No. 23-5067

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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

v.

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

Appeal from the United States District Court for the District of Columbia
No. 22-cv-00499
The Honorable Beryl A. Howell, U.S. District Judge

BRIEF OF *AMICI CURIAE* THE NATIONAL ASSOCIATION OF MANUFACTURERS AND WASHINGTON LEGAL FOUNDATION IN SUPPORT OF PLAINTIFFS-APPELLANTS AND REVERSAL

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

In accordance with D.C. Circuit Rule 28(a)(1), *amici curiae* state as follows:

I. Parties and *Amici Curiae*

Except for *amici curiae* the National Association of Manufacturers, Washington Legal Foundation, and Americans for Prosperity Foundation, all parties, intervenors, and *amici* appearing before the district court and in this Court are listed in the Brief for Plaintiffs-Appellants at page i.

II. Rulings Under Review

Reference to the ruling at issue appears in the Brief for Plaintiffs-Appellants at page i.

III. Related Cases

To *amici curiae*'s knowledge, there are no related cases pending before this or any other Court.

/s/ David Y. Chung
David Y. Chung

CORPORATE DISCLOSURE STATEMENT

The National Association of Manufacturers ("NAM") states that it is a nonprofit industrial trade association representing small and large manufacturers in every industrial sector and in all 50 states. The NAM has no parent corporation, and no publicly held company has 10% or greater ownership in the NAM.

Washington Legal Foundation states that it has no parent company, issues no stock, and no publicly held company owns a ten percent or greater interest in it.

/s/ David Y. Chung
David Y. Chung

RULE 29(D) CERTIFICATION

Pursuant to Circuit Rule 29(d), *amici* certify that a separate brief is necessary because *amici* have a unique perspective—including broadly representing the Nation's manufacturing community—and expertise on issues raised in this appeal, and they seek to address those issues for which that perspective and expertise is most relevant. *Amici* respectfully submit that a separate brief is required to offer their unique perspective on the practical consequences of this case.

/s/ David Y. Chung
David Y. Chung

STATEMENT REGARDING CONSENT TO FILE

All parties have consented to the filing of this *amicus* brief.

Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), *amici* affirm that no part of this brief was authored by counsel for any party, and no person or entity has made any monetary contribution to the preparation or submission of the brief other than *amici curiae* and their counsel.

/s/ David Y. Chung
David Y. Chung

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GLOSSARY

APA	Administrative Procedure Act
FDA	Food & Drug Administration
DMCA	Digital Millennium Copyright Act
Library	Library of Congress
MITA	Medical Imaging & Technology Alliance
NAM	National Association of Manufacturers
OEM	Original Equipment Manufacturer
WLF	Washington Legal Foundation

INTRODUCTION AND INTERESTS OF *AMICI CURIAE*

The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States, representing small and large manufacturers in all 50 states and in every industrial sector. Manufacturing employs nearly 13 million men and women, contributes $2.9 trillion to the United States economy annually, has the largest economic impact of any major sector, and accounts for over half of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

Founded in 1977, Washington Legal Foundation ("WLF") is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as *amicus curiae* in important cases to hold government agencies accountable. WLF believes that judicial review of federal agency actions is a cornerstone of the American legal system.

Amici have a substantial interest in this appeal for two reasons. First, *amici* seek to ensure that governmental authorities wielding executive powers—as the Library of Congress ("Library") unquestionably does when promulgating rules under the Digital Millennium Copyright Act ("DMCA")—are not able to avoid

judicial review of their actions. The Supreme Court has long applied a strong presumption in favor of judicial review, and the Government bears the burden of overcoming that presumption by pointing to clear and convincing evidence of Congressional intent to withhold judicial review. Congress did not so clearly withhold judicial review of the Library's DMCA rules in either the Administrative Procedure Act ("APA") or any other relevant statute. Thus, the challenged rule, like other administrative regulations, is subject to review under the APA.

Second, *amici* are concerned that the absence of a meaningful judicial check on the Library's triennial rulemakings, which promulgate an ever-expanding list of exemptions to federal copyright protections, significantly harms manufacturers across various industries. The erosion of meaningful copyright protections will have a chilling effect on innovation. And if this particular rule escapes judicial review, the many negative consequences will be borne by medical device manufacturers and the patients their products are meant to assist.

