IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MEDICAL IMAGING & TECHNOLOGY ALLIANCE, et al., *Plaintiffs*, *v.* LIBRARY OF CONGRESS, et al., *Defendants*.	No. 1:22-cv-499 (BAH)

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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GLOSSARY

APA:	Administrative Procedure Act
DMCA:	Digital Millennium Copyright Act
ISO:	independent service operator
NPRM:	notice of proposed rulemaking
NOI:	notice of inquiry
OEM:	original equipment manufacturer
TPM:	technological protective measure

INTRODUCTION

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 under the Digital Millennium Copyright Act of 1998 (DMCA).

In today's computer-driven economy, owners of digital copyrighted content frequently use technological protective measures—known as TPMs—to control access to their works. Common examples are password protection and file encryption. As the House Judiciary Committee explained at the time of the DMCA's enactment, circumventing a TPM to gain unauthorized access to copyrighted digital content "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*). The DMCA thus prohibits users from circumventing any "technological measure that effectively controls access to a work." 17 U.S.C. § 1201(a)(1)(A).

At the same time that Congress made it unlawful to circumvent a copyright holder's TPM, it recognized that the DMCA's anticircumvention rule might be used to prevent "otherwise lawful access to works and information." *House Report* 36. It thus directed the Register of Copyrights to "monitor developments in the marketplace for copyrighted materials" and authorized the Library of Congress, upon the Register's recommendation, to promulgate, by formal rulemaking, selective exemptions from 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 purposes. *Id.*; *see* 17 U.S.C. § 1201(a)(1)(C).

This case concerns an exemption adopted under this framework, granting a waiver from DMCA liability for the circumvention of TPMs that protect copyrighted software used for servicing and repairing medical devices. Such devices include sophisticated and complex machines like computerized tomography scanners, ultrasound systems, positron emission tomography scanners, and surgery-assisting robots. But the exemption is for a manifestly infringing

use. It was granted at the behest—and solely for the commercial benefit—of two so-called independent service operators, or ISOs, which are unregulated third-party service providers who freeride on the creative labors of device manufacturers. And the Librarian readily admitted the true reason for her decision: Allowing ISO circumvention would reduce the cost of machine servicing contracts and thus serve a separate executive-branch policy. But the DMCA does not grant the Librarian free-ranging policymaking authority untethered to copyright law. In approving the exemption, moreover, the Library failed to address numerous substantial comments that called into question the underlying fair-use analysis. The exemption is thus unlawful many times over: It is contrary to the statutory text, it is arbitrary and capricious, and it was promulgated without observance of procedure required by law. *See* 5 U.S.C. § 706(2).

In the mine run of APA cases, that would be an end to the matter; the Court would vacate the agency action, and the case would be over. But as much as this case is about the Library's clear-cut violations of the APA, it is equally about this Court's power to set things right. The government no doubt will say that the Court has no such power. The APA covers only "agency" actions, the government will argue, and the Library of Congress is a component of the legislative branch and thus not an "agency" within the meaning of the APA. But that is not a defensible position in this context. It is settled that the Library is in fact a hybrid entity that performs both legislative and executive functions. And when it is engaged in rulemakings that implement statutory programs (as it was here), it is plainly acting in its executive capacity. *See Intercollegiate Broadcasting System v. Copyright Royalty Board*, 684 F.3d 1332, 1341-1342 (D.C. Cir. 2012). That is all the more clear here because the exemption was published in the Federal Register and promulgated in the Code of Federal Regulations. Those are avenues of lawmaking that are open only to an executive "agency" and expressly *not* a "legislative" entity. 44 U.S.C. §§ 1501, 1510(a).

The canons in favor of judicial review and avoiding constitutional doubts lend further support to the conclusion that the Library was functioning as an "agency" in this case, within the

meaning of the APA. The Supreme Court has long recognized an especially "strong presumption favoring judicial review of administrative action." *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 486 (2015) (quotation marks omitted). To say that the Library is not an agency in the relevant sense would mean that its rulemakings under the DMCA are largely unreviewable. It also would invite serious constitutional questions. If the Library is acting as a component of the legislature and yet "the power [it is exercising] is executive, the Constitution does not permit [it]." *Metropolitan Washington Airports Authority v. Citizens for Abatement of Aircraft Noise*, 501 U.S. 252, 276 (1991). Alternatively, "[i]f the power [it is exercising] is legislative, Congress must exercise it in conformity with the bi-cameralism and presentment requirements of Art. I, § 7." *Id*. Either way, the exemption is unconstitutional. These problems are easily avoided by construing the Library as an executive agency in this context.

Even if the Court were to disagree, review would be available instead under *Larson v. Domestic & Foreign Commerce Corporation*, 337 U.S. 682 (1949), which authorizes suits alleging that "(1) action by officers [was undertaken] beyond their statutory powers [or] (2) even though within the scope of their authority, the powers themselves or the manner in which they are exercised are constitutionally void." *Dugan v. Rank*, 372 U.S. 609, 621-622 (1963). Review is available here under both prongs. Thus, no matter how it is characterized, the Library's action was unlawful, judicially reviewable, and must be declared void and unenforceable.

BACKGROUND

Statutory background

1. At its core, this is a case about copyright law, which traces to the Founding. *See* U.S. Const. Art. I, § 8, cl. 8 (empowering Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"). Today, the Copyright Act prohibits the unauthorized reproduction of "original works of authorship fixed in any tangible medium of expression." 17 U.S.C.

§ 102(a). Among the "works of authorship" covered by the Act are "literary work[s]," including "computer program[s]." *Id*. §§ 101, 102(a)(1), 109(b)(1)(A). As Judge Learned Hand long ago remarked, even works that "communicate nothing" in natural language still "may be the productions of high ingenuity, even genius" and are fully entitled to the protections of copyright law. *Reiss v. National Quotation Bureau*, 276 F. 717, 719 (S.D.N.Y. 1921).

Copyright law serves practical objectives, foremost "to encourage the production of works" that, without copyright protection, could be "reproduce[d] more cheaply" by freeriders in the marketplace. *Google LLC v. Oracle America*, 141 S. Ct. 1183, 1195 (2021). But precisely because copyright rules are meant to encourage the production of new creative works, their protections are not limitless, or else they might "stand in the way of others exercising their own creative powers." *Id*. Courts have thus long recognized that certain "fair" uses of copyrighted materials are noninfringing. *See Gyles v. Wilcox*, 26 Eng. Rep 489 (Ch. 1740) (first recognizing the doctrine of "fair abridgement"); *Folsom v. Marsh*, 9. F. Cas. 342 (C.C.D. Mass. 1841) (Story, J.) (first recognizing the "fair use" doctrine in the United States).

Consistent with law's overall practical objectives, the fair-use doctrine—since codified by Congress (*see* 17 U.S.C. § 107)—limits copyright protections as necessary to encourage "criticism, comment, news reporting, teaching . . . scholarship, [and] research." *Id*. The statute provides four factors for determining whether a particular use is a noninfringing "fair" use: (1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes; (2) the nature of the copyrighted work: (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and (4) the effect of the use upon the potential market for or value of the copyrighted work. 17 U.S.C. § 107. Although the fair-use framework calls for carefully calibrated case-by-case determinations, it is well settled that a party's use of a work "to make their own commercial profit" does not serve the purposes of copyright and generally "diminishes the potential value of th[e] [copied] work," and

thus that it ordinarily "is not fair use." *United Video, Inc. v. FCC*, 890 F.2d 1173, 1192 (D.C. Cir. 1989).

2. The proliferation in the 1990s of digital copyrighted works—and the ease with which they could be reproduced—introduced new challenges for copyright owners. To protect their creative works, many began using technological protective measures to control access to their creations, including password protection and encryption. To support those efforts, "Congress enacted the DMCA in 1998 'to strengthen copyright protection in the digital age.'" *Egilman v. Keller & Heckman, LLP*, 401 F. Supp. 2d 105, 112 (D.D.C. 2005) (quoting *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 435 (2d Cir. 2001)); *see also* Staff of H. Comm. on the Judiciary, 105th Cong., Section-by-Section Analysis of H.R. 2281, at 6 (Comm. Print 1998) (observing that TPMs can "support new ways of disseminating copyrighted materials" while "safeguard[ing] the availability of legitimate uses of those materials").

In plain terms, the DMCA prohibits users of a copyrighted work from "circumvent[ing] a technological measure that effectively controls access to [the] work." 17 U.S.C. § 1201(a)(1)(A). To circumvent a TPM is to "descramble" or "decrypt" a work or otherwise "avoid, bypass, remove, deactivate, or impair [a TPM], without the authority of the copyright owner." *Id.* § 1201(a)(3). Violations of the DMCA's anticircumvention rule are punishable with private civil remedies, and in the case of a willful violation "for purposes of commercial advantage or private financial gain," criminal penalties. *Id.* § 1204(a).

3. Congress recognized, however, that unchecked use of TPMs might threaten "a diminution of otherwise lawful access to works and information." *House Report* 36. Because it did not intend for the DMCA to inhibit noninfringing uses, Congress 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." *Id*. It further authorized the Librarian, upon the Register's recommendation, to grant selective waivers of the anticircumvention rule "for lim-

ited time periods, if necessary to prevent a diminution in the availability to individual users of a particular category of copyrighted materials" for noninfringing uses. *Id*.

