what's
12 need to do the AIAT service; right.

13 The other reason that I -- the other thing that I
14 incorporated in it was not to need a key because we were also
15 finding that reports of keys getting broken or keys not
16 working when we plugged them into a system because of
17 drivers.

18 So throughout the years, it was -- as a backup tool, it
19 was important to just have it open things up and let the
20 engineer determine what needs to get done.

21 Q. You've said this term "backup tool." What do you mean
22 by "you used it as a backup tool?"

23 A. Well, I mean, obviously we had the first hurdle, the
24 first roadblock where if there's no SOID, then that's got to
25 get added. And that happened more often than you would

1 think, happened -- we ran into it all the time. So I created
2 a button that would do that. You know, get a routine to do
3 that.

4 And then we were trying to overcome some issues that we
5 were having in the field. Number one was Level 0 was
6 insufficient for fixing the equipment. Number two was that
7 the key didn't work. And the key could not work because
8 there wasn't a driver on the system for that key. It did
9 work, it could work -- it could not work because the key
10 wasn't -- didn't have a little letter assigned to it. It
11 could not work because your laptop crashed. It could not
12 work because you didn't -- weren't able to connect to the
13 Internet to download the certificate. It could not work
14 because your key, the USB reader on the machine stopped
15 working. We had all of those happen.

16 And so we needed a backup tool that would cover all of
17 that.

18 Q. Okay. And just to be clear, does Transtate use the menu
19 items for anything other than repair and maintenance of
20 Allura cath labs?

21 A. No. We just fix systems. That's all we do.

22 Q. Okay. And does -- there was some questions --

23 A. And install them.



UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA

CERTIFICATE OF OFFICIAL REPORTER

I, Kathy Cortopassi, RDR, CRR, CRC, Federal Official Court Reporter, in and for the United States District Court for the Western District of North Carolina, do hereby certify that pursuant to Section 753, Title 28, United States Code, that the foregoing is a true and correct transcript of the stenographically reported proceedings held in the above-entitled matter and that the transcript page format is in conformance with the regulations of the Judicial Conference of the United States.

Dated this the 18th day of April 2023.

/s/ Kathy Cortopassi
Kathy Cortopassi, RDR, CRR, CRC
U.S. Official Court Reporter

EXHIBIT C

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

Philips North America LLC, a Delaware Company, Koninklijke Philips N.V., a Company of the Netherlands, and Philips India Ltd., an Indian Company,

Plaintiffs,

vs.

Global Medical Imaging, LLC d/b/a Avante Ultrasound, Avante Health Solutions f/k/a Jordan Health Products, LLC, and Jordan Industries International, LLC,

Defendants.

Case No.: 1:21-cv-03615

The Honorable Robert M. Dow

**DEFENDANT GLOBAL MEDICAL IMAGING, LLC'S RESPONSES AND
OBJECTIONS TO PLAINTIFFS' FIRST SET OF INTERROGATORIES**

Pursuant to Federal Rules of Civil Procedure 26 and 33, Defendant Global Medical Imaging, LLC d/b/a Avante Ultrasound (“GMI”), by and through its undersigned counsel, hereby submits these objections and responses to Plaintiffs Philips North America LLC, a Delaware Company, Koninklijke Philips N.V., a Company of the Netherlands, and Philips India Ltd., an Indian Company (collectively, “Plaintiffs” or “Philips”) First Set of Interrogatories, dated October 27, 2021 (the “Interrogatories,” and each individually an “Interrogatory”).

GMI’s objections and responses are based on its interpretation and understanding of the Interrogatories and its current knowledge, understanding, and belief as to the facts and the information available to GMI as of the time of preparation of these objections and responses. Additional discovery and investigation may lead to additions to, changes in, or modifications of

these objections and responses. These objections and responses, therefore, are being given without prejudice to GMI's rights to revise, amend, correct, supplement, modify, or clarify its objections and responses. GMI reserves the right to supplement or amend the responses or objections to these Interrogatories at any time via written discovery responses, expert reports, testimony, and/or documentation. GMI also reserves the right to complete its investigation and discovery of facts, to produce subsequently discovered information, and to introduce such subsequently discovered information at the time of any hearing or trial in this action.