ARGUMENT

I. Judicial Review of Federal Action Is a Cornerstone of the American Legal System that Must Be Available for Rulemaking by Hybrid Instrumentalities of Congress and the Executive Branch.

Appellants' brief explains in detail why: (i) the Library's exercise of executive rulemaking authority that conforms with the APA's notice-and-comment requirements should be subject to judicial review under the APA; and (ii) this

Court's prior precedents do not stand in the way of reversal and instead support a holding that the Library *does* sometimes constitute an Executive Branch "agency" whose rulemaking actions are reviewable under the APA. *See* Appellants' Br. 21–42. *Amici* write separately to underscore the absence of a clear statement or clear and convincing evidence of Congressional intent to insulate the Library's DMCA rules from judicial review under the APA.

A. The strong presumption of judicial review of administrative actions cedes only to a clear statement of Congressional intent to withhold review.

"[L]egal lapses and violations occur, and especially so when they have no consequence[,]" and "[t]hat is why th[e] [Supreme] Court has so long applied a strong presumption favoring judicial review of administrative action." *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 489 (2015). The Supreme Court has adhered to that strong presumption for well over a century, even before the APA's enactment. *E.g.*, *Am. Sch. of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 108 (1902) ("That the conduct of the postoffice [sic] is a part of the administrative department of the government is entirely true, but that does not necessarily and always oust the courts of jurisdiction to grant relief to a party . . . . The acts of all its officers must be justified by some law[.]"); Louis L. Jaffe, *The Right to Judicial Review I*, 71 Harv. L. Rev. 401, 428 (Jan. 1958) ("The presumption of

reviewability was reinforced in the twenties and thirties by a judicial zeal, often excessive, to contain administrative action.").

The presumption favoring judicial review is grounded in longstanding principles of American law: that judges, not administrators, are best positioned to determine what the law commands or forbids. It has for centuries been "emphatically the province and duty of the judicial department to say what the law is[,]" *Marbury v. Madison*, 1 Cranch 137, 177 (1803), and "[t]he rise of the modern administrative state has not changed that duty." *City of Arlington, Tex. v. FCC*, 569 U.S. 290, 316 (2013) (Roberts, C.J., dissenting).

Congress reinforced the strong presumption favoring judicial review of administrative actions when it enacted the APA. "[F]ramed against a background of rapid expansion of the administrative process[,]" the APA acts "as a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 109 (2015) (Scalia, J., concurring) (internal quotation marks and citation omitted); *see also* 92 Cong. Rec. at 2149 (1946) (statement of Sen. McCarran) (characterizing the APA as a "bill of rights for the hundreds of thousands of Americans whose affairs are controlled or regulated . . . by agencies of the Federal Government").

Given the need to ensure that administrators carry out their duties in accordance with enabling laws and to grant relief to parties aggrieved by administrative action that is contrary to those laws, it is unsurprising that courts require a clear statement from Congress before foreclosing judicial review of a rulemaking. *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 141 (1967), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977) ("[O]nly upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review."). And "where substantial doubt about the congressional intent exists, the general presumption favoring judicial review of administrative action is controlling." *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 672 n.3 (1986) (internal quotation marks and citation omitted).

The APA's legislative history reinforces this clear statement rule. In discussing the "judicial review" section in 1945, the House Judiciary Committee noted: "To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review." H.R. Rep. No. 79-1980, at 275 (1945). The Report further provides the policy justification for this clear statement requirement: "Very rarely do statutes withhold judicial review. It has never been the policy of Congress to prevent the administration of its own

statutes from being judicially confined to the scope of authority granted or to the objectives specified. Its policy could not be otherwise, for in such a case statutes would in effect be blank checks drawn to the credit of some administrative officer or board." *Id*.

Where, as here, a "statute is reasonably susceptible to divergent interpretation, [courts are to] adopt the reading that accords with traditional understandings and basic principles: that executive determinations generally are subject to judicial review[.]" *Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 434 (1995). And even in cases where "a statutory provision expressly prohibits judicial review, the presumption [favoring judicial review] applies to dictate that such a provision be read narrowly." *Am. Clinical Lab'y Ass'n v. Azar*, 931 F.3d 1195, 1204 (D.C. Cir. 2019).