To implement that directive, the DMCA instructs that "the Librarian of Congress . . . shall make the determination in a rulemaking proceeding . . . of whether persons who are users of a copyrighted work" and who petition for relief should be granted a three-year "exemption" from the DMCA's prohibitions for limited purposes. 17 U.S.C. § 1201(a)(1)(C). But such exemptions are statutorily authorized only if users are "adversely affected by" the anticircumvention rule "in their ability to make *noninfringing* uses." *Id*. (emphasis added).

A DMCA exemption thus requires the Librarian to make two findings: *first*, that the proposed uses of the class of copyrightable works at issue are noninfringing; and *second*, that the DMCA's anticircumvention rule would "adversely affect[]" users' ability to make those noninfringing uses. *Id.* The statute directs the Librarian to consider five factors in determining whether users are adversely affected. Those factors—the third and fourth of which are most pertinent here—are: "(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." 17 U.S.C. § 1201(a)(1)(C).

4. The Copyright Office commences the triennial rulemaking processes required by 17 U.S.C. § 1201(a)(1)(C) with a notice of inquiry (NOI). As a matter of practice, the notice is published 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).

Following publication of an NOI, proponents of new or renewed exemptions file petitions and supporting evidence on the regulatory docket. At the conclusion of the NOI process, the

Copyright Office publishes in the Federal Register a notice of proposed rulemaking (NPRM) identifying the exemptions that the Office proposes to adopt. *See* U.S. Copyright Office, *Exemptions to Permit Circumvention of Access Controls on Copyrighted Works*, 85 Fed. Reg. 65,293 (October 15, 2020). The NPRM is subject to staged comments from proponents and opponents of the proposed exemptions, who file argument and evidence in support of their respective views. The Register also holds a public hearing.

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. *See* Library of Congress, *Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies*, 86 Fed. Reg. 59,627 (October 28, 2021). The exemptions are codified at 37 C.F.R. § 201.40(b).

Factual background

1. Physicians, nurses, and healthcare technicians rely on complex medical devices every day to provide high quality patient care. Advanced medical devices like MRI machines, CT scanners, and defibrillators have transformed patient care over the past few decades by enabling healthcare providers to diagnose disease accurately and promptly, and by providing safe and often life-saving assistance in treatment. As a result, patients stay healthier longer and recover more quickly.

These highly sophisticated medical devices rely on complex software to function properly. Compl. ¶ 37. Software is a set of instructions and data that guide the device's operability. Device manufacturers—known as "original equipment manufacturers," or OEMs—create the innovative computer code embedded in these machines to make them run safely and effectively. *Id*. The original computer code created by OEMs is protected by copyright, like any other creative work. *See* 17 U.S.C. §§ 101, 102(a). Without these copyrighted creations, medical devices could not deliver their advanced capabilities.

Many medical devices operate on a network and store large amounts of confidential patient health data. Compl. ¶ 37. An imaging device, for instance, is typically connected to the internet and linked to a hospital's internal network. *Id*. And in the process of carrying out their functions, devices capture and store patients' medical data to relay that information to providers connected to the network. Copyrighted software plays a critical role in ensuring this confidential health information remains private. Compl. ¶¶ 37, 45. It also safeguards the devices from hackers and other cybersecurity risks, which could impair the devices' safe operation.

The importance of software innovations in this space cannot be overstated. Advances in medical technology today are driven just as well by advances in software as they are by advances in hardware engineering and design. And OEMs must make enormous investments of time and money to develop and bring medical devices and their software to market. Compl. ¶ 53. They rely on copyright protections—and the licensing agreements they make possible—to recoup their substantial investments and facilitate further innovations. Compl. ¶¶ 53-54. Without those protections, OEMs would not be able to recover their costs or to continue developing more effective and efficient devices. Compl. ¶¶ 54-55.

2. OEMs use a variety of TPMs, such as passwords and encryption, to guard against unauthorized access to and copying of their copyrighted software. Compl. ¶ 39. TPMs limit aspects of their software that may be viewed, used, copied, and modified. These limits not only safeguard OEMs' intellectual property, but they also ensure the privacy of patient data and that only appropriate users operate medical device software. Compl. ¶¶ 39, 44-45. For example, OEMs license to healthcare providers the clinical software they need to treat patients, and they use TPMs to ensure that only authorized providers have access. Compl. ¶¶ 44-45. In short, TPMs are vital to the safety and functionality of medical devices.

Evaluation, maintenance, and repair of medical devices is facilitated by accessing (and necessarily copying) the machine's computer code. Compl. ¶¶ 41-42, 55. But improper use of

OEM software for servicing medical devices creates substantial risks to users, risking serious injury to patients and providers. Compl. ¶¶ 44-45. In addition to these direct safety risks, failure to repair devices properly can cause delays and misdiagnoses. *Id*. In light of these risks to patients and providers, the Food and Drug Administration (FDA) strictly regulates OEMs, requiring them to receive various FDA approvals before commercially distributing certain devices (21 C.F.R. Parts 801 & 814) and to report serious malfunction incidents (21 C.F.R. Part 803), among other things. The FDA also regulates the quality control of medical devices, which includes requirements relating to their servicing and maintenance. *See* 21 C.F.R. Part 820.

Given the very serious risks involved in servicing such sophisticated machines, the FDA has recognized the importance of allowing OEMs to train and equip their "own service personnel with additional documentation or enhanced software programs, with privileged access codes" to provide particularly complex services and repairs. *See* Letter from Mary S. Pastel, Sc.D., Deputy Director for Radiological Health, FDA, to Gail M. Rodriguez Ph.D., Executive Director, MITA 2 (Jan. 30, 2014), perma.cc/BX3V-3U5B (*Pastel Letter*).

3. Independent service operators provide unregulated third-party maintenance and repair services for medical devices. Compl. ¶¶ 42, 49-50. They are not subject to the FDA regulations that apply to OEMs. Compl. ¶ 47. Nor are they subject to the same training and quality control measures. *Id*. Many OEMs nevertheless provide support to ISOs to enable them to perform basic maintenance and repair services, sometimes including limited licensing of copyrighted documentation and software. Compl. ¶ 51. But some ISOs have routinely attempted to circumvent TPMs to gain unauthorized access to copyrighted software. Compl. ¶ 50. Such ISOs use unauthorized access to market advanced maintenance services for medical devices that they otherwise would be unable to sell. Circumventing TPMs for medical-device software thus allows ISOs to copy OEM innovations without internalizing any of the research-and-development costs necessary to produce the software and the machine it runs.

The act of circumventing TPMs in medical devices itself creates software vulnerabilities. Compl. ¶ 45. By using passcode-generating algorithms or other technological or physical measures to bypass TPMs, unauthorized users can inadvertently modify the device or its operating systems, thus compromising software integrity. Compl. ¶ 45, 48. This can also unintentionally introduce security vulnerabilities to the device and its networks, as well as interfere with the device's intended functionality. Those are serious risks, which for medical devices, "have the potential to result in patient illness, injury, or death." *FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices* (May 2018), at 25, perma.cc/5QFU-72E4 (*FDA Report*). For this reason, FDA recommends that OEMs "limit[] privileged access to operating systems and applications" and restrict "software or firmware updates to authenticated code only" in order to mitigate the "specific cybersecurity challenges related to" TPM circumvention. *Id.*

Rulemaking background

This case concerns the eighth triennial DMCA rulemaking, which the Register of Copyrights commenced 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 Copyright Office took comments from proponents and opponents of various exemptions over the next three months.

1. Two ISOs petitioned for access to device software and data files stored on medical devices and systems for purposes of diagnosis, maintenance, and repair. *See* U.S. Copyright Office, *Petitions for Newly Proposed Exemptions*, perma.cc/HDV5-XLWG. They did not assert that access to the protected materials was necessary to stimulate creation, expression, or learning; rather, they asserted that it was necessary to stimulate their profits. *See* Summit Imaging Petition 2, perma.cc/3HHR-N9C2 (asserting without explanation that the commercial sale of "diagnosis, repair, and maintenance [services for] medical devices" is a "fair use"); Transtate Equipment Petition 2, perma.cc/V54Y-HBL5 (asserting among other things that repair is "fair use" because

"to perform the servicing activities, it is necessary to" copy software code and "data file[s] to obtain specification information").

The Register published an NPRM identifying seventeen proposed exemptions, including the exemption sought by the ISOs. *See* U.S. Copyright Office, *Exemptions to Permit Circumvention of Access Controls on Copyrighted Works*, 85 Fed. Reg. 65,293 (October 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. The Register left unaddressed the content of the proposed rule, only "invit[ing] comment on the extent to which its prior analysis of" exemptions for third-party service providers in other contexts "may be applicable here." *Id.*

2. Plaintiffs and one of their mutual members submitted comments in opposition to the proposed exemption, arguing that it was for infringing purposes, not any fair use; and that to grant it would offend the basic purposes of the copyright laws. In particular, they argued:

- **Purely commercial use.** The proposed uses are purely commercial—namely, to facilitate competing maintenance and repair services. The exemption would not in any way promote the creation of new works or the proliferation of "criticism, comment, news reporting, teaching . . . scholarship, or research." 17 U.S.C. § 107. Related, there is nothing transformative about the ISOs' intended uses. *See* Dkt. 1-3 at 7-8 (*AdvaMed Comments*); Dkt. 1-2 at 8-9 (*MITA Comments*); Dkt. 1-4 at 7-8 & n.24 (*Philips Comments*). The proposed uses are thus infringing.

