IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MEDICAL IMAGING &
TECHNOLOGY ALLIANCE
1300 North 17th Street, Suite 900
Arlington, VA 22209,

and

ADVANCED MEDICAL
TECHNOLOGY ASSOCIATION
701 Pennsylvania Avenue NW, Suite 800
Washington, DC 20004-2654

Plaintiffs,

v.

THE LIBRARY OF CONGRESS,
101 Independence Avenue SE
Washington, DC 20540,

and

CARLA HAYDEN, *in her official capacity as Librarian of Congress*,
101 Independence Avenue SE
Washington, DC 20540

Defendants.

No. 1:22-cv-499

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs the Medical Imaging & Technology Alliance (MITA) and the Advanced Medical Technology Association (AdvaMed)—for their complaint against defendants the Library of Congress and Carla Hayden, in her official capacity—allege on knowledge as to the plaintiffs, and on information and belief as to all other matters, as follows.

INTRODUCTION

1. This is a challenge pursuant to the Administrative Procedure Act and *Larson v. Domestic & Foreign Commerce Corporation*, 337 U.S. 682 (1949), to a final rule of the Library of Congress adopted after notice-and-comment rulemaking under the Digital Millennium Copyright Act, or DMCA. The rule is codified at 37 C.F.R. § 201.40 and grants an exemption from DMCA liability for the circumvention of technological measures that control access to

copyrighted digital content when necessary to diagnose, service, and repair medical devices, including sophisticated devices like magnetic resonance imaging (MRI) machines, computerized tomography (CT) scanners, ultrasound systems, positron emission tomography (PET) scanners, X-ray machines, defibrillators, and surgery assisting robots.

2. Creators of digital content—and the manufacturers of the machines and devices that depend on such content for operation, maintenance, and repair—rely on federal copyright laws to protect their creative works so they can control who uses the content and predictably recover the gains of their labors. As a reliable backstop against unfair exploitation by competitors (for whom the marginal cost to make perfect digital copies of most digital content is effectively zero), copyright law is vital to the way that modern markets function. Indeed, it drives the licensing negotiations that take place between creators and users.

3. In the mid-1990s, amidst the growing role of the internet and digital content in the American economy, Congress came to understand the importance of a creator's ability to secure copyrighted digital content from unlawful duplication and tampering. Its answer was the DMCA. Among other things, the DMCA conforms U.S. copyright law to international treaty standards that "require [the United States] to provide effective legal remedies against the circumvention of protective technological measures used by copyright owners." *MDY Industries, LLC v. Blizzard Entertainment, Inc.*, 629 F.3d 928, 942 (9th Cir. 2010).

4. In simple terms, the DMCA prohibits users of a copyrighted work from circumventing a "technological measure that effectively controls access to [the] work." 17 U.S.C. § 1201(a)(1)(A). As the House Judiciary Committee explained at the time of the DMCA's enactment, circumventing a technological protective measure (a TPM) "is the electronic equivalent of breaking into a locked room in order to obtain a copy of a book." H.R. Rep. No. 105-551, pt. 1, at 17 (1998) (*House Report*).

5. At the same time, Congress understood that, with the growing importance of digital content to expression and learning, unchecked use of TPMs might threaten "a diminution of otherwise lawful access to works and information." *House Report* 36. After all, a copyright

is not an absolute bar to the copying of a work; Congress has long permitted certain non-infringing "fair uses" of copyrighted works to protect freedom of expression and promote further creation. *See* 17 U.S.C. § 107. Fair uses are generally non-commercial uses that promote the objective of copyright law, which is to stimulate creation, expression, and learning.

6. In the DMCA, Congress therefore directed the Register of Copyrights—the head of the Copyright Office within the Library of Congress—to "monitor developments in the marketplace for copyrighted materials" and authorized the Librarian, upon the Register's recommendation, to grant selective exemptions to the DMCA's anti-circumvention rule "for limited time periods, if necessary to prevent a diminution in the availability to individual users of a particular category of copyrighted materials." *House Report* 36.

7. To that end, the DMCA calls for triennial rulemakings in which "the Librarian of Congress . . . shall make the determination . . . of whether persons who are users of a copyrighted work" qualify for a three-year "exemption" from the DMCA's prohibitions. 17 U.S.C. § 1201(a)(1)(C). Such exemptions are statutorily authorized only for noninfringing "fair" uses of the copyrighted works at issue. *Id*.

8. The process by which the Librarian undertakes its triennial exemption review has all the trappings of a traditional agency rulemaking:

(a.) The process commences with a Notice of Inquiry (or NOI) published in the Federal Register. In response to the NOI, proponents of new or renewed exemptions must file petitions and supporting evidence on the regulatory docket. These petitions are then subject to a traditional comment process.

(b.) At the conclusion of the NOI comment process, the Copyright Office publishes a Notice of Proposed Rulemaking (NPRM) in the Federal Register identifying the exemptions that the Office proposes to adopt. The NPRM is followed by a similar comment process, as well as by a public hearing.

(c.) At the conclusion of the NPRM comment process, the Register of Copyrights issues a formal recommendation to the Librarian of Congress, who in turn adopts the

recommendation in a final rule published in the Federal Register. The exemptions are thereafter codified in the Code of Federal Regulations, at 37 C.F.R. § 201.40.

9. Independent service operators, or ISOs, are companies that provide unregulated third-party maintenance and repair services for medical devices (among other machines). ISOs do not create new content or expression as part of their service.

10. In the most recent rulemaking, two ISOs petitioned for an exemption allowing circumvention of TPMs on software-enabled medical devices for purposes of diagnosis, maintenance, and repair of those devices. The ISOs sought access to device software and data files, asserting that the materials otherwise available were sometimes inadequate for them to execute certain repairs. The ISOs did not assert that access to the protected materials was necessary to stimulate creation, expression, and learning; rather, they asserted that it was necessary to stimulate their profits.

