UNITED STATES COPYRIGHT OFFICE

Long Comment Regarding a Proposed Exemption Under 17 U.S.C. § 1201

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ITEM A. COMMENTER INFORMATION

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Commenter is the Coalition of Medical Device Patients and Researchers (the "Coalition" or "Commenter"), whose members examine the safety and effectiveness of networked and personal medical devices. Commenter previously filed a petition for an expanded exemption, which is covered by "Proposed Class 9: Literary Works—Medical Device Data." Further details on Commenter are included in its initial comment in support of the proposed exemption.

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ITEM B. Proposed Class Addressed

This reply comment address Proposed Class 9: Literary Works—Medical Device Data.

In the Coalition's first comment, the Coalition proposed the following language for the exemption:

> Literary works consisting of compilations of data generated by medical devices or by their corresponding personal monitoring systems, where such circumvention is undertaken by or on behalf of a patient for the sole purpose of lawfully accessing the data generated by their own device or monitoring system.

ITEM C. Overview

The Coalition submits this reply comment in support of its December 14, 2020 comment supporting its request for an expanded exemption for Proposed Class 9: Literary Works—Medical Device Data. The Coalition supports the proposed exemption in order to (a) allow patients to use the data from their medical devices to make informed decisions regarding their own health and treatment, and (b) assist researchers in aggregating patient data to study device effectiveness, treatments, and genetic factors.

Only one comment was filed in opposition to the proposed exemption, by the App Association ("ACT" or "Opposer"). Opposer's principal arguments against the exemption are that (1) online complaint forms and rules promulgated by other agencies *might* help patients access their own data, (2) the proposed exemption would allegedly interfere with federal and international regulations relating to the safety and efficacy of medical devices, and (3) allowing patients to circumvent TPMs to access their data would purportedly allow software competitors to access proprietary code of competing products, stifling competition. As explained below, none of Opposer's arguments is applicable to the proposed exemption. And the lack of other oppositions here suggests there is minimal resistance to Commenter's proposed expansion.

First, the current harm to users is their inability to access their medical data without risking DMCA liability. Opposer fails to rebut the Coalition's argument that the DMCA interferes with lawful patient access to real-time medical data, suggesting only that there are procedures available to *request* help from other agencies that may—or may not—result in improved access.

Second, Opposer conflates allowing medical device users to circumvent TPMs to access their own data without violating § 1201 of the DMCA with requiring device manufacturers to use weaker encryption or other software or data protection methods, which is not the case.

Third, granting an exemption to allow *patients* to circumvent TPMs to access medical data to manage their health and support research does not extend to allowing third-party software competitors to circumvent TPMs to pirate software or other proprietary information. The language of the proposed exemption does not refer to third parties circumventing TPMs outside of the narrow purpose of assisting medical device users to access their own data. Circumvention for those other purposes would still be prohibited by § 1201.

ITEM D. Technological Protection Measure(s) and Method(s) of Circumvention

ITEM E. Asserted Adverse Effects on Noninfringing Uses

1. Patients are Adversely Affected by § 1201 Because They Cannot Lawfully Access Their Medical Data in Real Time

The current harm to patients is their inability to access their medical data without risking liability under § 1201. As discussed in the initial comment, Continuous Positive Airway Pressure ("CPAP") machines, Wearable Cardioverter-Defibrillators ("WCD"), and hearing aids are all non-implantable devices with proprietary readers that restrict patient access to their data. Patients need this proposed expansion because passive monitoring, which is the only permissible way to circumvent under the current exemption, is not a sufficient means for patients who use these devices to access their data. For example, many older models of CPAP machines store data exclusively on removeable SD cards and do not transmit data wirelessly,[1] thereby making it impossible for the data from these machines to be accessed through passive monitoring of wireless transmissions.

In the same breath, Opposer argues that open source tools that assist patients in accessing their own data violate the DMCA, and that those tools show there is no adverse effect on the patients' ability to access their own data. But this just proves the adverse effects—the possibility that using these tools is a DMCA violation *is the adverse effect*. Without other lawful means to access their data, patients who wish to do so risk liability under the DMCA. The shortage of healthcare professionals that can provide patients with their data merely compounds this problem.[2]

Additionally, patients' widespread use of open source software to access their medical data, coupled with the prevalence of sleep disorders in the United States, demonstrates the high demand for access to medical device data. It is very likely that many more patients would access their data from other types of non-implantable devices if they did not risk liability under the DMCA by doing so.

Opposer also makes the bare assertion that patients can use two alternative options to obtain their medical data: (1) a Cures Act prohibition on "information blocking," and (2) a FDA online complaint form for device functionality. However, Opposer cites no particular statutory or regulatory language and does not demonstrate that the rules would actually allow patients to access their data.

Opposer does not provide any information detailing any examples, let alone statistics, regarding whether the Cures Act helps patients obtain TPM-protected data. Rather, Opposer makes only a conclusory assertion that patients' ability to *submit* "[c]omplaints of information blocking . . .

[1] Kingshuk De, *Rise and Fall of Sleepyhead: How Community Backed CPAP Hacking Got Jeopardized*, Piunikaweb (Feb. 2019), https://perma.cc/2UY5-R7QJ.