GMI's agreement to provide any responsive and non-privileged or non-work-product information or documents in response to these Interrogatories shall not be construed as a waiver of any right or objection to these Interrogatories or other discovery procedures involving or relating to the subject matter of these Interrogatories. The responses by GMI shall be without prejudice to any objections GMI may have as to: (a) the use for any purpose of any information given in response to the Interrogatories, or (b) the authenticity, admissibility, relevance, or materiality of any of the information to any issue in this case. All objections as to privilege, immunity, relevance, authenticity, or admissibility of any information or documents related to herein are expressly reserved.

In the event of a discovery dispute, GMI's counsel is prepared to meet with Philips' counsel to discuss and, if possible, resolve any disputes that may arise concerning the meaning, scope, and relevance of Philips' Interrogatories or the adequacy of GMI's responses.

Where GMI responds to an Interrogatory by stating that GMI will provide information and/or documents that GMI deems to embody material that is private, confidential, proprietary, a trade secret, or otherwise protected from disclosure pursuant to Federal Rule of Civil Procedure 26(c)(1), or other applicable rules, GMI reserves the right to request that any such production of

confidential information be subject to a Protective Order against unauthorized use or disclosure of such information.

GENERAL OBJECTIONS

The following General Objections apply to each of Plaintiffs' Interrogatories and, unless otherwise stated, shall have the same force and effect as if set forth in fully in response to each of the numbered Interrogatories. The failure to assert any additional objection to a Interrogatory does not waive any of GMI's objections set forth in this section.

1. GMI objects to the Instructions and Interrogatories to the extent they seek to impose obligations beyond what is required by the Federal Rules of Civil Procedure, the Local Rules of this Court, and any Orders which may be entered in this case.

2. GMI objects to the Interrogatories to the extent they seek discovery that is not proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

3. GMI objects to the Interrogatories to the extent they seek discovery that is not directly related to the claims or defenses at issue in this litigation. Any Interrogatory that encompasses time periods, activities, or locations beyond those at issue in this case is overly broad.

4. GMI objects to the Interrogatories to the extent they attempt or purport to seek information protected by the attorney-client privilege, the work-product doctrine, or any other applicable privilege held by GMI.

5. GMI objects to the Interrogatories to the extent they seek confidential business, proprietary, commercially sensitive, competitively significant, protected health, personal, or

sensitive financial information related to GMI, its employees, and/or trade secrets of GMI, its predecessors, and/or third-parties.

6. GMI objects to the Interrogatories as premature to the extent they seek information that is properly the subject of expert analysis. GMI will produce responsive, non-privileged information relating to the subjects of expert analysis at the time called for by any applicable scheduling order in this action, the Federal Rules of Civil Procedure, the Local Rules of the United States District Court for the Northern District of Illinois or any other applicable local rules, case law or court orders.

7. GMI objects to the Interrogatories to the extent they seek information not in its possession, custody or control, or information more easily obtained from sources other than GMI, including but not limited to public sources. GMI further objects to the Interrogatories to the extent they seek information already in Plaintiffs' possession. GMI also objects to the Interrogatories on the grounds and to the extent they seek information available through other means of discovery that are more convenient, more efficient and more practical, including depositions.

8. GMI objects to the Interrogatories to the extent they seek documents or information, the disclosure of which is prohibited by contractual obligations or agreements between GMI and third parties.

9. GMI's responses do not constitute admissions relative to the existence of any information or documents, to the relevance or admissibility of any information or documents, or to the truth or accuracy of any statement or characterization contained in the Interrogatories. All objections as to relevance, authenticity, or admissibility of any document are expressly reserved.