11. Original equipment manufacturers, or OEMs, manufacture—and hold copyrights to the software useful to diagnose, maintain, and service—medical devices. OEMs use TPMs to safeguard their machines' software and to ensure the safety and privacy of patients that use their devices. TPMs are thus vital to the safety and functionality of medical devices. Although OEMs typically make some copyrighted materials useful to service their machines available either for free or for a licensing fee, in light of the technological complexity of some devices, OEM technicians (who are subject to extensive federal regulations that ISOs are not) can more safely use OEM proprietary software.

12. As part of the rulemaking at issue here, plaintiffs submitted comments in opposition to the proposed exemption. They showed, in particular, that the proposed uses of the copyrighted material, when used by ISOs to make repairs, are not noninfringing within the meaning of the fair use doctrine. Rather, ISOs sought to circumvent TPMs to view and use copyrighted material purely for their own commercial benefit, instead of to serve any creative or transformative purpose.

13. Despite this well-supported opposition, the Register of Copyrights recommended granting an exemption (the "Exemption"), which expressly covers "[c]omputer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files," shielding from DMCA liability circumvention of TPMs when it "is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system." Register of Copyrights, *Section 1201 Rulemaking: Eighth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention*, Recommendation of the Register of Copyrights, 233 (Oct. 19, 2021) (*Register's Recommendation*) (attached as Exhibit A). In making that recommendation, the Register failed to engage with numerous significant comments provided by the Exemption's opponents, including plaintiffs. For her part, the Librarian adopted the recommendation without further changes.

14. The Exemption is manifestly unlawful. By issuing a rule that enables unregulated, for-profit service providers to piggyback off the creative efforts and intellectual property of medical device manufacturers, it not only thwarts the purpose of the Copyright Act, but also puts patient safety, device integrity, and device cybersecurity at risk. What is more, the process by which the Exemption was adopted was infected with major procedural errors, including a failure to address many of the significant legal concerns raised by plaintiffs and other opponents.

15. In the course of the rulemaking at issue here, moreover, the Library of Congress was acting as an executive agency and is therefore subject to the strictures of, and judicial review under, the Administrative Procedure Act (APA). Because the Exemption is not in accordance with law and was adopted without observance of required procedures, it should be set aside. Alternatively, if the Library of Congress did not assume the character of an executive agency within the meaning of the APA, the Exemption violates separation-of-power principles twice over. Either way, it should be vacated.

PARTIES

16. Plaintiff MITA is a non-profit, membership-based trade association. It is the leading voice of medical imaging equipment manufacturers, innovators, and product developers. Its member-companies' sales comprise more than ninety percent of the global market for advanced imaging technologies. MITA's mission is to establish standards and advocate for the medical imaging industry, with the vision that medical imaging drives effective patient care. MITA is a division of the National Electrical Manufacturers Association and is headquartered in Arlington, Virginia.

17. Plaintiff AdvaMed is a non-profit, membership-based trade association that represents the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. It leads the effort to advance medical technology to achieve healthier lives and healthier economies around the world. It is a world leader in advocating for health care policies that support diagnostic testing through robust innovation and the rapid adoption of new, safe, and effective diagnostic tests. It advocates for regulatory and payment policies tailored to the specific issues facing the device and diagnostics industry and that support patient access to innovation. AdvaMed members manufacture much of the life-enhancing and life-saving healthcare technology purchased annually in the United States and globally.

18. AdvaMed is headquartered in Washington, D.C. Although it anticipates moving its offices in April 2022, it will remain located within Washington, D.C.

19. Plaintiffs' members include companies that manufacture software-enabled medical devices. A complete list of MITA's membership is available at perma.cc/XVG8-2K9Q. A complete list of AdvaMed's membership is available at perma.cc/AR6V-MBWP.

20. Both of plaintiffs' members rely on TPMs to protect their intellectual property from unlawful infringement. Consistent with both plaintiffs' missions, each participated in the triennial exemption rulemaking to try to ensure that exemptions are appropriately limited. *See* Exhibit B (*MITA Comments*); Exhibit C (*AdvaMed Comments*).

21. MITA's and AdvaMed's members are harmed by the Exemption. The Exemption enables entities to circumvent the protective measures that their members rely on to safeguard their intellectual property. One of their joint members provided its own comments in the rulemaking, elaborating on this harm and urging the Register to recommend denying the proposed exemption for a variety of reasons. *See* Exhibit D (*Philips Comments*).

22. Defendant the Library of Congress is the federal agency charged with overseeing and implementing the DMCA's triennial exemption rulemaking. The Copyright Office, headed by the Register of Copyrights, is located within the Library of Congress.

23. Defendant Carla Hayden is the Librarian of Congress. She is the official charged with promulgating exemptions through the triennial exemption rulemaking pursuant to 17 U.S.C. § 1201(a)(1). She is sued in her official capacity.

JURISDICTION AND VENUE

24. Plaintiffs bring this suit pursuant to the APA, the Declaratory Judgment Act, and this Court's inherent equitable powers, including as recognized in *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682 (1949).

25. This case arises under the Constitution and laws of the United States. The Court's jurisdiction is thus invoked under 28 U.S.C. § 1331.

26. Venue is proper in this District under 28 U.S.C. § 1391(b) and (e) because at least one plaintiff and one defendant resides in this District and a substantial part of the events or omissions giving rise to the claim occurred in this district.

27. Sovereign immunity does not bar this suit. The APA's waiver of sovereign immunity extends to the Library, which acted here as an "agency" in all relevant respects. *See* 5 U.S.C. § 701(e). Alternatively, jurisdiction is provided under *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682 (1949).