B. There is no clear statement precluding review of the Library's DMCA rulemakings.

The Government cannot meet its "heavy burden of overcoming the strong presumption" of judicial review in this case. *Bowen*, 476 U.S. at 672 (internal quotation marks and citation omitted). Under the APA, any person "adversely affected . . . by agency action . . . is entitled to judicial review[,]" 5 U.S.C. § 702, and "agency" means "each authority of the Government of the United States," *id.* § 701(b)(1). The Library is plainly an authority that exercises power on behalf of the United States Government when promulgating rules implementing the DMCA. *See*

Eltra Corp. v. Ringer, 579 F.2d 294, 300 (4th Cir. 1978) ("the Librarian is an 'Officer of the United States'"). Although the APA's exclusion of "the Congress" from the definition of "agency" introduces some ambiguity as to whether the Library's rulemakings are reviewable under the APA, *see* Appellants' Br. 36–37, it does not constitute clear and convincing evidence of legislative intent to exclude the *Library* of Congress from APA review under any circumstance, including when it exercises executive powers. *See Bowen*, 476 U.S. at 671–72. Because the APA's definition of "agency" can be read to encompass the Library when it exercises its executive power, this Court should adopt such a reading to adhere to the basic principle "that executive determinations generally are subject to judicial review[.]" *Gutierrez de Martinez*, 515 U.S. at 434.

The Library's unique history illustrates why it does not clearly and categorically fall within the APA's reference to "the Congress" in 5 U.S.C. § 701(b)(1). The Library originally served limited functions such as purchasing "such books as may be necessary for the use of Congress" and setting up "a suitable apartment for containing them[,]" which explains why Congress first exercised direct control over the Library's operations and regulations. Act of Apr. 24, 1800, ch. 37, § 5, 2 Stat. 55, 56. When Congress later vested in the Library principal responsibility over the administration of copyright laws in 1870, it initially kept the Library "under the supervision of the joint committee of Congress

on the [L]ibrary[.]" Act of July 8, 1870, ch. 230, § 85, 16 Stat. 198, 212. All of this changed in 1897, however, when Congress relinquished direct control and supervision over duties relating to copyrights and instead placed the Library under the President's direct control and supervision. *See* Act of Feb. 19, 1897, ch. 265, 29 Stat. 538, 544 ("Librarian of Congress to be appointed by the President, by and with the advice and consent of the Senate[.]").

The legislative history of the 1897 Act elucidates that Congress gave "the Joint Committee on the Library no supervision of the regulations to be made by the Librarian." 29 Cong. Rec. at 1947 (1897) (statement of Rep. Dockery). It was equally clear that Congress understood that passage of the 1897 Act meant that "Congress forever puts it out of their power to control the Library. It now loses its name and function of a Congressional Library, and becomes a national or Presidential Library, beyond the control of Congress, except by the President's consent." 29 Cong. Rec. at 977 (1897) (statement of Sen. Call).[1] All of this is to

[1] Likewise, when debating an earlier bill, members of Congress plainly viewed the Library as exercising executive authority. *E.g.*, 29 Cong. Rec. at 318–19 (1896) (statement of Rep. Dockery) (the Library is "a bureau of the Government," whose employees are "not under the control of the House"; "[the Library] is an executive bureau, and as such should be presided over by some executive officer with authority to appoint and remove its employees"); 28 Cong. Rec. at 5497 (1896) (statement of Sen. Mills) ("It has the name of Congressional Library, but . . . [i]t is . . . created by the law of the United States, and its officers must be appointed by the President" or by "the head of a Department."); *id.* at 5498 (statement of Sen. Platt) ("I insist that whether it be the Librarian or whether it be a register of

say that Congress enacted the APA against a legislative background where it had already effectively removed the Library from "the Congress" whenever the Library exercises its rulemaking functions. Although Congress's decision to locate the Congressional Research Service within the Library illustrates that the Library sometimes also carries out functions relevant to the legislative process, *see* 2 U.S.C. § 166, that does *not* "make[] the *Entire* operations of the Librarian of Congress legislative[.]" *Eltra Corp.*, 579 F.2d at 300–01 (emphasis added).