- **Discouragement of further creations.** The software at issue is innovative and essential to the devices' safety, integrity, and security. It also represents a substantial investment of time and labor made in anticipation of a financial return. By permitting ISOs to freeride on OEMs' innovations and investments, the exemption would discourage the production of further creations. *MITA Comments* 9; *AdvaMed Comments* 8-9.

- **Damage to the market.** The proposed exemption would decrease the value of the copyrighted software and the medical devices that require the software to function. It also would increase the rate at which medical-device TPMs are circumvented, which would exacerbate cybersecurity risks, thus damaging consumer trust and further reducing the market value of the machines and their software. *AdvaMed Comments* 3, 11-15; *MITA Comments* 10-11. It would yet further damage the market for medical device software by broadly exposing OEMs' valuable intellectual property. *MITA Comments* 3, 10; *see also AdvaMed Comments* 8, 11; *Philips Comments* 9-10, 17.

- **Risks to patient safety and privacy.** The requested exemption would expressly invite TPM circumvention, which threatens patient privacy and puts patient and user safety at risk. The devices at issue use advanced technologies that, if not employed according to well-researched and regulated safety standards, can introduce dangers such as electrical shock, mechanical failure, improper dosing, and burns. It also would undermine FDA regulations that protect patient safety. *AdvaMed Comments* 3, 11-15; *MITA Comments* 3-5; *Philips Comments* 17-19.

3. Notwithstanding these and other extensive comments, the Register recommended granting an exemption covering "[c]omputer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files." Dkt. 1-1 at 233 (*Register's Recommendation*). We refer to this as the "Exemption," which shields ISOs from DMCA liability when they circumvent TPMs when "necessary . . . to allow the diagnosis, maintenance, or repair of such a device or system." *Id.*

In making her recommendation, the Register first addressed the fair-use question. *See Register's Recommendation* 208-212. Concerning the commercial nature of the proposed uses, the Register stated without explanation that "[c]ommerciality is not fatal to a fair use determination." *Id*. at 209. Beyond that, she concluded that "that proponents' proposed use is likely transformative and so the first factor favors fair use." *Id*. In reaching that conclusion, however, the Register offered no explanation. Nor did she attempt to square her transformative-use finding with her own prior acknowledgement that the ISOs themselves had not claimed transformative use and thus did "not seek an exemption to *modify* medical devices or systems, or their software." *Id*. at 208 (emphasis added).[1]

[1] The ISOs' conspicuous omission of a request for an exemption to modify code makes sense because FDA guidance suggests that transformative modifications of medical-device system software, even just for maintenance and repair, may constitute device "remanufacturing," which would be subject to extensive FDA reporting and registration requirements. *See* FDA Center for Devices and Radiological Health, *Remanufacturing of Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff*, perma.cc/M3Q9-WF8C (June 21, 2021); *see also* 21 C.F.R. § 820.3(w); *Register's Recommendation* 229.

The Register further opined that medical-device system software is entitled to diminished copyright protection because it is "not used for [its] expressive qualities, but rather for [its] functional and informational aspects that enable users to control and understand the operation of the equipment." *Register's Recommendation* 210 (citing *Google v. Oracle America*, 141 S. Ct. 1183, 1202, 1208-1209 (2021)). The Register concluded, in addition, that ISOs' copying of the entirety of OEMs' works "should be given little weight here because the use is necessary to accomplish the transformative purposes of diagnosis, maintenance, and repair." *Id*. at 211. Concerning harm to the market for the copyrighted software, the Register concluded that "there is no indication that the software serves any function, or has any value, except for use with the medical device or system for which it was designed." *Id*. at 212. But the Register declined to take account of downstream effects on the market, including misuse and abuse of disclosed code. *Id*.

Moving next to the Section 1201(a)(1)(C) factors, the Register "consider[ed] whether the prohibition against circumventing TPMs on medical devices and systems . . . is adversely affecting the repair of those devices and systems." *Register's Recommendation* 224. In response to plaintiffs' objections concerning the purely commercial nature of ISOs' proposed uses, the Register stated, again without elaboration, that she "[found] these factors not especially relevant to the [Section 1201(a)(1)(C)] determination." *Id*. at 227.

As for plaintiffs' comments concerning harm to the market, the Register analogized sophisticated medical devices like MRI machines and surgery-assisting robots to consumer electronics, stating that "[a]s with other software-enabled devices," unrestricted access to "software and manuals to diagnose, maintain, or repair the device or system" will "support rather than [undercut the value of] the embedded computer programs." *Id*. at 227. For support, the Register pointed to her 2018 analysis concerning software-enabled consumer devices and video game consoles. *Id*. at 227 n.1260; *see also id*. at 203 (addressing same). But the Register elsewhere 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" without a complete factual record and an analysis as to each specific device category. *Id*. at 202. The Register did not explain why a consumer-electronics analogy was appropriate with respect to complex medical devices, which are used in patient-care settings where safety is paramount.

Finally, with respect to her discretion to consider other factors under the Section 1201-(a)(1)(C) framework, the Register observed that "OEMs charge higher prices" than ISOs for maintenance and repair and therefore "that medical service providers must spend more to service their equipment" if they use OEM services "than if they were able to engage in self-repair or have an ISO perform repairs on their behalf." *Register's Recommendation* 228. Without acknowledging that the point of copyright law is to ensure that competitors who do not bear the costs of creation cannot copy works so as to compete at lower prices, the Register opined that granting the Exemption would "help to address the broader competitive concerns recently highlighted by the Executive Branch" concerning repair and maintenance. *Id.*

"After weighing the statutory factors," the Register concluded that "the prohibition on circumvention of TPMs is causing, or is likely to cause, an adverse impact on the noninfringing diagnosis, repair, and maintenance of medical devices and systems." She accordingly recommended that the Librarian grant the requested Exemption. *Id*. at 232-233.

The Librarian adopted the Exemption "based upon the Register's Recommendation" and without further response to comments. *See* 86 Fed. Reg. at 59,627. The Exemption is codified at 37 C.F.R. § 201.40(b)(15) and went into immediate effect.

ARGUMENT

The Exemption is unlawful several times over and should be vacated. The Librarian erred right out of the gate, determining the ISOs' proposed uses are categorically "fair use," and thus noninfringing. That is simply wrong as a matter of law—the proposed uses are *not* fair uses, as

the only two courts to consider the issue each have concluded. The Librarian's contrary conclusion is not only legally wrong, but it is also based on illogical and unexplained factual assumptions that are unsupported by evidence. Related, the Librarian failed to consider and respond to significant public comments, thus violating the APA's procedural requirements. The Library's rulemaking accordingly should be set aside under the APA.[2]

The government doubtless will assert that the APA does not apply in this case because the Library of Congress is not an "agency" within the meaning of the APA. That position is not defensible in this context. The Librarian's promulgation of the Exemption has all the trappings of a traditional rulemaking, and the Library plainly assumed the character of an executive "agency" in undertaking the rulemaking at issue here. The APA's text, the broader statutory context, judicial precedent, and the legislative history all confirm Congress's intent on this point. To the extent there is any room for doubt (there is none), the applicable canons of construction resolve it in favor of plaintiffs. Congress intended the Library's DMCA rulemakings to be subject to the APA's strictures. That is the only plausible construction of the statute, and it avoids significant constitutional concerns that otherwise arise.

Even if the Library's rulemaking is not subject to the APA, plaintiffs' claims may proceed alternatively under *Larson v. Domestic & Foreign Commerce Corporation*, 337 U.S. 682 (1949), which authorizes claims for non-monetary relief against federal officers when the officer's actions are either beyond statutory authority or unconstitutional. The D.C. Circuit has previously authorized *Larson* claims against the Library under similar circumstances. *See Clark v. Library of Congress*, 750 F.2d 89, 102 (D.C. Cir. 1984). Under *Larson*, the Librarian's action here is *ultra vires* for the same reasons the Exemption is substantively unlawful under the APA: She lacked statutory authority to grant an exemption for infringing uses. What's more, if the

[2] Because the Librarian effectively adopted the Register's reasoning as her own (86 Fed. Reg. at 59,627 & 59,637), we attribute the Register's analysis to the Librarian.

Library did not assume the character of an "agency" within the meaning of the APA, but instead is a component of "the Congress," the Library's rulemaking violated separation-of-power principles, and the Exemption is void and unenforceable for that reason as well.

The Exemption is thus unlawful under any theory, and, no matter the basis for review, it must be set aside.

I. THE EXEMPTION SHOULD BE VACATED UNDER THE APA

Plaintiffs' first two causes of action challenge the Librarian's grant of the Exemption as violations of the APA. In that light, this case is straightforward: The Exemption is not in accordance with law, is arbitrary and capricious, and was adopted without complying with procedural requirements. It must be vacated. *See* 5 U.S.C. § 706(2).