LEGAL BACKGROUND

28. Copyrights trace to the Founding. Their purpose, the Constitution says, is to "promote the Progress of Science and useful Arts." U.S. Const. Art. I, § 8, cl. 8. Copyrights

achieve this purpose "by securing for limited Times to Authors . . . the exclusive Right to their respective Writings." *Id.* This exclusive right is not a "special reward," but rather an incentive "to encourage the production of works that others might reproduce more cheaply." *Google LLC v. Oracle America*, 141 S. Ct. 1183, 1195 (2021).

29. Congress implemented the Copyright Clause with the Copyright Act. *See* 17 U.S.C. §§ 101, *et seq*. It provides protection to "original works of authorship fixed in any tangible medium of expression." *Id.* § 102(a). Congress amended the Act in 1980 explicitly to include computer programs within the statute's ambit. *See* Computer Software Copyright Act of 1980, Pub. L. No. 96-517, § 10, 94 Stat. 3015, 3018 (1980). Software code is therefore treated the same as any other work of authorship—if it is original, it is protectable by copyright. *See* 17 U.S.C. § 101 (defining "computer program").

30. In enacting the Copyright Act, Congress also recognized that granting exclusive rights could "sometimes stand in the way of others exercising their own creative powers." *Google*, 141 S. Ct. at 1195. Accordingly, it codified the longstanding framework for determining whether a particular use is a noninfringing "fair use." 17 U.S.C. § 107. Congress envisioned noninfringing uses "for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research." *Id.* It specified four factors for courts to evaluate in determining whether a particular use is a noninfringing fair use (*id.*): (a.) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes; (b.) the nature of the copyrighted work; (c.) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and (d.) the effect of the use upon the potential market for or value of the copyrighted work.

31. When it comes to digital versions of copyrighted material, a copyright owner may put in place a TPM, such as password protection or encryption, to control access to the work. In connection with enactment of the DMCA, the House Committee on the Judiciary observed that TPMs can "support new ways of disseminating copyrighted materials to users, and . . .

safeguard the availability of legitimate uses of those materials by individuals." Staff of H. Comm. on the Judiciary, 105th Cong., Section-by-Section Analysis of H.R. 2281 as Passed by the United States House of Representatives on August 4, 1998, at 6 (Comm. Print 1998).

32. The DMCA thus prohibits "circumvent[ing] a technological measure that effectively controls access to a [copyrighted] work." 17 U.S.C. § 1201(a)(1)(A). The statute defines "circumvent a technological measure" to mean "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).

33. In parallel with the anti-circumvention rule, Congress directed the Copyright Office to "monitor developments in the marketplace for copyrighted materials" and authorized the Librarian, upon recommendation of the Register of Copyrights, to grant selective waivers of the anti-circumvention rule "for limited time periods, if necessary to prevent a diminution in the availability to individual users of a particular category of copyrighted materials" for noninfringing uses. *House Report* 36.

34. Congress called for a triennial rulemaking process for the promulgation of such exemptions. The DMCA specifies that "the Librarian of Congress, upon the recommendation of the Register of Copyrights . . . shall make the determination in a rulemaking proceeding . . . of whether persons who are users of a copyrighted work are, or are likely to be in the succeeding 3-year period, adversely affected by" the anti-circumvention law "in their ability to make noninfringing uses." 17 U.S.C. § 1201(a)(1)(C). The Act further directs the Librarian to examine the following factors in making such a determination (*id.*): (i.) the availability for use of copyrighted works; (ii.) the availability for use of works for nonprofit archival, preservation, and educational purposes; (iii.) the impact that the prohibition on the circumvention of technological measures applied to copyrighted works has on criticism, comment, news reporting, teaching, scholarship, or research; (iv.) the effect of circumvention of technological measures on the market for or value of copyrighted works; and (v.) such other factors as the Librarian considers appropriate.

35. The DMCA's anti-circumvention exemption process thus entails a two-part inquiry. *First*, the Librarian must determine whether there are noninfringing uses of a particular class of copyrightable works at stake. *Second*, if there are, she must apply the statutory factors to determine whether the DMCA's anti-circumvention bar would "adversely affect[]" users' ability to make those noninfringing uses. 17 U.S.C. § 1201(a)(1)(C).

FACTUAL BACKGROUND

A. Medical devices and the repair industry

36. Plaintiffs' members develop and manufacture all kinds of sophisticated medical devices, which have revolutionized healthcare. These technologies have transformed patient care by enabling healthcare providers to diagnose disease accurately and promptly. As a result, patients stay healthier longer and recover more quickly after treatment because clinicians can detect disease earlier.

37. So these devices can deliver their advanced capabilities safely and effectively, OEMs design and write software embedded within the machines. To function properly, medical devices typically operate on a network (such as a hospital's internal internet) and store large amounts of data, including confidential patient health information. The computer code that drives the functioning of this software—and ultimately the operability of these complex devices—is original copyrighted work created by the OEM.

38. Computer software and service materials used for the diagnosis, maintenance, and repair of medical devices are original works of authorship protected by the Copyright Act. *See Register's Recommendation* 199-200.

39. As contemplated by the DMCA, OEMs use a range of TPMs to guard against unauthorized access and copying of copyrighted material. These include passwords, encryption, access codes, physical access keys with embedded authorization codes, and digital signatures.

40. Unauthorized users employ a variety of methods to circumvent TPMs, such as copying physical access keys, "brute force" password cracking, passcode-generating algorithms, and sometimes simply obtaining access keys or passwords from authorized users.

41. Medical device software is broadly licensed and available to healthcare providers. TPMs do not restrict healthcare providers from using licensed clinical software on medical devices; they limit only what aspects of the software may be viewed, used, copied, and modified. In this way, TPMs provide critical protection to ensure the privacy of patient data and that appropriate users operate the proprietary OEM software.