10. GMI objects to the Interrogatories to the extent they are improperly compound and contain multiple subparts. GMI may answer compound Interrogatories, but reserves all rights to

cease responding to Interrogatories and/or subparts of Interrogatories in excess of the limits set forth in Federal Rule of Civil Procedure 33, agreed upon by the parties, or ordered by the Court.

11. GMI objects to the Plaintiffs' Definitions the extent that they purport to extend beyond a reasonable scope and/or their natural meaning. GMI interprets the Interrogatories reasonably and in good faith in accordance with common English usage, as supplemented by its understanding of the common meanings of terms in the medical device industry, and as provided in the Federal Rules of Civil Procedure.

12. GMI objects to Plaintiffs' Definitions and Interrogatories to the extent they are vague, or ambiguous, or require GMI to speculate as to the information sought.

13. GMI objects to the Interrogatories as overly broad, unduly burdensome, and disproportionate to the needs of this case for failing to define the relevant time period. GMI will interpret the "Relevant Time Period" for all Interrogatories as January 1, 2015 to the present, consistent with the five (5) year statutory period for the Illinois Trade Secrets Act, 765 Ill. Comp. Stat. 1065/7, and the instructions in Plaintiffs' First Set of Requests for Production of Documents dated October 27, 2021 ("Plaintiffs' Request for Production").

14. GMI's investigation into this matter is ongoing. Accordingly, GMI reserves the right to alter, amend, or supplement their initial objections and responses as this matter progresses.

OBJECTIONS TO DEFINITIONS

1. GMI objects to Plaintiffs' definitions of the terms "You, " "Your," "Avante," "GMI," and "Jordan Health" as vague, ambiguous, overly broad, unduly burdensome, and disproportionate to the needs of the case. Further, Jordan Industries International, LLC, which Plaintiffs confusingly define as "Jordan Health," has no ownership or operational role in GMI. GMI, as defined by Defendant Global Medical Imaging, LLC, responds on behalf of itself only.

2. GMI objects to Plaintiffs' definition of the term "System" as vague, ambiguous, overly broad, unduly burdensome, and disproportionate to the needs of the case.

3. GMI objects to Plaintiffs' definition of the term "Software" as vague, ambiguous, overly broad, unduly burdensome, and disproportionate to the needs of the case.

4. GMI objects to Plaintiffs' definition of the term "document" as overly broad, unduly burdensome, and disproportionate to the needs of the case.

5. GMI objects to Plaintiffs' definition of the term "communication" as vague, ambiguous, overly broad, unduly burdensome, and disproportionate to the needs of the case.

OBJECTIONS AND RESPONSES TO INTERROGATORIES

INTERROGATORY NO. 1:

List all hospitals and/or other sites where You have used an access key to repair or service Philips Systems, to access the Software on Philips Systems and/or to which You have provided and/or sold an access key, including the date on which You used or sold the access key.

RESPONSE TO INTERROGATORY NO. 1:

GMI objects to Interrogatory No. 1 as vague and ambiguous because it does not define the terms "access key," "access," "repair," or "service." Further, GMI objects to this interrogatory unduly burdensome and in violation of Federal Rule of Civil Procedure 34(b) because GMI does not keep such records in its usual course of business and any response to this Interrogatory would be speculative. Additionally, GMI objects to this interrogatory because the discovery sought is unreasonably cumulative and duplicative.

Subject to and without waiving the foregoing objections and General Objections, the information requested in this interrogatory may be derived from documents produced by GMI in response to Plaintiffs' Requests for Production.

INTERROGATORY NO. 2:

Describe the specific methods or techniques You have used or use to modify or access all Philips Systems, including methods or techniques to modify or access the Software on Philips Systems.

RESPONSE TO INTERROGATORY NO. 2:

GMI objects to Interrogatory No. 2 as vague and ambiguous because it does not define the terms “modify” or “access.”