Other statutory provisions suggest that Congress did not clearly intend to withhold judicial review of the Library's rulemakings under the APA by excluding "the Congress" from the definition of "agency." For instance, the Federal Register Act provides that only a "document" may "be published in the Federal Register," 44 U.S.C. § 1505, and under that statute, a "document" is necessarily "an order, regulation, rule, . . . or similar instrument, issued, prescribed, or promulgated *by a Federal agency*." *Id.* § 1501 (emphasis added). Furthermore, the Code of Federal Regulations is reserved for the codification of "documents of [an] agency . . . promulgated by the agency by publication in the Federal Register[.]" *Id.* § 1510(a). Those statutory provisions track with the Library's function as an administrative agency here. The triennial rulemaking process began with the publication of a

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copyrights, he exercises both judicial functions and executive functions with relation to the issue of copyrights, and he must under the statute.").

notice of inquiry in the *Federal Register*, *see* 85 Fed. Reg. 37,399 (June 22, 2020); then a notice of proposed rulemaking in the *Federal Register*, *see* 85 Fed. Reg. 65,293 (Oct. 15, 2020); a final rule in the *Federal Register*, *see* 86 Fed. Reg. 59,627 (Oct. 28, 2021); and finally, codification of the challenged rule at 37 C.F.R. § 201.40(b). These actions place the Library rulemaking squarely within the realm of agency action contemplated by the statutory regime animating the *Federal Register* and Code of Federal Regulations. *See* Appellants' Br. 26–28.

Additionally, the DMCA and its legislative history provide further evidence that the Library functions as an administrative agency when promulgating rules such as the one at issue here. Congress directed the Library to conduct "a rulemaking proceeding" every three years, upon the recommendation of the Register of Copyrights—who in turn consults with the Department of Commerce—to address the propriety of exemptions to the Act's anti-circumvention provisions. *See* 17 U.S.C. § 1201(a). In a 1998 Conference Report, the House Committee recognized: "***Like the Library of Congress,*** its parent agency, the Copyright Office is a hybrid entity that historically has performed both legislative ***and executive or administrative functions***. *Eltra Corp. v. Ringer*, 579 F.2d 294 (4th Cir. 1978)." H.R. Rep. No. 105-796, at 77 (1998) (Conf. Rep.) (emphasis added). Similarly, a House Committee on Commerce report described section 1201(a)(1) of the DMCA as "the convening of a rulemaking proceeding,

consistent with the requirements of the Administrative Procedures [sic] Act." H.R. Rep. No. 105-551, pt. II, at 37 (1998).

To be sure, this Court has previously found that the Library is not part of "the Congress" in cases unrelated to the Library's exercise of executive powers. *See, e.g.*, *Wash. Legal Found. v. United States Sent'g Comm'n*, 17 F.3d 1446, 1449 (D.C. Cir. 1994) (referencing, in dictum, that the Library does not fall within the APA's definition of "the Congress" when analyzing whether the Sentencing Commission is an "agency" under the APA); *Ethnic Emps. of Libr. of Cong. v. Boorstin*, 751 F.2d 1405, 1416 n.15 (D.C. Cir. 1985) (concluding, in the context of an employment discrimination case, that Library is not an "agency" under either FOIA or the APA); *Clark v. Libr. of Cong*., 750 F.2d 89, 102–03 (D.C. Cir. 1984) (concluding, without discussion, that the Library is not an "agency" under 5 U.S.C. § 701(b)(1)(A)). But as the Plaintiffs-Appellants cogently explain (38–42), those cases do not stand in the way of reversal here, because none of them addressed the key questions before this Court: whether the Library is fairly considered an "agency" under the APA when it undertakes notice-and-comment rulemaking and whether the APA's reference to "the Congress" categorically encompasses the Library. *Cf. Nat'l Pork Producers Council v. Ross*, 143 S. Ct. 1142, 1155 (2023) ("we emphasize, our opinions dispose of discrete cases and controversies and they must be read with a careful eye to context").

II. There Are Significant Adverse Consequences from Withholding Judicial Review of the Library's Rule.

Allowing the Library's rule to escape judicial review will have significant negative consequences. The Library is free to continue chipping away at copyright protections based on a gross misapplication of the fair use doctrine, knowing its decisions are unreviewable. This unchecked erosion of copyright protections harms manufacturers and will have a significant chilling effect on innovation, which in turn limits consumer choice. Moreover, the challenged exemption jeopardizes the health and safety of third-party repair personnel, medical device operators, and patients by allowing untrained and unauthorized third parties to repair and modify equipment. Finally, allowing third-party service providers to circumvent technological protective measures designed to protect against unauthorized access to copyrighted software poses cybersecurity risks. Judicial review of the Library's rule is therefore needed to fend off these consequences.