42. The medical device servicing market is large and growing rapidly. Precedence Research, *Medical Equipment Maintenance Market to Hit USD 65 Bn by 2030* (Dec. 6, 2021), perma.cc/N5W2-RY32. The servicing of medical imaging equipment is the leading and fastest-growing segment of the market. Two groups of service providers are relevant here: (1) OEMs and their authorized agents, and (2) ISOs.

43. OEMs use their own authorized repair technicians whom they train extensively to service and repair their devices consistent with federal regulations and patient safety demands. They are able to meet the repair demand for their own devices.

44. Improper use of OEM software for servicing or repair of medical devices presents serious risks to patients and healthcare providers. The devices use advanced technologies that, if not employed according to well-researched and regulated safety standards, can introduce dangers to users. These risks include electrical shock, mechanical failure, improper dosing, infection, and burns. Some imaging devices, including X-Ray machines and CT scanners, emit ionizing radiation which, if not properly calibrated and maintained, could result in overexposure that severely harms or kills patients. Other devices, such as imaging contrast agent power injectors, could potentially cause a fatal air embolism if serviced improperly. In addition to these direct safety risks, failure to maintain or repair these devices properly could cause interference with other equipment, a delay in care, and misdiagnosis.

45. The act of circumventing TPMs to access medical device operating systems and software applications creates cybersecurity vulnerabilities that risk the functionality of devices and the privacy of confidential patient health information stored on them. Whenever a software hack tool is used to access a device for diagnostic and maintenance purposes, the de-

vice is modified, potentially compromising the integrity of the software. This can produce unintended consequences. For example, it may introduce security vulnerabilities to the device and to any networks to which the device is connected. And it may interfere with the device's operability as intended. Thus, circumvention increases the cybersecurity risk of highly regulated and confidential patient data, and it puts the functionality of life-saving medical equipment in jeopardy, raising patient safety concerns. *See FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices* (May 2018), at 25, perma.cc/5QFU-72E4 (*FDA Report*) (explaining that device cybersecurity risks "in turn may have the potential to result in patient illness, injury, or death").

46. Because of these risks to patients and providers, the Food and Drug Administration (FDA) strictly regulates the manufacturers of medical equipment. OEMs must register with the FDA (21 C.F.R. Part 807), list their devices with the FDA (*id.*), receive various FDA approvals before commercially distributing certain devices (21 C.F.R. Part 814), receive FDA label approval for devices (21 C.F.R. Part 801), and report serious malfunction incidents (21 C.F.R. Part 803). The FDA also regulates the quality control of medical devices, which includes requirements relating to the design, manufacture, installation, and servicing of medical devices. 21 C.F.R. Part 820. To comply with these important regulatory requirements, OEMs, among other things, periodically audit their quality control systems.

47. Unlike OEMs, ISOs are unregulated service providers. They are not subject to the FDA regulations that apply to OEMs. Nor are they subject to the same training and quality control measures. As a result, they are not subject to the same regulatory oversight and do not have the same accountability as OEMs, increasing the potential that their circumvention of TPMs will result in faulty repairs that jeopardize patient care and safety. *See MITA Comments* 18-36. In addition, ISO repairs that circumvent TPMs "raise[] specific cybersecurity challenges related to" circumvention and frustrate FDA recommendations that OEMs "limit[] privileged access to operating systems and applications" and restrict "software or firmware updates to authenticated code only." *FDA Report* 25.

48. It is more difficult to upgrade medical devices if the service history is unknown, improper parts have been used, or the device has been altered. The lack of regulatory reporting by ISOs can impair the tracking of significant device events and complicate root-cause investigations of device malfunctions.

49. From the ISOs' perspective, the ability to circumvent TPMs in medical devices allows access to OEM software without internalizing any of the development or investment costs necessary to develop such software. The reason an ISO wants TPM circumvention is to benefit its commercial interests, resulting in greater market share and more profits, even at the expense of patient safety and device integrity.

50. ISOs have previously used unauthorized access to copyrighted software and other content to sell advanced services for medical devices that they otherwise would be unable to sell.

51. Many OEMs already provide service specifications to ISOs to enable them to perform maintenance and repair services. *Philips Comments*, Exs. A-B. ISOs are also typically able to access necessary documentation and software by contacting the OEM. *Id.*, Ex. B. The FDA has recognized that OEMs may reserve enhanced software programs for their own employees. *See, e.g.*, Letter from Mary S. Pastel, Sc.D., Deputy Director for Radiological Health, Food & Drug Administration, to Gail M. Rodriguez Ph.D., Executive Director, Medical Imaging & Technology Alliance 2 (Jan. 30, 2014), perma.cc/BX3V-3U5B ("[T]he manufacturer of the original system may provide the user or its own service personnel with additional documentation or enhanced software programs, with privileged access codes. This additional documentation or enhanced software programs may operate in conjunction with other proprietary accessories or functions.").

52. The ISOs that petitioned for the Exemption have a track record of circumventing TPMs without authorization for commercial gain.

53. OEMs must make enormous investments to develop and bring medical devices to market, including investments in creating the software that runs and maintains them. Be-

cause of extensive FDA regulation, there are massive costs to ensuring the devices are safe and to securing approval for distribution to the commercial market.

54. OEMs rely on their ability to recoup these substantial costs by protecting their valuable intellectual property through copyrights and licensing agreements. Without assurance that their intellectual property is adequately protected, OEMs may be unable to cover the costs of developing and improving these life-saving devices. Indeed, this reliance is consistent with the purpose of the Copyright Act.

55. It chills innovation when a creator cannot secure the benefit of meaningful copyright protection for its creations. Without that benefit here, OEMs may be unable to justify the costs of researching and developing improved products. Patents do not mitigate this problem because they provide a different scope of protection, and replication of uncovered intellectual property is extremely difficult to detect. Thus, the Exemption significantly reduces the incentives for continued innovation of life-saving medical devices and associated creative expressions.