Subject to and without waiving the foregoing objection and General Objections, GMI responds as follows: GMI does not modify and has not modified any Philips Systems. GMI further states that it does not access the Philips Software. When a GMI customer authorizes GMI to replace a part on its Philips system or otherwise to service its Philips system, GMI only accesses the system user interface to diagnose and service the system. On some occasions, GMI uses the system user interface to update the system to recognize a newly installed part and/or to make a full backup of the system so that the system can be reloaded with all of its original settings. On those occasions, GMI may use a key generated by its key generator.

INTERROGATORY NO. 3:

Identify the person or entity from whom You received any tools and/or learned or acquired any methods or techniques identified in Your response to Interrogatory No. 2.

RESPONSE TO INTERROGATORY NO. 3:

GMI objects to Interrogatory No. 3 as vague and ambiguous because it does not define the terms “tools.”

Subject to and without waiving the foregoing objection and General Objections, GMI responds as follows: GMI’s ability to service its customers is a result of years of experience working on ultrasound systems, including Philips ultrasound systems. GMI field service

engineers receive training as needed. GMI's key generator was developed by one or more members of its technical operations team.

INTERROGATORY NO. 4:

If You contend that a third party was responsible for making changes to any Philips Systems that You acquired, repaired, serviced and/or sold, Identify any third parties that You contend made changes.

RESPONSE TO INTERROGATORY NO. 4:

GMI objects to Interrogatory No. 4 as vague, ambiguous, unduly burdensome, and not proportional to the needs of the case because it does not define the term "change." GMI further objects to this Interrogatory No. 4 because it calls for conjecture and speculation. GMI further objects to this interrogatory because it seeks information from third parties and information not within GMI's possession, custody, control, or personal knowledge.

Subject to and without waiving the foregoing objection and General Objections, GMI responds as follows: GMI does not have the necessary personal knowledge to determine if any Philips System was modified prior to being in GMI's possession or after leaving GMI's possession. GMI does not have the personal knowledge to either confirm or deny that any Philips Systems that it acquired, repaired, serviced and/or sold was changed by a third party when it was not in GMI's possession, custody, or control.

INTERROGATORY NO. 5:

If You contend that You were authorized to make changes to any Philips Systems, Describe all facts that Support Your contention, and Identify all Persons who gave You the alleged authority.

RESPONSE TO INTERROGATORY NO. 5:

GMI objects to Interrogatory No. 5 as vague, ambiguous, unduly burdensome, and not proportional to the needs of the case because it does not define the terms "change."

Subject to and without waiving the foregoing objection and General Objections, GMI responds as follows: GMI is authorized by its customers to perform all necessary servicing. Additionally, GMI purchases software directly from Philips that it installs on GMI's customers' Philips Systems. GMI contends that the software license purchased and obtained directly from Philips provides Philips' authority to update Philips Systems. The specific details requested in this Interrogatory may be derived from documents produced by GMI in response to Plaintiffs' Requests for Production.

INTERROGATORY NO. 6:

Identify all Documents in Your possession, custody or control that are designated at a CSIP Level higher than CSIP Level 0, and Identify all Persons or entities who gave You each Document, including without limitation any Documents You received from the GMI Sister Companies.

RESPONSE TO INTERROGATORY NO. 6:

GMI specifically objects to this interrogatory as overly broad, unduly burdensome, and not relevant or proportional to the needs of the case.

Subject to and without waiving the foregoing objection and General Objections, GMI responds as follows: To the extent that any such documents exists, the information requested in this interrogatory may be derived from documents produced by GMI in response to Plaintiffs' Requests for Production.

Dated: December 10, 2021

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CERTIFICATE OF SERVICE

I, Matthew A. Lafferman, an attorney, hereby certify that on December 10, 2021, I caused a true and correct copy of Defendants' Responses to Plaintiffs' First Set of Interrogatories to be served via electronic mail upon all counsel of record.