A. The Library's rule threatens to erode copyright protections, stifle innovation, and harm consumers.

The Library's fair use analysis, which the district court allowed to go unchecked—threatens to undermine important protections for manufacturers who devote substantial resources and effort to creating copyright-protected software that enables a broad range of devices and equipment to function properly. Before discussing those practical consequences, a brief discussion of why the Library's

fair use finding is wrong is warranted.

In determining that third party use of copyright-protected software for repair, diagnosis, and maintenance is "likely transformative," the Library summarily concluded that the purely commercial goals of third-party service providers—to compete with original equipment manufacturers ("OEMs") for repair contracts—was not fatal to a fair use determination. *See* Appellants' Br. 45–47. But the Supreme Court recently reinforced the importance of considering the commercial purpose of an allegedly infringing use, while placing important limitations on what constitutes a transformative use. *See Andy Warhol Found. for the Visual Arts, Inc. v. Goldsmith*, 143 S. Ct. 1258, 1273 (2023). Put simply, "[i]f an original work and a secondary use share the same or highly similar purposes, and the secondary use is of a commercial nature, the first [of the four fair use] factor[s enumerated in 17 U.S.C. § 107] is likely to weigh against fair use, absent some other justification for copying." *Id*. at 1277.

In framing the first fair use factor this way, the Supreme Court cautioned that "an overbroad concept of transformative use, one that includes any further purpose, or any different character, would narrow the copyright owner's exclusive right to create derivative works." *Id.* at 1275. Thus, to protect a copyright owner's exclusive right to prepare derivate works—*i.e.*, any other form in which a work may be recast, transformed, or adapted—"the degree of transformation required to

make 'transformative' use of an original must go beyond that required to qualify as a derivative." *Id.* In considering whether a use is transformative, whether a use is commercial must "be weighed against the degree to which the use has a further purpose or different character." *Id.* at 1276. Equally important, the Court underscored that a "use that has a distinct purpose is justified because it furthers the goal of copyright, namely, to promote the progress of science and the arts, without diminishing the incentive to create." *Id.* By contrast, uses that share the purpose of a copyrighted work simply provide a "substantial substitute for matter protected by the copyright owner's interests in the original work or derivatives of it, . . . which undermines the goal of copyright." *Id.* (original alterations omitted, internal quotation marks and citation omitted).

Applying these standards, the Supreme Court concluded that the commercial licensing of a painting of Prince for publication in a magazine did *not* constitute fair use of the copyrighted photograph of Prince it was based on, which was itself published in a magazine many years earlier. *See id.* at 1280. While acknowledging the differences in portrayal and the alleged infringer's claim that the painting added a new meaning or message—that it served as a comment on the dehumanizing nature of celebrity—the Court nonetheless determined that the "commercial nature of the use . . . looms larger." *Id.* at 1285 (original alterations omitted, internal quotation marks and citation omitted). Thus, because "[Lynn]

Goldsmith's original photograph of Prince, and [the Andy Warhol Foundation for the Visual Art's] copying use of that photograph in an image licensed to a special edition magazine devoted to Prince, share substantially the same purpose, and the use is of a commercial nature," the first fair use factor, which was the only factor at issue in that case, weighed in favor of the copyright owner. *Id.* at 1287.

Following the Supreme Court's logic, it is clear that the challenged exemption undermines the goal of copyright. The exemption allows third party service providers to circumvent technological protective measures to diagnose and repair software-enabled medical devices. That is, they seek to use the copyrighted software for an identical purpose (so the devices can function as intended by the OEM) and in exactly the same way in which the software was designed to be used. And the interests represented by the only proponents of the rule are clearly commercial. *See* JA041 (district court opinion) (petitions noticed for comment as to medical equipment were two independent service organizations, Summit and Transtate); JA269 (Philips Comment) (Summit and Transtate "have a track record of circumventing Philips' access controls – without an exemption – for their own commercial gain. Summit and Transtate, as they admit, are defendants in ongoing litigation in which Philips has alleged DMCA violations against both companies"). Under *Goldsmith*, such uses "share substantially the same purpose" and are of a

commercial nature and thus, they are not transformative. *Goldsmith*, 143 S. Ct. at 1280.