B. The eighth triennial DMCA rulemaking

56. The Register of Copyrights commenced the eighth triennial Section 1201 rulemaking on June 22, 2020, with the publication of a Notice of Inquiry in the Federal Register. *See* U.S. Copyright Office, *Exemptions to Permit Circumvention of Access Controls on Copyrighted Works*, 85 Fed. Reg. 37,399 (June 22, 2020). The office took comments from proponents and opponents of various exemptions over the next three months.

57. Two ISOs, Summit Imaging and Transtate Equipment, petitioned for the circumvention of TPMs for purposes of diagnosis, modification, and repair of medical devices. *See* U.S. Copyright Office, *Petitions for Newly Proposed Exemptions*, perma.cc/HDV5-XLWG. The ISOs sought access to device software and data files stored on medical devices and systems.

58. ISOs do not create new content or expression when they service medical devices. Nor did they assert in their petitions for an exemption that plaintiffs' members' copyright protections are thwarting "the Progress of Science and useful Arts" (U.S. Const. Art. I, § 8, cl. 8)

that the copyright laws are meant to promote. Rather, the ISOs sought an exemption only so that they can freeride off the creative efforts and intellectual property of OEMs.

59. The Register published an NPRM identifying the exemptions that she proposed to recommend to the Librarian. *See* U.S. Copyright Office, *Exemptions to Permit Circumvention of Access Controls on Copyrighted Works*, 85 Fed. Reg. 65,293 (Oct. 15, 2020). Without elaboration, the NPRM noted that the ISOs "petition for an exemption allowing circumvention of TPMs for purposes of diagnosis, modification, and repair of medical devices." 85 Fed. Reg. at 65,307. Other than "invit[ing] comment on the extent to which its prior analysis of [third-party service providers] may be applicable here," the Register did not address the content of the proposed rule or request comments regarding the ISOs' petitions in the NPRM. *Id.*

60. Plaintiffs submitted comments in opposition to the proposed exemption, making several significant arguments that an exemption was unwarranted. At a general level, they argued that the intended uses broadly infringed the copyrights of OEMs, thus foreclosing the possibility of an exemption. *AdvaMed Comments* 7-9; *MITA Comments* 7-11. Even if the intended uses were noninfringing, they asserted, the statutory factors weighed strongly in favor of rejecting an exemption due to the commercial nature of the ISOs' desire for an exemption, the consequential increased risk to patient safety and care, and an exemption's deleterious effects on the market for medical devices. *AdvaMed Comments* 10-15; *MITA Comments* 2-7.

61. As to whether the intended uses were noninfringing, MITA argued that a categorical fair use determination here was inappropriate. *MITA Comments* 8. The Copyright Act demands a fact-specific inquiry to each "particular case," 17 U.S.C. § 107, and the Supreme Court has noted accordingly that "fair use analysis must always be tailored to the individual case." *Harper & Row v. Nation Enterprises, Inc.*, 471 U.S. 539, 552 (1985). Considering the complexity and varied applications of medical devices, and the range of services provided by ISOs, a categorical fair use determination based on the surface-level descriptions in the ISOs' petitions was inappropriate.

62. Opponents of the exemption asserted further (*AdvaMed Comments* 7-9; *MITA Comments* 8-10; *Philips Comments* 7-10) that the purpose and character of the ISOs' proposed uses, and the effect of those uses upon the market, weigh strongly against a finding of fair use:

(a.) Because the ISOs' proposed uses are not for "criticism, comment, news reporting, teaching . . . scholarship, or research" (17 U.S.C. § 107) but instead for promoting the financial interests of for-profit companies who are not engaged in the creation of new works, opponents explained that the fair use inquiry should end at the first step with a finding of no fair use. *AdvaMed Comments* 7-8; *MITA Comments* 8-9; *Philips Comments* 7-8.

(b.) Opponents explained that, in addition to their commercial nature, there is nothing transformative about the ISOs' intended uses. Indeed, any alterations to the operability of devices would circumvent FDA regulatory oversight and put patients at risk. *MITA Comments* 9; *Philips Comments* 7-8 & n.24.

(c.) They noted also that the creative nature of the copyrighted materials, which provide for the operation of complex machines and store and protect patient data, are essential to the safety, integrity, and security of medical devices, weighing against a fair use exception. *MITA Comments* 9; *Philips Comments* 8-9. Moreover, the unpublished nature of the work cuts against a finding of fair use. *AdvaMed Comments* 8.

(d.) Commenters also explained that the broad scope of the proposed exemption meant that their copyrighted software and materials would be exposed in their entireties, again cutting against fair use. *AdvaMed Comments* 8; *MITA Comments* 10; *Philips Comments* 9-10.

(e.) Opponents argued that the proposed exemption decreased the value of medical device software by increasing the share of the service-and-repair market held by unregulated ISOs. *AdvaMed Comments* 3; *MITA Comments* 10. At a general level, it harms OEMs by allowing competitors to view, replicate, and exploit their innovations without bearing the cost of their development. More specifically, because ISOs are not subjected to the same stringent

FDA requirements as manufacturers, they face less accountability concerning their servicing of medical devices. Further, the ISOs' circumvention of TPMs to use OEM proprietary software creates unnecessary cybersecurity vulnerabilities that put patient safety in jeopardy. An increase in ISO services would therefore decrease confidence in the functioning of serviced medical devices. *See AdvaMed Comments* 11-15; *MITA Comments* 18-36. This diminishes the market value of the devices and their software. *MITA Comments* 10-11.