[2] Opposer suggests that the primary problem is the shortage of healthcare professionals that can provide access to medical data, but this shortage is only a contributing factor to the harm patients suffer in using unlawful means to access their data under the current DMCA.

provid[es] patients an option to obtain their medical data." Similarly, Opposer does not demonstrate that the FDA online complaint form does anything for patients beyond allowing patients to state grievances about product quality. Opposer does not provide any evidence that the FDA complaint system actually helps patients access their data.

Opposer argues that the proposed exemption would "remove all restrictions on circumvention of medical devices," but this is simply untrue for two reasons: First, the proposed exemption only allows for circumvention by or on behalf of a medical device user to access the medical data generated by that device. Outside of those narrow parameters, the proposed exemption does not allow a party to circumvent TPMs on medical devices. Second, the proposed exemption does not affect any additional prohibitions on circumvention by other regulations or statutes and accordingly will not necessarily remove all restrictions on circumvention. Furthermore, as stated in the Coalition's first comment, "policy considerations unrelated to the protection of copyright law should not underly any decision about the scope or appropriateness of an exemption"[3] because the DMCA is concerned with copyright considerations, not other regulatory policy.

2. The Proposed Exemption Will Not Prevent Medical Device Manufacturers from Using Strong TPMs to Protect Devices and Comply with Applicable Regulations

Throughout its comment, Opposer repeatedly states that allowing medical device users to circumvent TPMs to access their own medical data without violating § 1201(a) will prevent device manufacturers from complying with various regulations.[4] This misapprehends the nature of an exemption, which would not require *any change whatsoever* on the part of device manufacturers. Whether or not it is a violation of copyright law for a patient to circumvent a TPM for a specific purpose is entirely separate from a manufacturer's obligations under unrelated regulations to include TPMs restricting access to medical data.

Further, Opposer fails to include any evidence to support its claims that allowing patients to circumvent TPMs to access data will put devices "out of compliance with FDA regulations, compromise the performance of the device, and put users' health in jeopardy."[5] Opposer does not specify which regulations it is concerned about, and exempting patient access to data from the prohibitions on circumvention will have no effect on manufacturer compliance with any of the types of regulations identified by Opposer. If forms of data access run afoul of FDA regulations—and Opposer provides only bare assertions that they would—granting the exemption will not change that; the FDA retains its ability to regulate in this area.

[3] Coalition of Medical Device Patients and Researchers, *Long Comment Regarding Proposed Exemption Under 17 U.S.C. § 1201*, Class 9: Literary Works—Medical Device Data, 13 (Dec. 14, 2020), https://perma.cc/WY5G-CXTH.
[4] ACT: The App Association, *Comments on Proposed Class 9: Literary Works-Medical Device Data*, 4-5 (Feb. 9, 2021), https://perma.cc/SLP9-RBQ8.
[5] *Id.* at 5.

3. Proposed Class Would Encourage Innovation, Not Inhibit It

Opposer argues that the permitted exemption would allow "software competitors access to product codes"[6] and "expose the entire mobile health marketplace to piracy."[7] These assertions vastly overstate the scope of the proposed exemption, which would allow medical device users to circumvent TPMs for a very narrow purpose: to access *their own* medical data, not the device's code or the data of other patients. Thus, circumventing TPMs to access proprietary code for copyright infringement purposes or to access other patients' medical data would fall outside the scope of the proposed exemption.

Opposer's sole example of a software that could be negatively impacted by the proposed exemption—Mimir Health's cloud-based analytic program—would not be affected by the proposed exemption. According to Opposer, the software is not used by patients—only healthcare executives and clinicians. A patient attempting to access their medical data under this proposed exemption would do so by accessing the data from their own device or corresponding monitoring system, not by accessing unrelated third-party services containing aggregated data from multiple patients. And, as stated explained, allowing patients to circumvent TPMs for a narrow purpose would not affect the ability of software developers to use the TPMs of their choice within their products.

Finally, contrary to Opposer's assertions, the proposed expansion would likely make connected health devices *more* successful in the marketplace. If patients could legally access their medical data through non-passive means—such as manually reading data outputs stored on SD cards in CPAP machines—medical devices, including the software embedded in them, would be more valuable to patients in regulating their health. Thus, the market for medical devices would increase.

Fundamentally, Opposer is seeking to ensure that TPMs continue to be a weapon that third-party app developers can use to protect their business model rather than to protect the security of copyrighted works. The purpose of § 1201 within the DMCA is to prevent copyright infringers from defeating anti-piracy protections added to copyrighted works and encourage the proliferation of copyrighted works online. But in practice, § 1201 has been used to stifle innovation by restricting otherwise lawful uses of works (or uncopyrightable data) through TPMs.[8] It is telling that ACT alone opposes the proposed exemption and no medical device manufacturers have submitted an opposition to Class 9. Opposer's purpose in opposing this proposed exemption appears to stem from either a significant misunderstanding of the ramifications of the proposed exemption, or a desire by its members to monopolize access to patient data for economic purposes.

[6] *Id.* at 6.
[7] *Id.* at 5.
[8] *See* Electronic Frontier Foundation, *Unintended Consequences - 16 Years Under the DMCA*, (Sep. 2014), https://perma.cc/QY7J-CQ7K.

4. Conclusion

The sole Opposer has failed to rebut the Coalition's evidence of adverse effects, and Opposer's concerns about the scope of the exemption or its interaction with other agencies' rules are misplaced. For these reasons, the Coalition respectfully request that the Office recommend granting the expanded exemption.