A. The Exemption is arbitrary and capricious and not in accordance with law

The DMCA permits the Librarian to issue exemptions to the anticircumvention rule only when "noninfringing uses . . . of a particular class of copyrighted works" are at stake. 17 U.S.C. § 1201(a)(1)(C). The threshold inquiry is therefore whether the proposed uses are noninfringing; if they are not, the Librarian has no authority to grant an exemption. Only if the proposed uses are noninfringing may the Librarian proceed to evaluating the statutory factors to determine whether such uses "are likely to be . . . adversely affected by" the anti-circumvention law. *Id.* It bears emphasis, moreover, that the burden of proof and persuasion are on the proponent of an exemption. *See* U.S. Copyright Office, *Section 1201 of Title 17: A Report of the Register of Copyrights* 110-112 (June 2017), perma.cc/2YZ5-EH4K.

The Librarian here determined the ISOs' uses were noninfringing because they qualified as fair use. *See* 17 U.S.C. § 107. But that conclusion is unsupportable under any plausible conception of the fair-use doctrine. In fact, none of the Section 107 factors support the Librarian's fair-use determination in this case.

1. The uses covered by the Exemption are purely commercial and not transformative

The first Section 107 factor—the "purpose and character of the use, including whether such use is of a commercial nature" (17 U.S.C. § 107(1))—overwhelmingly weighs against the Exemption. As a baseline matter, "every commercial use of copyrighted material is presumptively an unfair exploitation of the monopoly privilege that belongs to the owner of the copyright." *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 451 (1984). 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 central point of copyright is to forestall such an outcome, encouraging the creation of innovative works in the first place.

Here, ISOs are commercial enterprises. And they petitioned for the Exemption for a single reason: to reduce their costs and thus gain market share and increase their profits, without having to pay for freeriding on the creative labors of OEMs. There is no room for fairminded dispute on this point. An ISO's use of an OEM's software to provide competing maintenance services is "entirely commercial in nature." *Triad Systems v. Southeastern Express*, 64 F.3d 1330, 1337 (9th Cir. 1995) (holding that use of OEM software by ISOs for device maintenance and service is not fair use). ISOs obviously are not using the copyrighted works at issue "for nonprofit educational purposes." 17 U.S.C. § 107(1). On the contrary, "the sole purpose of [the ISOs'] use of [the] copyrighted software is in connection with the provision of [device] maintenance services," which "is a commercial use" that "is presumptively an unfair exploitation" of the copyright holder's privilege. *Advanced Computer Services of Michigan v. MAI Systems*, 845 F. Supp. 356, 364-366 (E.D. Va. 1994) (holding that use of OEM software by ISOs for device maintenance and service is not fair use).

The Librarian dismissed this critical point with virtually no analysis, concluding in an *ipse dixit* that ISOs' commercial use of the copyrighted works to compete with OEMs for main-

tenance and service contracts at lower cost "is not fatal to [the] fair use determination." *Register's Recommendation* 209. Indeed, the Librarian concluded that "the first factor *favors* fair use" because the ISOs' proposed use here "is likely transformative." *Id*. (emphasis added).

That conclusion makes no sense. 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*, 510 U.S. at 579). A parody, for example, "needs to mimic an original to make its point" but in so doing transforms the work in an independently expressive way, imbuing it with a new message. *Campbell*, 510 U.S. at 580-581. Likewise, an Andy Warhol painting might technically replicate a copyrighted logo and yet do so in way that transforms the meaning of the work into a commentary on consumerism. *See* 4 Nimmer on Copyright § 13.05[A][1][b]. And the Supreme Court held in *Google* that Google's use of copyrighted code "to create new products" was transformative because it offered programmers "a highly creative and innovative [new] tool" that broadly expanded the creation of expressive content across an all-new smartphone platform. 141 S. Ct. at 1203; *accord Triad Systems*, 64 F.3d at 1336 (suggesting that a use is transformative and thus fair when "the copying result[s] in the proliferation of independent, creative expression"). The transformative-use inquiry thus asks, at bottom, "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. *Google*, 141 S. Ct. at 1202 (internal quotations omitted). The underlying idea, again, is that copyright law should be shaped and applied "to promote science and the arts," and not to stifle it. *Campbell*, 510 U.S. at 579.

The proposed uses at issue here share none of the characteristics that courts have previously found transformative. Quite the opposite, an ISO "simply commandeer[s]" the copyright holder's "software and us[es] 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. More simply put, an ISO that copies documents and code for purposes of device maintenance and servicing "invent[s] nothing

of its own." *Id.* at 1336. And allowing ISOs to copy an OEM's code to further their own business objectives does not in any respect advance the "goal of copyright, to promote science and the arts." *Campbell*, 510 U.S. at 579.

Despite the centrality of the "transformative use" finding to her fair-use determination, the Librarian gave no explanation—*none at all*—for her view that an ISO's use of software for maintenance services can be understood in any way to "'alter' the copyrighted work 'with new expression, meaning or message.'" *Google*, 141 S. Ct. at 1202 (quoting *Campbell*, 510 U.S. at 579). It manifestly cannot. In fact, as the Librarian herself observed, the ISOs seeking the exemption here very notably did "*not* seek an exemption to modify medical devices or systems, or their software" in any way; they wish to copy it only for the purely instrumental reasons for which it was created. *Register's Recommendation* 208 (emphasis added). The ISOs did not seek an exemption for modification because transforming a medical device's code would risk implicating a raft of burdensome FDA regulations that ISOs are eager to avoid. *See supra* at 12 n.1.

The Librarian's "transformative use" finding also undergirded her dismissal of the third Section 107 factor, concerning "the amount and substantiality of the portion used in relation to the copyrighted work as a whole." 17 U.S.C. § 107(3). On this front, she acknowledged that ISOs intended to copy the entirety of OEMs' works, but baldly concluded that this "should be given little weight here because the use is necessary to accomplish the transformative purposes of diagnosis, maintenance, and repair." *Register's Recommendation* 211. As the Ninth Circuit has noted, however, the fact that an ISO must "copy[] programs in their entirety" to perform its third-party maintenance services weighs strongly against fair use. *Triad Systems*, 64 F.3d at 1337 (citing *Advanced Computer Services*, 845 F. Supp. at 366 n.13). The Librarian gave no discernable explanation for concluding otherwise.

These glaring deficiencies in the Librarian's reasoning are alone enough to warrant vacatur of the Exemption. The Librarian's conclusions with respect to the first and third Section 107 fair-use factors were contrary to precedent (*see Triad Systems*, 64 F.3d at 1337; *Advanced Com-*

puter Services, 845 F. Supp. at 364-366), factually unexplained, and flatly contradicted by the only relevant evidence in the record, which indicated that ISOs intend not to modify any device code or maintenance materials.[3] An agency action is arbitrary and capricious and must be set aside if "the agency . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is [simply] implausible." *Delaware Riverkeeper Network v. FERC*, 753 F.3d 1304, 1313 (D.C. Cir. 2014). Just so here.

2. The uses covered by the Exemption will harm the market for and value of the copyrighted works

Having dodged the purely commercial nature of the ISOs' proposed use of the copyrighted work at issue here, the Librarian also sidestepped the fourth Section 107 factor, which 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. 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 defendant would result in a substantially adverse impact on the potential market' for the original." *Campbell*, 510 U.S. at 590 (alteration incorporated) (quoting 3 Melville B. Nimmer & David Nimmer, *Nimmer on Copyright* § 13.05[A][4], at 13–102.61 (1993) (footnotes omitted)). In evaluating this factor, the court "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.

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[3] The Ninth Circuit has suggested in dictum that *Triad Systems* "has been legislatively overruled" by 17 U.S.C. § 117(c). *See Apple Inc. v. Psystar Corp.*, 658 F.3d 1150, 1159 (9th Cir. 2011). Not so in this context. Section 117(c) authorizes the copying of software code only by the "owner or lessee of a machine," and not by third-party ISOs; and it does not permit access to or use of machine software except as "necessary for that machine to be activated." Here, the Librarian herself observed that "section 117(c) covers a narrower range of activities than those proposed" by the ISOs, inasmuch as some "involve loading or accessing software that are not necessary to activate the machine." *Register's Recommendation* 207. Because at least some proposed uses "would not be protected under the statute," the Librarian expressly disclaimed reliance on Section 117(c). *Id.* And as the Ninth Circuit noted in *Apple*, to the extent Section 117(c) is inapplicable, *Triad Systems* remains good law. 658 F.3d at 1150.

a. To begin with, 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 364-366. That is because, as a matter of common sense, 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.

That is undeniably the case here. Commenters showed that adoption of the Exemption would decrease 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, this harms OEMs by allowing competitors to view, replicate, and exploit their innovations without bearing the cost of their development. Moreover, because ISOs are not subjected to the same stringent FDA requirements as manufacturers, they face less accountability concerning their servicing of medical devices. In addition, the ISOs' circumvention of TPMs to carry out certain repairs creates unnecessary technical vulnerabilities that put patient safety in jeopardy. An increase in unregulated ISO circumventions would therefore decrease confidence in the functioning of serviced medical devices. *See AdvaMed Comments* 11-15; *MITA Comments* 18-36. This not only cuts into OEM revenues directly, but it also diminishes the market value of the devices and their software. *MITA Comments* 10-11. None of the proponents of the Exemption provided any evidence or argument for concluding otherwise.