(f.) Finally, plaintiffs argued the copyrighted materials reflected "a substantial investment of time and labor made in anticipation of a financial return." *MITA Comments* 9 (quoting *Hustler Magazine Inc. v. Moral Majority Inc.*, 796 F.2d 1148, 1154 (9th Cir. 1986)); *see also AdvaMed Comments* 8-9. They explained that ISOs' unchecked access to copyrighted material in its entirety would threaten the market for medical devices.

63. Even assuming the intended uses were noninfringing, moreover, opponents argued that the Section 1201 factors also weigh against an exemption in this case:

(a.) *First*, opponents explained (*AdvaMed Comments* 4-6, 10-11; *MITA Comments* 3; *Philips Comments* 5-6, 14-16) that TPMs do not prevent healthcare providers from using the device software, and OEMs already provide access to their code for most repairs. *MITA Comments* 3. As the FDA concluded, the repair market was already adequately served by authorized providers and ISOs prior to the Exemption. *Philips Comments* 3 (citing *FDA Report i* (declining to conclude there was a health or safety concern presented by the medical device servicing market)).

(b.) *Second*, opponents explained (*MITA Comments* 3; *Philips Comments* 16) that the proposed exemption would not serve any "archival, preservation, [or] educational purposes." *See* 17 U.S.C. § 1201(a)(1)(C)(ii).

(c.) *Third*, opponents noted (*MITA Comments* 3; *Philips Comments* 16-17) that an exemption would not impact "criticism, comment, news reporting, teaching, scholarship, or research." *See* 17 U.S.C. § 1201(a)(1)(C)(iii).

(d.) *Fourth*, opponents demonstrated (*AdvaMed Comments* 11; *MITA Comments* 3; *Philips Comments* 17) that by unveiling valuable intellectual property, an exemption would diminish "the value of copyrighted works" and damage the market for medical device software and materials, thwarting future innovation. *See* 17 U.S.C. § 1201(a)(1)(C)(iv).

(e.) *Finally*, opponents explained (*AdvaMed* 11-15; *MITA Comments* 4-5; *Philips Comments* 17-19) that an exemption would undermine comprehensive FDA regulations that ensure the devices are safe.

64. The Register of Copyrights issued a formal recommendation to the Librarian of Congress to grant an exemption when circumvention is a necessary step for the diagnosis, maintenance, and repair of medical devices and systems. *See Register's Recommendation* 193, 208-212, 224-229, 233.

65. The recommendation failed to respond, or to respond adequately, to many significant comments. These unaddressed comments related to matters of central relevance to the rule and genuinely cast doubt on the reasonableness of the Librarian's position:

(a.) The recommendation did not address MITA's argument that as a threshold matter, a categorical fair use determination as the basis for reasoning the proposed uses are noninfringing is fundamentally incompatible with the fact-specific fair use inquiry demanded by the statute. *MITA Comments* 8; *see* 17 U.S.C. § 107 (requiring fair use analysis to each "particular case"). The Register's belief that she could categorically sanction the proposed uses as fair use was a key assumption that went unjustified despite this challenge.

(b.) The recommendation did not address opponents' argument that the ISOs' proposed uses were generally barred from fair use consideration because they were not "for purposes such as criticism, comment, news reporting, teaching . . . scholarship, or research." 17 U.S.C. § 107; *see AdvaMed Comments* 7-8; *MITA Comments* 8-9; *Philips Comments* 7-8.

(c.) The recommendation did not respond adequately to opponents' argument that the proposed uses were entirely commercial in nature, conveniently avoiding response to MITA's point that the Copyright Office itself has recognized that third-party software repairs

"would likely be considered a commercial use." *MITA Comments* 9; *see also AdvaMed Comments* 7-8; *Philips Comments* 7-8.

(d.) The recommendation did not address opponents' argument that the copyrighted software "represented a substantial investment of time and labor made in anticipation of a financial return." *MITA Comments* 9 (quoting *Hustler*, 796 F.2d at 1154); *see also AdvaMed Comments* 8-9.

(e.) The recommendation did not respond adequately to opponents' argument that once intellectual property is made public, any protection to its value is lost as a practical matter. *MITA Comments* 10; *see also AdvaMed Comments* 11; *Philips Comments* 17. The Register merely remarked that misuse of copyrighted material would not be permissible, but she did not address the simpler point that supposedly permissible uses will lead to impermissible ones, thus affecting the market for medical devices and their software. *Register's Recommendation* 212.

(f.) The recommendation did not address opponents' numerous significant arguments concerning the statutory factors the Librarian "shall examine" when considering an exemption for a noninfringing use:

(g.) The recommendation did not address MITA's argument that the "users" of copyrighted medical device software are "the patients themselves undergoing the medical imaging procedures." *MITA Comments* 2-3. By disregarding this argument and failing to consider patients as the ultimate users, the Register took an unduly narrow view of the scope of users as it pertains to the first statutory factor. *See* 17 U.S.C. § 1201(a)(1)(C)(i).

(h.) The recommendation did not address MITA's argument that the copyrighted software at issue remains usable even though a physical component of a medical device needs maintenance or repair. *MITA Comments* 3. The Register instead focused on software being less *accessible* to ISOs. *Register's Recommendation* 224-226. But that interest is independent from the "availability for use of [the] copyrighted [software]." 17 U.S.C. § 1201(a)(1)(C)(i). The copyrighted works remain available for use, a fact explained by MITA that

the Register failed to address.

(i.) The recommendation did not respond adequately to opponents' arguments that an exemption did not serve any "nonprofit archival, preservation, and educational purposes," and that it would not "impact . . . criticism, comment, news reporting, teaching, scholarship, or research." 17 U.S.C. § 1201(a)(1)(C)(ii)-(iii); *see MITA Comments* 3; *Philips Comments* 16. The Register's only response was that these factors (which comprise nearly half of the statutorily mandated considerations) were "not especially relevant," *Register's Recommendation* 227, an impermissible (and flatly incorrect) non sequitur. *See City of Vernon v. FERC*, 845 F.2d 1042, 1048 (D.C. Cir. 1988).