/s/ Matthew A. Lafferman

Matthew A. Lafferman

EXHIBIT D

No. 23-5067

**United States Court of Appeals
for the District of Columbia Circuit**

MEDICAL IMAGING & TECHNOLOGY ALLIANCE, ET AL.,
Plaintiffs - Appellants,

v.

LIBRARY OF CONGRESS, ET AL.,
Defendants - Appellees.

On appeal from a final judgment of the
United States District Court for the District of Columbia
Case No. 22-cv-499 (BAH)

APPELLANTS' OPENING BRIEF

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**CERTIFICATE AS TO PARTIES,
RULINGS, AND RELATED CASES**

Parties and amici. The parties before the Court are appellants Medical Imaging & Technology Alliance (MITA) and Advanced Medical Technology Association (AdvaMed); and appellees the Library of Congress and Carla Hayden, in her official capacity as Librarian of Congress.

Rulings under review. The ruling under review is *MITA v. Library of Congress*, No. 1:22-cv-499, Dkt. 26 (Mar. 7, 2023).

Related cases. This case has not previously been before this Court, and there are no related cases currently pending in this or any other court.

/s/ Michael B. Kimberly

CORPORATE DISCLOSURE STATEMENT

The Medical Imaging & Technology Alliance is a division of the National Electrical Manufacturers Association (NEMA), which is a non-profit trade association. No publicly held corporation owns an interest in MITA or NEMA.

The Advanced Medical Technology Association is a non-profit trade association that represents the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. It has no parent corporation. No publicly held corporation owns an interest in AdvaMed.

/s/ Michael B. Kimberly

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EXHIBIT D

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GLOSSARY

- APA - Administrative Procedure Act
- DMCA - Digital Millennium Copyright Act
- FDA - Food & Drug Administration
- ISO - independent service operator
- NPRM - notice of proposed rulemaking
- OEM - original equipment manufacturer

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* * *

The district court's analysis rests on an implausible premise: the Library is a component of "the Congress" (5 U.S.C. § 701(b)(1)), regardless whether it is exercising legislative or executive authority. That view is wrong as a matter of statutory text, is inconsistent with longstanding Library practice, ignores the presumption in favor of judicial review, needlessly implicates separation-of-powers concerns, and is inconsistent with the reasoning in *Intercollegiate*. When the Library exercises executive power, as it did here, it does so as an Executive Branch "agency," and the APA makes judicial review available.

II. ALTERNATIVELY, THE COURT SHOULD REVERSE UNDER THE LARSON DOCTRINE

The Court can and should hold that the Library's executive rulemakings are subject to judicial review under Section 702. But even if the Court were to conclude otherwise, reversal still would be warranted.

The Supreme Court and this Court have long recognized that "sovereign immunity does not bar suits for [non-monetary] relief against government officials where the challenged actions of the officials are alleged to be unconstitutional or beyond statutory authority." *Clark*, 750 F.2d at 102 (citing *Larson v. Domestic and Foreign Corp.*, 337 U.S. 682, 689–91 (1949) and *Dugan v. Rank*, 372 U.S. 609, 621–22 (1963)). "Review for *ultra vires* acts rests on the longstanding principle that if an agency action is 'unauthorized by the

statute under which [the agency] assumes to act,’ the agency has ‘violate[d] the law’ and ‘the courts generally have jurisdiction to grant relief.’” *National Association of Postal Supervisors v. United States Postal Service*, 26 F.4th 960, 970 (D.C. Cir. 2022) (quoting *American School of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 108 (1902)).

That describes this case: In granting the Exemption, the Librarian plainly went beyond the powers delegated to her under the DMCA. The district court’s determination that *Larson* relief is unavailable here turns on a misunderstanding of the nature and magnitude of the Librarian’s error.