Judicial review of the Library's rule is thus necessary to correct this glaring error. Otherwise, the challenged exemption—and any similar exemptions[2] that the district court's ruling emboldens the Library to promulgate free of judicial oversight—will continue to erode copyright protections to the detriment of manufacturers and consumers. As a general matter, copyright owners enjoy a "bundle of exclusive rights," including the rights to "publish, copy, and distribute" their work. *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 546–47 (1985). Indeed, Congress "shall have Power . . . [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." U.S. Const. art. I, § 8, cl. 8. This clause "implies not only that technological innovation is desirable but also that, *but for legal subsidization*, the quantity of innovation forthcoming would or might be less than optimum." William F. Baxter, *Legal Restrictions on*

[2] Although the challenged exemption in this case is limited to medical devices and systems, *see* 37 C.F.R. § 201.40(b)(15), it is part of a growing body of repair-focused exemptions to the DMCA's prohibition against circumventing technological measures protecting copyright work. Proponents of such exemptions have argued that independent repair providers should be entitled to gain access to copyright-protected (and patented) diagnostic and repair information, software, tools, and parts created by original equipment manufacturers. *See* Daniel Cadia, *Fix Me: Copyright, Antitrust, and the Restriction on Independent Repairs*, 52 U.C. Davis L. Rev. 1701, 1704 (2019).

Exploitation of the Patent Monopoly: An Economic Analysis, 76 Yale L.J. 267, 267 (1966) (emphasis added). In other words, without the promise of legal protections, inventors are less incentivized to dedicate scarce resources toward innovating repair methods and improving existing products.

As to software-enabled devices, the U.S. Copyright Office similarly has acknowledged the important role that robust copyright protection plays in ensuring innovation and consumer choice:

> If the law provides more expansive legal benefits for certain types of products or software, manufacturers may have an incentive to reengineer their products to fit within those definitions. Conversely, if the law limits or eliminates legal benefits for other products or software, manufacturers may have an incentive to remove features benefiting consumers, or to add extraneous features that increase costs without providing corresponding benefits for the consumer.

U.S. Copyright Office, *Software-Enabled Consumer Products* 11 (Dec. 2016).[3]

Companies currently are incentivized to create new repair methods, choose product designs that help consumers, and protect consumers from ineffective or even dangerous repairs that might erode the value of the OEM's brand when their inventions are copyright-protected. Manufacturers invest substantial time and resources in expensive and often risky research and development efforts to create new, innovative works. Without the promise of strong copyright protection,

[3] *Available at* https://www.copyright.gov/policy/software/software-full-report.pdf.

however, manufactures are less incentivized to dedicate scarce resources toward creating new and innovative repairs and improvements for existing products. Instead, manufacturers may resort to standardizing products to more easily comply with the law or modifying designs to better comply with mandates in an economically efficient way. *See* Alex Reinauer, *Two Wrongs Don't Make a Right to Repair: How State "Right to Repair" Legislation Harms Consumers and Innovation*, On Point, at 6–7 (Mar. 1, 2023).[4]

In short, eroding intellectual property protections disincentivizes innovating repair solutions and new product design choices. *See, e.g.*, *id.* at 4–7; *see also* Luyi Yang *et al.*, *Research: The Unintended Consequences of Right-to-Repair Laws*, Harvard Bus. Rev. (Jan. 19, 2023).[5] The rulemaking record here confirms this chilling effect. *See* JA232 (Medical Imaging & Technology Alliance ("MITA") Comment) ("There is a massive cost to develop and secure premarket clearance from the [FDA] for medical imaging devices. If innovators are not able to recoup those costs by protecting their valuable intellectual property embodied in software and related materials, the incentives for future innovations will be weakened."); JA282 (Philips Comment) ("This wholesale invasion of intellectual property rights

[4] *Available at* https://cei.org/studies/two-wrongs-dont-make-a-right-to-repair/.
[5] *Available at* https://hbr.org/2023/01/research-the-unintended-consequences-of-right-to-repair-laws.

would destroy the value of those copyrighted works and undermine the incentive for Philips and other OEMs to produce medical devices with their related software in the first instance—an endeavor that requires substantial time and expense as OEMs develop and secure regulatory clearance for medical devices."). And in the end, consumers will ultimately suffer from a lack of innovation. *Cf. United States v. AT&T, Inc.*, 916 F.3d 1029, 1045 (D.C. Cir. 2019) (enumerating "reduced innovation" alongside "decreased product quality" and "higher prices" as harms to consumers); Aurelien Portuese, *Is Congress Committed to Making American Consumers' Lives Costlier?*, WLF Legal Pulse (Jan. 12, 2022) (discussing harm to consumers from proposed bill that would slow down rate of innovations).[6]