Commenters showed further that the Exemption will have a significant chilling effect on further innovations, including for derivative works. *MITA Comments* 3; *Philips Comments* 17. OEMs rely upon recouping their substantial research and development costs by protecting their valuable intellectual property embodied in copyrighted software. Without meaningful copyright protection, OEMs cannot be assured that they will be able to recoup their significant investments in new, software-driven medical-device innovations. *Id*.

ISOs' circumvention of TPMs and subsequent use of copyrighted OEM software also increases the potential for device malfunction and cybersecurity attacks. *See AdvaMed Comments* 11-15; *MITA Comments* 18-36. FDA strictly regulates OEMs to ensure that sophisticated medical devices and the software needed to run them operate safely and effectively. Compl. ¶ 46. This regulation serves an important purpose: Improper use of OEM software or faulty repairs can result in serious injury or death in the patients and providers that use them. Compl. ¶¶ 46-47. Accordingly, FDA has recognized the importance of OEMs reserving certain enhanced software programs for their own employees, safeguarded by TPMs. *See, e.g.*, *Pastel Letter* at 2 (OEMs "may provide . . . its own service personnel with additional documentation or enhanced software programs, with privileged access codes" to provide certain services and repairs); *FDA Report* at 25 (recommending that OEMs "limit[] privileged access to operating systems and applications" and restrict "software or firmware updates to authenticated code only" in order to mitigate the "cybersecurity challenges"). Allowing unregulated ISOs to circumvent TPMs thus further impairs "the potential market for or value of the copyrighted work." 17 U.S.C. § 107.

b. In response to all of this, the Librarian analogized sophisticated medical devices to simple consumer electronics. She thus asserted without explanation that "[a]s with other software-enabled devices" like cell phones and gaming consoles, unrestricted access to "software and manuals to diagnose, maintain, or repair the device or system" will "support rather than [undercut the value of] the embedded computer programs," in effect helping rather than hurting the market. *Register's Recommendation* 227. But that analogy is both unexplained and inapt. "[A]pplication of [the fair-use factors] requires judicial balancing, depending upon relevant circumstances, including [differences] in technology." *Google*, 141 S. Ct. at 1197; *see also id*. at 1198 (the fair-use doctrine must be applied "to particular situations on a case-by-case basis") (quoting H.R. Rep. No. 94-1476, 65-66 (1976)); *id*. at 1199 ("fair use depends on the context") (citing *Campbell*, 510 U.S. at 577-578). Thus, as the D.C. Circuit has put it, "each case raising a fair use [inquiry] must be decided on its own facts" and cannot be resolved by reflexive categori-

cal analyses. *American Society for Testing and Materials, et al., v. Public.Resource.Org, Inc.* 896 F.3d 437, 448 (D.C. Cir. 2018). That is why the Librarian herself elsewhere 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." *Register's Recommendation* 202.

Here, plaintiffs' submitted significant evidence and argumentation showing that circumvention of TPMs for diagnosis, maintenance, and repair of sophisticated medical devices implicate very different considerations even just among different medical devices, let alone compared with diagnosis, maintenance, and repair of iPhones and Nintendos. *E.g., MITA Comments* 4. The Librarian's decision not to pay heed to those differences, despite paying lip service to their importance, was arbitrary, capricious, and unsupported by evidence.

3. The Exemption undercuts rather than promotes the objectives of copyright

Finally, the Librarian opined with respect to the second Section 107 factor that medical-device system software is entitled to diminished copyright protection because it is "not used for [its] expressive qualities, but rather for [its] functional and informational aspects that enable users to control and understand the operation of the equipment." *Register's Recommendation* 210 (citing *Google*, 141 S. Ct. at 1202). That misses the point entirely. The software at issue here, "although used for a functional purpose, is essentially a creative work" that is "specially designed and crafted" for an innovative use, and it "represents a substantial investment of time and labor." *Advanced Computer Services*, 845 F. Supp. at 365.

It is true that "some works are closer to the core of intended copyright protection than others." *Campbell*, 510 U.S. at 586. And "computer programs . . . almost always serve functional purposes." *Google*, 141 S. Ct. at 1198. But that alone does not deprive them of copyright protection. *Id*. On the contrary, Congress thought "long and hard about whether to grant computer programs copyright protection" and decided to do so on the view that "copyright's existing doctrines

(*e.g.*, fair use), applied by courts on a case-by-case basis, could prevent holders from using copyright to stifle innovation" with respect to high technology. *Id*.

On that front, the driving consideration is and must always be whether the proposed use "fulfills the objective of copyright law to stimulate creativity for public illumination." *Google*, 141 S. Ct. at 1203 (cleaned up). Here, the Librarian entirely lost sight of that objective, promulgating an Exemption that harms rather than serves the purposes of copyright. She did so out of apparent concern that "OEMs charge higher prices" than ISOs "to service their equipment," resulting in supposed "competitive concerns." *Register's Recommendation* 228. That is a bewildering concern in the context of a statutory grant of monopoly privileges. "[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).

To be sure, courts "should 'consider the public benefit resulting from a particular use notwithstanding the fact that the alleged infringer may gain commercially.'" *Advanced Computer Services*, 845 F. Supp. at 365 (quoting *Sega Enterprises, Ltd. v. Accolade, Inc.*, 977 F.2d 1510, 1523 (9th Cir. 1992)). But the only relevant public benefit for copyright purposes is "'the development of art, science, and industry,' and not, as here, the purely financial interests of customers" who all along have been "on notice" of the licensing terms of the software at issue. *Id*. (quoting *Rosemont Enters. v. Random House, Inc.*, 366 F.2d 303, 307 (2nd Cir. 1966)). OEMs should be able to "rely on service fees to recoup its investment costs in developing the software." *Id*. To conclude otherwise will discourage OEMs' creative energies by depriving them of the fruits of their investments, with no new, offsetting innovations to show for it.

Having lost sight of the objectives of copyright, the Librarian badly misconstrued the fair-use doctrine, ultimately granting the Exemption for uses that are plainly infringing. For that reason and all the foregoing reasons, the Exemption is arbitrary and capricious and not in accordance with law. It should be vacated.

B. The Exemption is procedurally defective

The Librarian's terse and incomplete reasoning supports more than just a finding that the Exemption is substantively deficient; it means that it is procedurally unlawful, too.

The governing standards are familiar: An agency "must examine the relevant data and articulate a satisfactory explanation for its action, including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Manufacturers Association v. State Farm Mutual Auto Insurance*, 463 U.S. 29, 43 (1983). Agencies are therefore obligated by the APA to "consider and respond to significant comments received during the period for public comment." *Perez v. Mortgage Bankers Association*, 575 U.S. 92, 96 (2015) (citing *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971)). "An agency's failure to respond to relevant and significant public comments generally 'demonstrates that the agency's decision was not based on a consideration of the relevant factors.'" *Lilliputian Systems v. Pipeline Hazardous Materials Safety Admin.,* 741 F.3d 1309, 1312 (D.C. Cir. 2014) (quoting *Thompson v. Clark*, 741 F.2d 401, 409 (D.C. Cir. 1984)). Although an agency need not "respond to every comment" (*Thompson*, 741 F.2d at 408), it must adequately respond to comments that genuinely "cast doubt on the reasonableness of a position taken by the agency." *HBO v. FCC*, 567 F.2d 9, 35 n.58 (D.C. Cir. 1977). This is consistent with an agency's "duty to examine key assumptions as part of its affirmative burden of promulgating and explaining a nonarbitrary, non-capricious rule." *Northeastern Maryland Waste Disposal Authority v. EPA*, 358 F.3d 936, 948 (D.C. Cir. 2004) (*NMWDA*).

The Librarian failed these basic requirements. Many of plaintiffs' significant comments concerning matters of central relevance to the Exemption went unaddressed. For example, MITA explained that a categorical fair-use determination based upon the surface-level descriptions in the ISOs' petitions was inappropriate because fair-use analysis must be tailored to the facts of the individual case, which was not possible here considering the varied applications of medical devices and the range of services provided by ISOs. *MITA Comments* 4, 8. The Librarian did not

address this point at all. Worse, she adopted the Exemption after inexplicably grouping complex and sensitive medical devices with cell phones and game consoles.

The Librarian also disregarded commenters' observation that the purpose of the ISOs' proposed uses were not "for purposes such as criticism, comment, news reporting, teaching . . . scholarship, or research" (17 U.S.C. § 107), but instead for promoting the financial interests of for-profit companies. *See AdvaMed Comments* 7-8; *MITA Comments* 8-9; *Philips Comments* 7-8. The Librarian's only response was the *ipse dixit* that maintenance and repair of medical devices is somehow transformative, supposedly making the commerciality of ISOs' use irrelevant. *Register's Recommendation* 209. But even on that score, the Librarian did not respond adequately to opponents' explanation that there is *not* anything transformative about the ISOs' intended uses. Opponents explained that the ISOs were not creating anything new, and any true alterations to the devices would circumvent FDA regulatory oversight, putting patients at risk. *MITA Comments* 9; *Philips Comments* 7-8 & n.24. The Librarian did not address the substance of these observations, simply asserting without explanation that the opposite is true.