Before proceeding further, however, we pause to note that the district court was in all events wrong to dismiss the case on immunity grounds. *See* JA56-58. As we explained in the Statement (*supra* at 5), “[t]here is nothing in the language of the second sentence of § 702 that restricts its waiver [of immunity] to suits brought under the APA.” *Trudeau v. FTC*, 456 F.3d 178, 186 (D.C. Cir. 2006). Thus, “the APA’s waiver of sovereign immunity applies to any suit” challenging a final agency action, “whether [it is brought] under the APA or not.” *Id.* (quotation marks omitted). It was on this ground that the Court in *Clark*—even while finding the Library not subject to judicial review under the APA in the context of that case—nonetheless proceeded to grant relief on the plaintiff’s constitutional claim.

In rejecting appellants' *Larson* claim, the district court was thus in actuality ruling on its merits. It concluded that the Library had not "acted so clearly in defiance of [the DMCA], as to warrant the immediate intervention of an equity court." JA60 (quoting *Federal Express*). We of course disagree with that holding—but setting that aside for the moment, the holding must be understood as a rejection of the claim on its own terms (a Rule 12(b)(6) dismissal), and not a finding that Section 702 of the APA did not waive the government's sovereign immunity (a Rule 12(b)(1) dismissal). That clarification aside, we turn to the nub of the issue.

A. There is no way to characterize the purely commercial uses at issue here as "fair use"

The DMCA authorizes the Librarian to promulgate exemptions to the anti-circumvention rules only when they threaten to suppress "noninfringing uses . . . of a particular class of copyrighted works." 17 U.S.C. § 1201(a)(1)(C). The Librarian's statutory authority to promulgate an exemption thus turns first and foremost on whether the proposed use is noninfringing. Promulgating an exemption for an *infringing* use, to advance separate policy reasons having nothing to do with the DMCA, would be contrary to the statute and in excess of the powers conferred by Congress.

That is just what the Librarian did. Ostensibly, she determined the ISOs' uses were noninfringing because they qualified as fair use. But on closer look,

her analysis was no fair-use analysis at all. Rather, as the Librarian admitted, she approved the Exemption because doing so would help lower prices for machine service and repairs, supporting an Executive Branch policy having nothing to do with the DMCA and directly contrary to fair use principles.

1. Congress has delineated four factors for analyzing fair use. The first factor is the “purpose and character of the use, including whether such use is of a commercial nature.” 17 U.S.C. § 107(1). This factor lies at the heart of copyright law—preventing uncompensated exploitation of proprietary material and thereby “enriching the general public through access to creative works.” *Kirtsaeng v. John Wiley & Sons, Inc.*, 579 U.S. 197, 204 (2016). The Librarian’s disregard for this objective raises a powerful inference that she did not intend to serve the goals of the DMCA or copyright at all.

There is no debate that an ISO’s use of OEM software for maintenance services is “entirely commercial in nature.” *Triad Systems v. Southeastern Express*, 64 F.3d 1330, 1337 (9th Cir. 1995) (holding that using OEM software for maintenance is not fair use); accord *Advanced Computer Services of Michigan v. MAI Systems*, 845 F. Supp. 356, 364-66 (E.D. Va. 1994) (same). Such commercial use “tends to weigh against a finding of fair use” because “the user stands to profit from exploitation of the copyrighted material without paying the customary price.” *Harper & Row Publishers, Inc. v. Nation Enterprises*, 471 U.S. 539, 562 (1985).

The Librarian brushed aside the purely commercial nature of the ISOs' intended use, stating without elaboration that their plan to compete with OEMs for maintenance contracts "is not fatal to [the] fair use determination." JA154. While true that commercial use is not singularly dispositive of a fair-use assertion, it weighs strongly against fair use when the user acts with "*the intended purpose* of supplanting the copyright holder's commercially valuable right." *Harper & Row*, 471 U.S. at 562.