B. The Library's rule risks compromising the safety of patients and operators.

Evidence from other contexts serves as a cautionary tale: an unhindered right to repair devices predictably endangers end-users and those attempting the repairs. For instance, the U.S. Consumer Product Safety Commission, the agency "charged with protecting the public from unreasonable risks of serious injury or death from thousands of types of consumer products under the agency's jurisdiction," regularly warns consumers *not* to attempt to repair their own products. *E.g.*, U.S. Consumer Product Safety Comm'n, *Repairing Aluminum Wiring* 2, 9 (June, 2011)

[6] *Available at* https://www.wlf.org/2022/01/12/wlf-legal-pulse/is-congress-committed-to-making-american-consumers-lives-costlier/.

("DO NOT TRY TO DO IT YOURSELF. You could be electrocuted, or you could make the problem worse.").[7] With respect to lithium-ion batteries, "[t]he Consumer Product Safety Commission recommends that all replacement parts be purchased from the source company to ensure the safety standards of the electronic device are maintained. This recommendation is only met if repairs are completed through authorized service providers." Marissa MacAneney, *If It Is Broken, You Should Not Fix It: The Threat Fair Repair Legislation Poses to the Manufacturer and the Consumer*, 92 St. John's L. Rev. 331, 340–41 (2018) (citations omitted).

These dangers are especially prevalent when it comes to repairing and maintaining sophisticated medical devices. For this reason, the U.S. government subjects them to numerous regulatory regimes. Specialized training is essential to proper servicing of medical devices to ensure safety and accurate patient diagnosis. Indeed, the Food and Drug Administration's ("FDA") Quality System Regulation regime requires that OEMs train and maintain certification for service personnel, 21 C.F.R. §§ 820.20, 820.25; develop and preserve proper records regarding the servicing of each medical device, *id.* § 820.181; and calibrate the equipment used to repair such devices, *id.* § 820.200. And importantly, OEMs of these devices are subject to an extensive array of regulations to ensure safety and quality. *See, e.g.*, 21 C.F.R. § 807 (registration of establishments and listing of medical devices with

[7] *Available at* https://www.cpsc.gov/s3fs-public/516.pdf.

the FDA); *id.* § 807 Subpart E and *id.* § 814 (premarket notification and premarket approval, including for modifications or servicing activities that impact the safety or performance of the device); *id.* § 803 (medical device reporting of incidents in which malfunction has caused or may have caused or contributed to death or serious injury); *id.* § 801 (labeling, including descriptive and informational literature).

Independent service operators and other individuals who might attempt repairs are not subject to any of these quality-control requirements geared toward patient safety. Allowing unhindered performance of repairs, modifications, or alterations of advanced medical devices by such parties would likely result in incomplete equipment records, a lack of proper product calibration, and a failure to report incidents—all of which would otherwise be addressed by the regulatory requirements imposed on OEMs.

The dangers are not theoretical. Adverse impacts from third-party repairs have already been documented. *See, e.g.*, JA226–227 (AdvaMed Comment) (collecting actual or potential impacts of improper servicing from 281 adverse events affecting up to 38,500 patients or operators). Such impacts include: risk of radiation exposure, internal or oral third-degree burns, physical trauma from the device, temporary hearing loss, and delayed or prolonged surgery. JA227. Other impacts can include electrical shock, mechanical failure, air embolism, improper

dosing, infection, interference with other equipment, and delay in patient care and misdiagnosis. JA233–234 (MITA Comment).

The Library's rulemaking record also contains photographs depicting the potential hazards of improper repairs by unregulated third-party servicers. These examples include:

- the repair of an endoscope with what appear to be plastic wrap and putty, JA227–228 (AdvaMed Comment);
- wrapping high voltage cables for an x-ray system in a hardware store vacuum hose, JA249 (MITA Comment);
- shielding an MRI system's high-voltage cables in the scan room with aluminum foil, JA254;
- holding together an overhead counterpoise system that suspends power injectors over patients with zip ties, JA253;
- repair of MRI signal cables using zip ties and plastic tubing, JA261;
- replacing an OEM steel pin with an ordinary wood screw to hold in place an angiographic power injector's syringe turret, JA256;
- improperly connecting a nuclear medicine camera and a cooling system, resulting in masked pixels in heart imaging, JA259–260; and
- improperly wiring connections to unknown points, resulting in ghosting on MRI images, JA257.