(j.) The recommendation did not respond to opponents' argument that the challenged exemption would unduly chill innovation and weaken incentives for further innovation, contrary to the purpose of copyright laws, including the DMCA. *MITA Comments* 3; *Philips Comments* 17; *see* 17 U.S.C. § 1201(a)(1)(C)(iv).

(k.) The recommendation did not respond to opponents' argument that an exemption would result in more ISO repairs consisting of risky TPM circumvention, which places patients at risk and ultimately undermines public confidence in medical devices, thus damaging the market for these devices. *AdvaMed Comments* 3; *MITA Comments* 3-4, 10-11; *see* 17 U.S.C. § 1201(a)(1)(C)(iv).

(l.) The recommendation did not adequately respond to MITA's distinction between medical devices and other consumer electronics—while the software of both has no independent market—there are paramount differences in the botched repairs between the two groups. *MITA Comments* 4. Instead of addressing this concern, the Register simply lumped sophisticated medical devices with "other software-enabled devices" in its reasoning. *Register's Recommendation* 227.

66. Without providing additional explanation or analysis, the Librarian adopted the Register's recommendation and issued a final rule published in the Federal Register and codified at 37 C.F.R. § 201.40, granting the Exemption. *See* 86 Fed. Reg. at 59,627. The Librari-

an's only explanation was to say that she had "duly considered and accepted the recommendation of the Register of Copyrights." *Id.* at 59,637.

C. Sovereign immunity does not bar this suit

67. For purposes of this rulemaking, the Library of Congress was acting as an executive agency subject to the strictures of the APA and judicial review by this Court.

68. The APA permits suit against "an agency or an officer or employee thereof." 5 U.S.C. § 702. The word "agency" includes "each authority of the Government of the United States . . . but does not include . . . the Congress." *Id.* § 701(b)(1).

69. The Library of Congress is a hybrid agency—it is located within the legislative branch, but at times it exercises executive functions. *See Intercollegiate Broad. Sys. v. Copyright Royalty Bd.*, 684 F.3d 1332, 1336 (D.C. Cir. 2012); *Live365, Inc. v. Copyright Royalty Bd.*, 698 F. Supp. 2d 25, 43 (D.D.C. 2010). In particular, "[t]he powers in the Library . . . to promulgate copyright regulations [and] to apply the statute to affected parties . . . are ones generally associated in modern times with executive agencies rather than legislators." *Intercollegiate*, 684 F.3d at 1341-1342.

70. The Library assumed the character of an executive "agency" within the meaning of the APA in undertaking the triennial DMCA rulemaking at issue here.

71. The DMCA provides that the Library's exemptions are regulations with the force and effect of law, promulgated following traditional rulemaking procedures.

72. The Library's use of the Federal Register and Code of Federal Regulations confirms its status as an "agency" for purposes of this suit. The Federal Register Act specifies that only a "document" may "be published in the Federal Register." 44 U.S.C. § 1505. It in turn defines "document" to be "an order, regulation, rule, . . . or similar instrument, issued, prescribed or promulgated by a Federal agency." *Id.* § 1501. The NOI, NPRM, and final rule all were published in the Federal Register.

73. The Code of Federal Regulations is likewise reserved for the codification of "documents of each agency . . . promulgated by the agency by publication in the Federal Reg-

ister." *Id.* § 1510(a). All DMCA exemptions, including the challenged exemption here, are codified in the Code of Federal Regulations. *See* 37 C.F.R. § 201.40(b)(15).

74. The term "agency" for purposes of the Federal Register Act covers agencies within "the administrative branch . . . but not the legislative" branch. 44 U.S.C. § 1501. The Library thus necessarily assumed the character of an administrative and not legislative "agency" under the Federal Register Act when it published the NOI, NPRM, and final rule in the Federal Register and codified the final rule in the Code of Federal Regulations.

75. A governmental body that is an "agency" within the meaning of the Federal Register Act is also an "agency" within the meaning of the APA.

76. The DMCA's legislative history further confirms that Congress intended the Library to act as an "agency" when exercising its exemption rulemaking duties. *See House Report* 37 (Congress intended the DMCA exemption rulemaking proceedings to be "consistent with the requirements of the Administrative Procedures Act.").

77. If the Library was not acting as an "agency" within the meaning of the APA in the course of the rulemaking here, review is available instead under *Larson*. "[S]overeign immunity does not bar suits for specific relief against government officials where the challenged actions of the officials are alleged to be unconstitutional or beyond statutory authority." *Clark v. Library of Congress*, 750 F.2d 89, 102 (D.C. Cir. 1984) (citing *Larson*).

CLAIMS FOR RELIEF

Count I
Substantive Violations of the Administrative Procedure Act

78. Plaintiffs incorporate and re-allege the foregoing paragraphs in full.

79. Under the APA, courts must set aside agency action that is arbitrary and capricious, not in accordance with law, or in excess of statutory authority. 5 U.S.C. § 706.

80. The DMCA permits the Librarian to issue exemptions to the anti-circumvention rule only when the evidence shows "that it is more likely than not that users of a copyrighted work will, in the succeeding three-year period, be adversely affected by the prohibition on cir-

cumvention in their ability to make noninfringing uses of a particular class of copyrighted works." 17 U.S.C. § 1201(a)(1)(C). Accordingly, "proponents [of an exemption] must show" that the "uses affected by the prohibition on circumvention are or are likely to be noninfringing." 86 Fed. Reg. at 59,628.