Moreover, to determine whether the "commercial nature" of a use is fatal to a fair-use finding, the Library was supposed to weigh it "against the degree to which the use has a further purpose or different character." *Andy Warhol Foundation for the Visual Arts v. Goldsmith*, No. 21-869, 2023 WL 3511534, at *10 (U.S. May 18, 2023) (citing *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 579 (1994)). "[T]he more transformative the new work, the less will be the significance of other factors, like commercialism, that may weigh against a finding of fair use." *Id.* (quoting same).

On that front, the Library concluded that the ISOs' use of the software was "likely transformative." JA154. But that is clearly, unequivocally wrong.

A transformative use of a copyrighted work is one that adds "new expression, meaning or message" by altering the content, context, or presentation of the work. *Google*, 141 S. Ct. at 1202 (quoting *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 579 (1994)). It asks "whether the copier's use adds

something new, with a further purpose or different character,” thus “altering the copyrighted work” with some new and different expression. *Id.* The underlying idea is that copyright law should “promote science and the arts” and not stifle it. *Campbell*, 510 U.S. at 579.

The ISOs’ proposed uses do not meet that definition in any conceivable respect; they “simply commandeered” the copyright holder’s “software and us[e] it for the very purpose for which, and in precisely the manner in which, it was designed to be used.” *Triad Systems*, 64 F.3d at 1337. That is to say, an ISO that copies documents and code for purposes of device maintenance “invent[s] nothing of its own.” *Id.* at 1336. Allowing ISOs to copy an OEM’s code to boost their own profits thus does not promote innovation or creativity at all.

There can be no dispute about this: The ISOs themselves expressly disclaimed transformative use, explaining in their petitions that they did “not seek an exemption to modify medical devices or systems, or their software,” in any way. JA153. They wished only to copy the software and use it precisely as it was designed, angling to avoid FDA regulations. That is not a “fair” use.

2. In finding otherwise, the Librarian’s only explanation was to say that she had “previously concluded that diagnosis and repair are likely to be transformative uses” (JA156), pointing to prior rulemakings concerning exemptions for the service and repair of consumer products like cell phones and game consoles. There are two glaring problems with that extrapolation.

First, the Librarian herself acknowledged that “fair use analysis is ultimately a fact-specific inquiry that can vary based on the type of device,” and that it is not possible to make a categorical fair-use determination with respect to maintenance and repair of “all software-enabled devices.” JA147. Thus, what the Librarian reasoned or concluded in some other rulemaking, with respect to some other device category, was admittedly irrelevant to her decision in *this* rulemaking concerning complex medical devices.

Second, the prior rulemakings from which the Librarian made her inappropriate extrapolation concerned uses that all agreed *were* transformative. In particular, the 2015 rulemaking cited in the Register’s recommendation (JA156 n.1167) concerned “diagnosis, *modification*, and repair” of electronic control units (ECUs) in automobiles. *See* JA123-124 (emphasis added). The Librarian thus observed in 2015 that “copying the work” embedded in automobile ECUs would often lead to “creat[ing] new applications” and “modification of ECU computer programs” to allow new modes of “interoperat[ion]” among auto parts. JA123. She concluded, therefore, that “at least some of the proposed uses of ECU computer programs are likely to be transformative.” *Id.* Later, in the 2018 rulemaking, the Librarian cited to its 2015 analysis, but without acknowledging this crucial factor. *See* JA129-131 & nn.1254, 1262.

The Register’s analysis of ECUs in 2015 was obviously inapplicable to the rulemaking here. Again, the ISOs in this case expressly disclaimed modification

of any software code or the creation of new applications. The Librarian's reference back to 2015 and 2018 rulemakings concerning other devices and technologies with no relation to medical devices is an abdication of her statutory duty to evaluate the facts before her.