These harms speak for themselves and ultimately flow back to the manufacturers themselves. Indeed, improper repairs that put device operators' and patients' safety in jeopardy also decrease consumer confidence in the functioning of serviced medical devices, which impacts OEM revenues and lowers the market value of their devices and software. The faulty repair of a CT scanner or X-ray machine "may expose hundreds or even thousands of patients to excessive levels of radiation. Other faulty repairs may instead compromise the visual or other informational outputs from the scan. That misinformation could contribute to missed diagnoses or incorrect diagnoses, leading to unnecessary medical procedures and even death." JA240; *see also* JA247–265 (MITA Comment) (documenting botched repairs); JA225–229 (AdvaMed Comment) (documenting botched repairs).

C. The Library's rule poses cybersecurity concerns.

These health and safety risks are just some of the practical consequences of the rule. The challenged exemption also increases the potential for cybersecurity attacks. There has been an exponential rise in the number of connected devices. *See* Satyajit Sinha, *State of IoT 2023: Number of connected IoT devices growing 16% to 16.7 billion globally*, IoT Analytics (May 24, 2023).[8] This expansion is coupled with an exponential rise in hacking incidents. *See, e.g.*, Rafi Spiewak,

[8] *Available at* https://iot-analytics.com/number-connected-iot-devices/.

Right to Repair and Its Alarming Cybersecurity Risks, Upstream (discussing 253% spike in vehicle hacking chatter in 2021).[9] It is significant that even New York's landmark right-to-repair law includes exemptions for security devices and home appliances, recognizing the security dangers posed by such legislation. *See* N.Y. S. 4104-A Reg. Sess. 2021-2022 (2022), § 399-nn(3)(e), (3)(g).

Circumventing the access controls by OEMs on sophisticated medical devices puts those devices, and their intended patients, at risk of cybersecurity threats. This issue is already a government priority: the FDA "regulates medical devices and works aggressively to reduce cybersecurity risks in what is a rapidly changing environment." U.S. Food and Drug Administration, *Medical Device Cybersecurity: What You Need to Know* (Feb. 4, 2022).[10] In a fact sheet on medical device cybersecurity, the FDA notes that it "works closely with several federal government agencies . . . [and] medical device manufacturers . . . to increase the security of the U.S. critical cyber infrastructure." U.S. Food and Drug Administration, *FDA Fact Sheet: The FDA's Role in Medical Device Cybersecurity.*[11] And although health care delivery organizations "are responsible

[9] *Available at* https://upstream.auto/blog/right-to-repair-and-its-alarming-cybersecurity-risks/ (last visited June 9, 2023).

[10] *Available at* https://www.fda.gov/consumers/consumer-updates/medical-device-cybersecurity-what-you-need-know.

[11] *Available at* https://www.fda.gov/media/103696/download.

for implementing devices on their networks . . . [because] changes require risk assessment, the FDA recommends working closely with medical device manufacturers to communicate changes that are necessary." *Id*.

Third-party servicers making unauthorized repairs—including the examples of jerry-rigging devices described above—may introduce cybersecurity risks unknown to either the OEM or the hospital. This is exacerbated by the fact that even physical changes from unauthorized repairs may be invisible to the ordinary observer. *See, e.g.*, JA228 (AdvaMed Comment) (documenting faulty repairs hidden from view so as to "show that a device can be modified such that the physician or patient cannot see the change"); JA257, JA259–260 (MITA Comment) (documenting faulty repairs involving wiring and connections that may also be out of view). Further, individuals who gain access to such devices for repair purposes may make unauthorized use of the data obtained. These are harms not to be taken lightly.

CONCLUSION

For these reasons, this Court should reverse the district court's judgment and remand with instructions to consider the merits of Appellants' APA claims.

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The undersigned certifies that, on this 9th day of June 2023, a true and correct copy of the foregoing was served via the Electronic Case Filing (ECF), which will send notice of such filing to all registered users of the CM/ECF system.

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