Related, the Librarian did not respond adequately to opponents' arguments that an exemption did not serve "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 Librarian's only response was to say that these factors—which comprise nearly half of the statutorily mandated considerations—were "not especially relevant." *Register's Recommendation* 227.

The Librarian did not address opponents' argument that the challenged exemption would unduly chill innovation, contrary to the purpose of copyright laws, including the DMCA. *MITA Comments* 3; *Philips Comments* 17. Commenters demonstrated that by unveiling valuable intellectual property, the Exemption would diminish "the value of copyrighted works" and damage the market for medical device software and materials, thwarting future innovation. *AdvaMed Comments* 11; *MITA Comments* 3; *Philips Comments* 17. They explained also that the Exemp-

tion would expose the copyrighted work in its entirety to the public, and once intellectual property is made public, any protection to its value is lost as a practical matter. *MITA Comments* 10; *see also AdvaMed Comments* 8, 11; *Philips Comments* 9-10, 17. The Librarian merely remarked that misuse of copyrighted material would not be permissible. *Register's Recommendation* 212. But that is no response at all; the point was that supposedly permissible uses will lead to impermissible ones, thus affecting the market for medical devices and their software.

The Librarian did not respond adequately to opponents' arguments that an exemption would decrease the value of the copyrighted software and medical devices generally. Opponents argued that the proposed exemption would make unregulated circumventions more common. *AdvaMed Comments* 3; *MITA Comments* 10. Because ISOs are not subjected to the same stringent FDA requirements as manufacturers, they face less accountability concerning their servicing of medical devices. And ISOs' circumvention of TPMs to use OEM proprietary software creates unnecessary cybersecurity vulnerabilities that put patient privacy and safety in jeopardy. An increase in ISO circumventions would therefore increase patient risk and decrease confidence in the functioning of serviced medical devices. *See AdvaMed Comments* 11-15; *MITA Comments* 18-36. This will diminish the market value of the devices and their software. *MITA Comments* 10-11. The Librarian did not address the substance of these concerns, remarking only—and irrelevantly—that the software had "no independent value separate from being used with the equipment." *Register's Recommendation* 212.

The Library's failure to consider and respond adequately to these comments "cast[s] [yet further] doubt on the reasonableness" of the Exemption. *HBO*, 567 F.2d at 35 n.58. Its fair-use determination was necessarily a "key assumption[]" undergirding the exemption analysis. *NMWDA*, 358 F.3d at 948. By failing to address a litany of critical comments concerning its fair-use determination, the Library flunked the APA's procedure requirements. That is an independent basis to set the Exemption aside.

II. WHEN ENGAGED IN DMCA RULEMAKINGS, THE LIBRARY OF CONGRESS ACTS AS AN "AGENCY" WITHIN THE MEANING OF THE APA

We anticipate that the government's principal response to our merits arguments will not be a denial that the Library violated the APA, but rather a denial that the APA applies at all. Section 702 of the APA waives the United States' sovereign immunity only for suits against "an agency" or "an officer or employee thereof." And Section 701(b)(1) defines "agency" to include "each authority of the Government of the United States" but not "the Congress." The government will say that the Library is a component of "the Congress" and not the executive branch, and that its action in promulgating the Exemption therefore is not an "agency action" made reviewable by Section 702. Any such argument would be meritless. The Library is in fact a hybrid entity, and in promulgating the Exemption, it was manifestly acting in its capacity as an executive "agency" in the APA sense. To hold otherwise would offend the presumption in favor of judicial review and raise a host of constitutional problems.

A. The Library acted in its capacity as an executive agency in all relevant respects

1. As a starting point, the Library of Congress is not purely a legislative body; rather, it has a "hybrid character" and performs functions belonging to both the "legislative [and] executive department[s]." *Live365, Inc. v. Copyright Royalty Board*, 698 F. Supp. 2d 25, 42-43 (D.D.C. 2010) (quoting *Eltra Corp. v. Ringer*, 579 F.2d 294, 301 (4th Cir. 1978)). Among its "functions which may be regarded as legislative" is the work it undertakes through the Congressional Research Service. *Eltra*, 579 F.2d at 301. At the same time, the Librarian "is appointed by the President with advice and consent of the Senate" and "subject to unrestricted removal by the President," not the Congress, indicating that she also may exercise executive powers. *Intercollegiate Broadcasting System v. Copyright Royalty Board*, 684 F.3d 1332, 1341 (D.C. Cir. 2012) (quoting *Buckley v. Valeo*, 424 U.S. 1, 127 (1976)); *cf. Bowsher v. Synar*, 478 U.S. 714, 726-732 (1986) (holding that the Comptroller General of the United States is "an officer of the Legislative Branch" because he is "removable only at the initiative of Congress," and therefore

"he may not be entrusted with executive powers").

To determine the capacity in which the Library is acting in any given circumstance, courts "consider each [of its] function[s] . . . separately and . . . determine the character of each, whether legislative or executive." *Eltra*, 579 F.2d at 301. Here, that task is an easy one. As the D.C. Circuit has said, "the powers in the Library . . . to promulgate copyright regulations" are "ones generally associated in modern times with executive agencies rather than legislators." *Intercollegiate Broadcasting*, 684 F.3d at 1341-1342. It hardly could be otherwise; "once Congress makes its choice in enacting legislation, its participation ends" and it "can thereafter control the execution of its enactment only indirectly—by passing new legislation." *Bowsher*, 478 U.S. at 733-734 (citing *INS v. Chadha*, 462 U.S. 919, 958 (1983)). The Library, in performing its rulemaking duties under the DMCA, is plainly exercising power allocated to it *by* a statute; it is not in any sense adopting or amending a statute in the first instance. And it should go without saying that to "implement[] [a] legislative mandate is the very essence of 'execution' of the law." *Collins v. Yellen*, 141 S. Ct. 1761, 1785 (2021) (quoting *Bowsher*, 478 U.S. at 733). Thus, in its rulemaking role, "the Library is undoubtedly" functioning in an executive capacity and is properly construed in that role as "a 'component of the Executive Branch.'" *Intercollegiate Broadcasting*, 684 F.3d at 1342 (quoting *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 511 (2010)).

That is confirmed straightforwardly by the DMCA's text, which directs the Library to undertake triennial "*rulemaking* proceeding[s]." 17 U.S.C. § 1201(a)(1)(C) (emphasis added). Rulemaking proceedings inextricably imply traditional notice-and-comment procedures, as used by the Librarian here. It is thus no surprise that lawmakers themselves expressly anticipated that the Library's adoption of anticircumvention exemptions under the DMCA would be "consistent with the requirements of the Administrative Procedures Act." H.R. Rep. No. 105-551, pt. 2, at 37 (1998). Moreover, the exemptions thereby promulgated are regulations published in the Code of Federal Regulations, with the force and effect of law, just like any other final rule. *See* 37 C.F.R.

§ 201.40(b)(15). Their adoption is thus an action "by which 'rights [and] obligations have been determined,' [and] from which 'legal consequences will flow.'" *Smith v. Berryhill*, 139 S. Ct. 1765, 1775-1776 (2019) (quoting *Bennett v. Spear*, 520 U.S. 154, 178 (1997)). This kind of rulemaking can be undertaken only by "executive agencies." *Intercollegiate Broadcasting*, 684 F.3d at 1342.[4]

2. That conclusion is confirmed textually beyond all doubt by the Federal Register Act. Again, the Library publishes all relevant documents in connection with its DMCA rulemakings in the Federal Register and promulgates its final exemptions in the Code of Federal Regulations. Yet the Act specifies that only a "document" may "be published in the Federal Register." 44 U.S.C. § 1505. It then defines a "document" as "an order, regulation, rule, . . . or similar instrument, issued, prescribed or promulgated *by a Federal agency*." *Id.* § 1501 (emphasis added). The Act similarly reserves the Code of Federal Regulations for the codification of "documents of [an] *agency* . . . promulgated by the *agency* by publication in the Federal Register." *Id.* § 1510(a) (emphasis added). And just like the APA, the Federal Register Act defines the term "agency" to mean "the President of the United States, or an executive department, independent board, establishment, bureau, agency, institution, commission, or separate office of the administrative branch of the Government of the United States *but not the legislative or judicial branches of the Government*." *Id.* § 1501 (emphasis added).