B. The Librarian's true rationale reflects economic policymaking that is unauthorized by the DMCA

Against this backdrop, to call the Librarian's analysis a "fair use" analysis would elevate labels over substance. As this Court has recognized, it is enough to state an *ultra vires* claim to show that the government official's "decision [is] so unreasonable that [she] must have used and applied criteria and reasoning that Congress did not permit in the governing statute." *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1070 (D.C. Cir. 2018). That is the case here. In fact, the Librarian openly stated her true intentions: The Exemption was warranted, she explained, because "OEMs charge higher prices" than ISOs "to service their equipment," creating "competitive concerns recently highlighted by the Executive Branch." JA173.

Although the DMCA permits the Librarian to consider "other factors as the Librarian considers appropriate" when determining whether a particular noninfringing use is "adversely affected" (17 U.S.C. § 1201(a)(1)(C)), that license does not obviate a fair-use finding. And the true reason cited by the

Librarian for the Exemption—competitive concerns and high prices—is utterly anathema to such a fair-use finding.

“[C]opyright is a commercial right, intended to protect the ability of authors to profit from the exclusive right to merchandise their own work.” *Authors Guild v. Google*, 804 F.3d 202, 214 (2d Cir. 2015). Here, the Librarian improperly considered how granting the Exemption would improve competition with copyright holders and thus lower prices, even though the central purpose of copyright laws is to stimulate creativity by *protecting* the right of producers of copyrightable work to recoup the expense of their creative labors.

Indeed, the fourth fair-use factor calls for consideration of “the effect of the use upon the potential market for or value of the copyrighted work.” 17 U.S.C. § 107(4). This factor “requires courts 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 for the original.” *Campbell*, 510 U.S. at 590 (cleaned up). In evaluating this factor, courts “must take account not only of harm to the original but also of harm to the market for derivative works.” *Harper & Row*, 471 U.S. at 568.

Other courts have held that “[b]ecause [an ISOs’ use of] software [is] commercial . . . the likelihood of future harm to the potential market for or to the value of the software may be presumed.” *Advanced Computer Services*, 845

F. Supp. at 364-66. That is because it “likely cause[s] a significant adverse impact on [OEMs’] licensing and service revenues and lower returns on its copyrighted software investment” for ISOs to “freely use[] . . . copyrighted software on a widespread basis to compete with” OEMs for service and maintenance contracts. *Triad Systems*, 64 F.3d at 1337.

These points were brought to the Librarian’s attention, but rather than explaining how harm to the market could be overcome, she cited harm to the commercial interests of the copyright holders as a *feature* of her reasoning. She observed “that medical service providers must spend more to service their equipment” if they use OEM services “than if they were able to . . . have an ISO perform repairs on their behalf.” JA173. In her view, granting the Exemption would thus “help to address the broader competitive concerns.” *Id.*

Such open disregard for Congress’s instruction moves the Librarian’s actions beyond merely “a claim of error in the exercise of the power” (*Doehla Greeting Cards v. Summerfield*, 227 F.2d 44, 46 (D.C. Cir. 1955)) to an assertion of policymaking authority “in excess of [her] delegated powers and contrary to” the DMCA’s express limits (*Aid Association for Lutherans v. U.S. Postal Service*, 321 F.3d 1166, 1173 (D.C. Cir. 2003) (quoting *Leedom v. Kyne*, 358 U.S. 184, 188 (1958))). Although thinly veiled as a fair-use analysis, the Librarian’s reasoning in fact reflects nothing more than naked economic policymaking that turns the purpose of copyright on its head.

Ultimately, the Librarian has no authority under the DMCA to grant the Exemptions for plainly infringing uses on the basis of policy considerations unmoored from the fair-use doctrine. For this reason, the Librarian exercised power in excess of a specific limitation of her delegated authority, and the Exemption should be reviewed, and ultimately set aside, as *ultra vires*.

CONCLUSION

The Court should reverse and remand with instructions to resolve MITA and AdvaMed's APA claims on their merits or to vacate the Exemption.

June 2, 2023

Respectfully submitted,

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EXHIBIT D

Addendum intentionally omitted to reduce file size