81. Because the ISOs' unauthorized uses of OEM software are infringing, the Librarian's grant of the Exemption exceeded her statutory authority and was not in accordance with law. Congress has specified that "the fair use of a copyrighted work" is not infringing only when the factors listed in 17 U.S.C. § 107 indicate a fair use consistent with the purposes of the Copyright Act. None of the Section 107 factors supports the Librarian's fair use determination in this case.

82. The copyrighted work at issue here is unpublished computer software that reflects cutting-edge innovation and creativity, a product of a substantial investment of labor. It also contains valuable intellectual property.

83. ISOs are for-profit companies that seek to use plaintiffs' members' copyrighted material for their own commercial interests only, not "for nonprofit educational purposes." 17 U.S.C. 107. The sole purpose of the ISOs' use of the copyrighted software is in connection with the provision of maintenance services, which is a commercial, non-transformative use. Like anyone else that merely views or copies copyrighted work for commercial benefit, the ISOs' use is presumptively an unfair exploitation of the copyright holder's privilege.

84. The ISOs' use would diminish the value of the copyrights themselves by exposing valuable intellectual property, thus undermining the "value of the copyrighted work." 17 U.S.C. § 107. The result is a diminished incentive to create and improve sophisticated, life-saving medical devices.

85. The Library's grant of the Exemption was arbitrary and capricious in that it was not grounded in the evidence before the agency; and not in accordance with law and in excess of its statutory authority in that the Exemption is not authorized by copyright law or the DMCA. The Exemption must be set aside.

Count II
Procedural Violation of the Administrative Procedure Act:
Failure To Respond To Critical Comments

86. Plaintiffs incorporate and re-allege the foregoing paragraphs in full.

87. The APA empowers courts to "hold unlawful and set aside agency action" that is undertaken "without observance of procedure required by law." 5 U.S.C. § 706(2).

88. Agencies are legally obligated to "consider and respond to significant comments received during the period for public comment." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 96 (2015) (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S 402, 416 (1971)). In addition, agencies have "a duty to examine key assumptions as part of its affirmative burden of promulgating and explaining a nonarbitrary, non-capricious rule." *Northeastern Maryland Waste Disposal Auth. (NMWDA) v. EPA*, 358 F.3d 936, 948 (D.C. Cir. 2004).

89. The Register of Copyrights failed to consider and respond adequately to several significant comments made during the public comment period. These unaddressed comments related to matters of central relevance to the rule and genuinely cast doubt on the reasonableness of the Library's position. The comments, if properly considered, likely would have changed the outcome of the Library's decisionmaking process.

90. The Librarian of Congress adopted the Register's recommendation without further consideration of plaintiffs' and other commenters' arguments or evidence.

91. The Exemption therefore was adopted without observance of procedure required by law and should be set aside.

Count III
Official Federal Actions Beyond Statutory Authority

92. Plaintiffs incorporate and re-allege the foregoing paragraphs in full.

93. Plaintiffs are entitled to non-monetary judicial relief against federal officials who act in excess of authority conferred by Congress. *See Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 689 (1949).

94. The DMCA permits the Librarian to issue exemptions only when "noninfringing uses . . . of a particular class of copyrighted works" are at stake. 17 U.S.C. § 1201(a)(1)(C).

95. The ISOs' uses of copyrighted medical device software and materials are demonstrably *not* noninfringing uses. They are purely commercial, non-transformative uses sought to boost ISOs' profits. By undermining the very purpose of copyright protection, the uses are infringing.

96. The Librarian therefore acted in excess of the authority conferred by the DMCA in granting the Exemption. The Exemption accordingly must be vacated.

Count IV
Exercise Of Unconstitutional Power By A Federal Official

97. Plaintiffs incorporate and re-allege the foregoing paragraphs in full.

98. If the Library did not assume the character of an executive agency in the course of the rulemaking at issue here, such that its actions are not subject to review under the APA, then the Exemption is unconstitutional and should be set aside under *Larson*.

99. Agency rulemakings are "exercises of . . . the 'executive Power.'" *City of Arlington v. FCC*, 569 U.S. 290, 304 n.4 (2013) (quoting U.S. Const. Art. II § 1, cl. 1). And legislative bodies are constitutionally prohibited from exercising executive power. *E.g.*, *MWAA v. Citizens for Abatement of Aircraft Noise, Inc.*, 501 U.S. 252, 276 (1991). If the Library's adoption of the Exemption was an exercise of executive power, and if the Library did not assume the character of an executive agency in the course of the rulemaking at issue here, the DMCA rulemaking was an unconstitutional arrogation of executive authority by a legislative body in violation of separate-of-powers principles, rendering the Exemption constitutionally void.

100. Federal legislative bodies must exercise legislative powers in conformity with Article I, Section 7 of the Constitution, which requires bicameralism and presentment. *See INS v. Chadha*, 462 U.S. 919, 951 (1983). If the Library's adoption of the Exemption was an exercise of legislative power, and the Library acted in its capacity as a legislative agency in the course of the rulemaking at issue here, the DMCA rulemaking was an unconstitutionally

unilateral exercise of legislative authority in violation of the Constitution's bicameralism and presentment requirements, rendering the Exemption constitutionally void.

101. In either event, if the Library did not assume the character of an executive agency in the course of the rulemaking at issue here, its adoption of the Exemption was constitutionally *ultra vires* and must be vacated.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs the Medical Imaging & Technology Alliance and the Advanced Medical Technology Association request that the Court enter judgment in their favor and

(a.) set aside the challenged exemption;

(b.) declare the challenged exemption to be unlawful and void;

(c.) enjoin defendants from enforcing, implementing, or otherwise carrying out the challenged exemption;

(d.) award plaintiff its attorney's fees and costs; and

(e.) award such other and further relief as the Court may deem just and proper.

February 25, 2022

Respectfully submitted,

/s/ *Michael B. Kimberly*

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** pro hac vice motion forthcoming*