The Library was thus necessarily functioning in its role as a component "of the administrative branch" and "not the legislative or judicial branches" within the meaning of the Federal Register Act (44 U.S.C. § 1501). The same must also be so for purposes of the APA, which

[4] This case is thus readily distinguished from *Clark v. Library of Congress*, 750 F.2d 89 (D.C. Cir. 1984), where the D.C. Circuit held that the Library's routine employment actions are undertaken in its role as a component of Congress and thus not subject to APA review. *Id.* at 102. "[T]he Office of the Librarian of Congress is codified under the legislative branch" and "it receives its appropriation as a part of the legislative appropriation" (*Eltra*, 579 F.2d at 301), rendering its ordinary employment decisions (which are not in any sense actions executing or implementing laws) as ones undertaken in its legislative role.

similarly defines an "agency" as an "authority of the Government of the United States," but not "the Congress" or "the courts of the United States." 5 U.S.C. § 701(b)(1). If the Library was an executive "agency" and not a component of the "legislative branch" for Federal Register Act purposes, it was an executive "agency" and not a component of "the Congress" for APA purposes as well. After all, Congress is not presumed to "silently attach[] different meanings to the same term in the same or related statutes" (*Azar v. Allina Health Services*, 139 S. Ct. 1804, 1812 (2019)), and it is inconceivable that it would have done so here. *See also Law v. Siegel*, 571 U.S. 415, 422 (2014) (describing as a "normal rule of statutory construction" the maxim that words repeated in related statutes "generally have the same meaning").

B. The canons in favor of judicial review and avoiding constitutional questions require treating the Library as an "agency" subject to APA review in this context

If any doubt on this front remained (and none should), the relevant statutory canons of construction would resolve the uncertainty.

1. The Supreme Court has long recognized an especially "strong presumption favoring judicial review of administrative action." *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 486 (2015); *see also Sackett v. EPA*, 566 U.S. 120, 128-29 (2012); *Bowen v. Michigan Acad. of Family Physicians*, 476 U.S. 667, 670 (1986). The presumption in favor of judicial review turns on the notion that "Congress rarely intends to prevent courts from enforcing its directives to federal agencies." *Mach Mining*, 575 U.S. at 486. Thus to withhold judicial review of an agency's rulemaking action under a statutory grant of authority, the government must provide "clear and convincing evidence of [such] intent." *Bowen*, 476 U.S. at 671 (quoting the legislative history of the APA). The presumption accordingly requires a clear statement to overcome the "heavy burden in attempting to show that Congress prohibited all judicial review of [an agency's] compliance with a legislative mandate." *Mach Mining*, 575 U.S. at 486 (cleaned up).

If Congress truly had intended to deprive courts of their traditional supervisory role with respect to the Library's DMCA rulemakings, it would have been a simple matter of saying so.

For example, it could have added a final paragraph to 17 U.S.C. § 1201(a)(1) providing that "No determination made in a rulemaking proceeding pursuant to subparagraph (c) shall be subject to judicial review under chapters 5 and 7 of title 5." *See, e.g.*, 5 U.S.C. § 805 (similar language applicable to Congressional disapprovals of rulemakings). Alternatively, it could have specified that "the provisions of chapters 5 and 7 of title 5 shall not apply to the exercise of the powers of the Library of Congress under subparagraph (c)." *See, e.g.*, 39 U.S.C. § 410(a) (similar language applicable to rulemakings of the Postal Service). But it did neither of those things. Rather, the statutory text points in the exact opposite direction, as we have just shown: Congress directed the Librarian to undertake a "rulemaking," implicating an exercise of executive power and the utilization of the Federal Register and the Code of Federal Regulations—all factors plainly suggesting the Library's status as an executive agency and thus reviewability under the APA.

2. To interpret the Library instead to function as a component of "the Congress" for purposes of its DMCA rulemakings, outside the scope of the APA, also would raise tremendous separation of powers problems. That weighs heavily in plaintiffs' favor here because "when a serious doubt is raised about the constitutionality of an act of Congress, [courts should] first ascertain whether a construction of the statute is fairly possible by which the question may be avoided." *Nielsen v. Preap*, 139 S. Ct. 954, 971 (2019) (cleaned up). As we have shown, there plainly is one here.

a. Characterizing the Library as a component of "the Congress" (5 U.S.C. § 701(b)(1)) in this context would first and foremost offend the rule against legislative exercises of executive power. "The Framers recognized that, in the long term, structural protections against abuse of power" are essential to the success of the American experiment. *Seila Law LLC v. Consumer Fin. Protection Bur.*, 140 S. Ct. 2183, 2202 (2020) (quoting *Bowsher v. Synar*, 478 U.S. 714, 730 (1986)). The Constitution thus divides the federal government's powers "into three defined categories, Legislative, Executive, and Judicial." *Free Enterprise Fund*, 561 U.S. at 483 (quoting *INS v. Chadha*, 462 U.S. 919, 951 (1983)). It in turn allocates each governmental power exclusively

to one branch and forbids its exercise by the other branches: "All legislative Powers herein granted shall be vested in a Congress of the United States" (Art. I, § 1), "[t]he executive Power shall be vested in a President of the United States" (Art. II, § 1, cl. 1), and "[t]he judicial Power of the United States, shall be vested in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish" (Art. III, § 1).

Against the background of Parliament's abuses in England, "the Framers recognized [in particular the] danger of the Legislative Branch's accreting to itself . . . [of] executive power." *Mistretta v. United States*, 488 U.S. 361, 382 (1989) (citing The Federalist No. 51, p. 350 (J. Cooke ed. 1961)); *see also Bowsher*, 478 U.S. at 723 (noting that "no argument [was] urged with more success" during the constitutional conventions than the objection to the "mingling of the Executive and Legislative branches of the Government in one body") (quoting 1 Annals of Cong. 380 (1789)). The Constitution's tripartite structure thus most especially "does not permit Congress to execute the laws." *Bowsher*, 478 U.S. at 726.

That spells an end to the Exemption if the Library is viewed as a component of Congress in this context. The promulgation of a regulation under statutory grant of authority is quintessentially an "exercise[] of—[and] under our constitutional structure . . . *must* be [an] exercise[] of—the 'executive Power'" within the meaning of Art. II, § 1, cl. 1. *City of Arlington v. FCC*, 569 U.S. 290, 304 n.4 (2013). In adopting exemptions under the DMCA, the Library must decide "what it must do, what it cannot do, and [apply] the standards" to determine exemptions. *Collins*, 141 S. Ct. at 1785. Again, the act of "implementing [a] legislative mandate" in this way "is the very essence of 'execution' of the law." *Id.* (quoting *Bowsher*, 478 U.S. at 733). Thus, if the Library, in performing its rulemaking duties, is acting in its role as an agency of "the Congress" (5 U.S.C. § 701(b)(1)), it would follow inexorably that Congress had arrogated to itself executive powers, in direct violation of basic separation-of-powers principles. Avoidance of that fundamental constitutional problem weighs strongly in favor of construing the Library as an executive "agency" within the meaning of Section 701(b)(1).

b. It would be no answer to say, instead, that the Library's rulemakings are in fact exercises of legislative rather than executive power. "In addition to allocating power among the different branches, the Constitution identifies certain restrictions on the *manner* in which those powers are to be exercised." *Department of Transportation v. Association of American Railroads*, 575 U.S. 43, 68 (2015) (Thomas, J., concurring). In particular, when Congress "exercises its legislative power, it must follow the single, finely wrought and exhaustively considered, procedures specified in Article I." *Metropolitan Washington Airports Authority v. Citizens for Abatement of Aircraft Noise, Inc.*, 501 U.S. 252, 274 (1991) (quotation marks omitted) (*MWAA*). That is to say, it must comply with bicameralism and presentment. *Chadha*, 462 U.S. at 951. But the Exemption here was assuredly not adopted by the House and Senate or signed by the President. Thus, characterizing the Library as a legislative agency would raise another insurmountable constitutional problem under Article I, even if its rulemaking powers are construed (illogically) as legislative in nature.

At bottom—and regardless of whether the Library's rulemaking power is executive or legislative—if the Library is understood as part of "the Congress" (5 U.S.C. § 701(b)(1)) in exercising it, serious constitutional problems will result. *See MWAA*, 501 U.S. at 276 ("If the power is executive, the Constitution does not permit an agent of Congress to exercise it. If the power is legislative, Congress must exercise it in conformity with the bicameralism and presentment requirements of Art. I, § 7."). These problems are avoided by reading the word "agency" in 5 U.S.C. § 701(b)(1) to include the Library of Congress when the Library engages in formal rulemaking to implement copyright statutes, as it did here. Indeed, that reading is compelled not only by the constitutional avoidance canon (*INS v. St. Cyr*, 533 U.S. 289, 299-300 (2001)), but also by the plain statutory text and strong presumption in favor of judicial review.

3. This Court's recent decision in *Green v. Department of Justice*, 392 F. Supp. 3d 68 (D.D.C. 2019) (Sullivan, J.), does not provide any basis for concluding otherwise. To be sure, *Green* held that, although the Library "arguably [is] a component of the Executive Branch" and

thus subject to APA review "in its role in the [DMCA] triennial rulemaking process," the APA did not apply in that case. *Id*. at 98-100. But *Green* does not control (*Jackson v. District of Columbia*, 696 F. Supp. 2d 97, 102 (D.D.C. 2010) ("district court decisions have no binding effect")), and it is unpersuasive on its own terms.

Both the parties' and the Court's focus in *Green* was on the plaintiff's unrelated First Amendment claim. The plaintiffs' APA claim was litigated only as an afterthought, and the parties' briefing was incomplete. *See Green*, Plaintiffs' Opp. to Mot. to Dismiss 42-45, No. 1:16-cv-1492 (Dkt. 18) (D.D.C. Oct. 18, 2016) (devoting just three pages to the issue). The plaintiffs did not raise the Federal Register Act, nor did they include a constitutional claim raising the separation-of-powers concerns that underly Count IV of the complaint in this case. *See* 392 F. Supp. 3d at 100 (noting plaintiffs did not challenge the exemption at issue in the case "on the grounds that [the DMCA's] structure violates separation of powers"). Because the broader statutory and constitutional issues were not fully ventilated in *Green*, the Court declined even to address the plaintiffs' underdeveloped constitutional avoidance arguments. 392 F. Supp. 3d at 100. And the plaintiffs made no mention of *Mach Mining* or the presumption in favor of judicial review.

Green cannot be taken to have examined and rejected arguments that were not raised by the parties. *Bismullah v. Gates*, 551 F.3d 1068, 1071 (D.C. Cir. 2009) (a court cannot be understood to have "decide[d]" an issue that "was not presented . . . or briefed" in the case). Simply put, *Green* did not resolve the same issues that are presented here.[5]

III. ALTERNATIVELY, THE COURT SHOULD INVALIDATE THE EXEMPTION UNDER THE *LARSON* DOCTRINE

Even if the Court concluded against all the evidence that the APA does not apply in this circumstance, sovereign immunity still would not bar this suit. The Supreme Court and the D.C. Circuit have long recognized the availability of non-monetary relief against federal officers when

[5] Although the plaintiffs in *Green* have noticed an appeal, they have not appealed the dismissal of their APA claim. *See* Appellants' Opening Br., No. 21-5195 (D.C. Cir. Jan. 12, 2022).

their actions are either beyond statutory authority or unconstitutional. *See Larson*, 337 U.S. at 689; *Dugan*, 372 U.S. at 621-622. Indeed, the D.C. Circuit sanctioned a *Larson* claim in similar circumstances as those here against the Librarian of Congress in particular. *See Clark*, 750 F.2d at 102. Review is available here under that framework: *First*, the Librarian's grant of an exemption for demonstrably infringing uses exceeded her statutory authority; and *second*, the rulemaking by which the Exemption was adopted was constitutionally infirm, either because "the Congress" was exercising executive authority or because "the Congress" was exercising legislative authority without bicameralism and presentment. No matter what, the Exemption is unlawful, and sovereign immunity does not preclude relief.

A. If the APA does not apply, the *Larson* doctrine permits judicial review of the Librarian's promulgation of the Exemption

1. Regardless of the APA's applicability, "[i]t is well-established 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* and *Dugan*). This long-settled rule "permit[s] a suit for specific relief against [a federal] officer as an individual if it is not within the officer's statutory powers or, if within those powers if the powers, or their exercise in the particular case, are constitutionally void." *Joint Anti-Fascist Refugee Comm. v. McGrath*, 341 U.S. 123, 140 (1951) (cleaned up) (quoting *Larson*). The rule reflects the view that "[u]nder our constitutional system, certain rights are protected against governmental action and, if such rights are infringed by the actions of officers of the Government, it is proper that the courts shall have the power to grant relief against those actions." *Larson*, 337 U.S. at 704. It thus follows from the fact that courts "cannot lightly infer that Congress does not intend judicial protection of rights it confers against agency action taken in excess of delegated powers." *Leedom v. Kyne*, 358 U.S. 184, 190 (1958).

The D.C. Circuit applied this rule in *Clark*, allowing nonmonetary claims to proceed against the Library of Congress even after holding that the APA did not apply to the Librarian's

routine employment decisions. 750 F.2d at 102 (holding under *Larson* that "sovereign immunity presents no obstacle to Clark's claims for non-monetary relief."); *see also supra* at 30 n.4.

2. In recent prior cases, the government has argued that *Larson* was abrogated by the APA, but courts and other respected authorities have uniformly rejected that position. The D.C. Circuit confirmed as recently as 2014 that "the absence of a cause of action for judicial review under the APA does not necessarily foreclose all judicial review." *Mittleman v. Postal Regulatory Commission*, 757 F.3d 300, 307 (D.C. Cir. 2014). That is because the APA did "not repeal the review of *ultra vires* actions" under *American School of Magnetic Healing v. McAnnulty*, 187 U.S. 94 (1902), and *Larson*. *See Aid Association for Lutherans v. U.S. Postal Service*, 321 F.3d 1166, 1173 (D.C. Cir. 2003); *see also* 14 Fed. Prac. & Proc. Juris. § 3659, at nn.21-27 & accompanying text (4th ed. 2022) ("[T]he APA did not eliminate the earlier forms of review" under *Larson*.); *E.V. v. Robinson*, 906 F.3d 1082, 1092 (9th Cir. 2018) (rejecting the defendant's assertion that "Congress abrogated the *Larson* exceptions" with the APA's enactment).

At bottom, "the case law in this circuit is clear that judicial review is available when an agency acts *ultra vires*," regardless of whether the APA itself applies. *Aid Association*, 321 F.3d at 1173; *see also Trudeau v. FTC*, 456 F.3d 178, 189 (D.C. Cir. 2006) (holding that when "a plaintiff is unable to bring his case predicated on either a specific or general statutory review provision, he may still be able to institute a non-statutory review action") (quoting *Chamber of Commerce v. Reich*, 74 F.3d 1322, 1327 (D.C. Cir. 1996)).

B. The Exemption must be set aside under the *Larson* doctrine

"The action of an officer of the sovereign can be regarded as illegal" and thus subject to review under the *Larson* framework "when such action is not within the officer's statutory powers" or when "the powers or their exercise in the particular case are constitutionally void." *Doehla Greeting Cards v. Summerfield*, 227 F.2d 44, 46 (D.C. Cir. 1955) (citing *Larson*). Here, both illegalities are present.

1. The Exemption is an exercise of power in excess of delegated authority and contrary to a specific requirement of the DMCA

In adopting the Exemption, the Librarian purported to exercise power well in excess of her delegated authority and contrary to the specific requirements of the DMCA. That is so for the same basic reasons that the Exemption is substantively unlawful under the APA—reasons that we do not repeat here. *See supra* at 16-24. It suffices for present purposes to note that the DMCA authorizes the Librarian to promulgate exemptions only for "noninfringing uses . . . of a particular class of copyrighted works." 17 U.S.C. § 1201(a)(1)(C). As we demonstrated in detail, the proposed uses underlying the Exemption here do not meet that requirement. They are, instead, textbook examples of infringing commercial exploitations of copyrighted works, which the Ninth Circuit and the Eastern District of Virginia both have not hesitated to declare unlawful. *See Triad Systems v. Southeastern Express*, 64 F.3d 1330, 1337 (9th Cir. 1995); *Advanced Computer Services of Michigan v. MAI Systems*, 845 F. Supp. 356, 364-366 (E.D. Va. 1994).

The Librarian's overstepping of her authority on this score is not merely "a claim of error in the exercise of the power" duly conferred upon her. *Doehla Greeting Cards*, 227 F.2d at 46. It is, instead, an assertion of policymaking authority "in excess of [her] delegated powers and contrary to" the express limits of the DMCA. *Aid Association*, 321 F.3d at 1173 (quoting *Leedom*, 358 U.S. at 188). Although thinly veiled as a fair-use analysis, the Librarian's reasoning in fact reflects nothing more than the view that OEMs' copyright protections, if appropriately enforced, will allow OEMs to "charge higher prices" than ISOs to "perform [service and] repairs" on complex medical devices. *Reporter's Recommendation* 228. Noting that "ISOs have asserted antitrust claims in litigation against OEMs, with mixed results," the Librarian concluded simply that "an exemption to facilitate repair of medical devices and systems [by ISOs] could help to address the broader competitive concerns recently highlighted by the Executive Branch." *Id*. (citing Exec. Order No. 14,036 of July 9, 2021, 86 Fed. Reg. 36987, 36992 (July 14, 2021)). But as we explained above, that line of reasoning turns the purpose of copyright on its head. And more to the

point, the Librarian has no authority under the DMCA to grant anticircumvention exemptions for plainly infringing uses on the basis of (misguided) policy considerations that have no bearing on the fair-use framework. In this way, the Librarian purported to exercise power in excess of her delegated authority, and the Exemption should be set aside.

2. The Library's promulgation of the Exemption was unconstitutional

The Librarian's exercise of power in adopting the Exemption also was unconstitutional. That is so for reasons we detailed previously as grounds for our constitutional-avoidance argument in support of holding that the Library is an "agency" within the meaning of the APA. *See supra* at 32-35. To recap, if the Library functions as a component of the legislative branch rather than the executive branch in the course of its DMCA rulemakings, either it is unconstitutionally exercising executive authority (running afoul of separation-of-powers principles) or it is unconstitutionally exercising legislative authority (running afoul Article I's bicameralism and presentment requirements). Either way, the rulemaking is constitutionally *ultra vires*. *MWAA*, 501 U.S. at 276. Both *Larson* claims therefore provide a basis for granting relief here.

CONCLUSION

The Court should grant summary judgment to plaintiffs and enter a final judgment setting aside the Exemption, declaring the Exemption to be unlawful and void, and enjoining defendants from enforcing, implementing, or otherwise carrying out the Exemption.

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Respectfully submitted,

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