

UNITED STATES COPYRIGHT OFFICE



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

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ITEM A. COMMENTER INFORMATION

Petitioner:

Coalition of Medical Device Patients and Researchers

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Members of Commenter Coalition of Medical Device Patients and Researchers (“the Coalition”) comment on, examine the safety of, and scrutinize the effectiveness of networked and personal medical devices. Our research requires access to a variety of networked medical devices, including but not limited to personal devices that are implanted or attached to our bodies. With the assistance of the Berkman Klein Center’s Cyber Law Clinic at Harvard Law School, we requested and were granted an exemption for Class 27: Software Networked and Personal Medical Devices in the Sixth Triennial Proceeding (2015). In the Seventh and Eight Triennial Proceedings (2018 and 2021), we successfully petitioned to renew the exemption. The Coalition now respectfully requests that the Copyright Office recommend expanding the exemption to remove unnecessary technical restrictions on what types of medical devices and circumvention methods are covered by the exemption.

Hugo Campos is an advocate for access to health data, patient autonomy, and community science. He was named a White House Champion of Change for Precision Medicine by President Barack Obama in 2015 for his data liberation advocacy. He has personal knowledge of the need for this exemption, as medical data being communicated from his own personal medical device

Privacy Act Advisory Statement: Required by the Privacy Act of 1974 (P.L. 93-579)

The authority for requesting this information is 17 U.S.C. §§ 1201(a)(1) and 705. Furnishing the requested information is voluntary. The principal use of the requested information is publication on the Copyright Office Web site and use by Copyright Office staff for purposes of the rulemaking proceeding conducted under 17 U.S.C. § 1201(a)(1). NOTE: No other advisory statement will be given in connection with this submission. Please keep this statement and refer to it if we communicate with you regarding this submission.

has, in the past, been off limits to him. Specifically, as he has written about in “The Heart of the Matter,”¹ he has at times been unable to access the data generated by his implanted defibrillator.

Jay Radcliffe (CISSP) is Director of Product Security Testing and Research at Thermo Fisher Scientific. Jay has been working in the computer security field for over 20 years. Coming from the managed security services industry as well as the security consultation field, Jay has helped organizations of every size and vertical secure their networks and data. Jay presented groundbreaking research on security vulnerabilities in multiple medical devices and was featured on national television as an expert on medical device cyber-security. As a Type I diabetic, Jay brings a lifetime of being a patient to helping medical facilities secure their critical data without compromising patient care. Not only is Jay a prolific public speaker, but also works with legal firms on expert witness consultation related to IoT and cyber security issues. Jay holds a Master's degree in Information Security Engineering from SANS Technology Institute, as well as a Bachelor's degree in Criminal Justice/Pre-Law from Wayne State University. SC Magazine named him one of the Top Influential IT Security Thinkers in 2013.

Karen M. Sandler is the executive director of the Software Freedom Conservancy, which is the nonprofit home of many free and open source software projects. She is known as a “cyborg lawyer” for her advocacy for free software as a life-or-death issue, particularly in relation to the software on medical devices. Prior to joining Conservancy, she was the executive director of the GNOME Foundation. Before that, she was the general counsel of the Software Freedom Law Center where she was the primary author of “Killed by Code: Software Transparency in Implantable Medical Devices”² in 2010. Karen co-organizes Outreachy, the award-winning outreach program for women globally and for people of color who are underrepresented in tech. Karen is an adjunct Lecturer-in-Law at Columbia Law School. She is the recipient of the Free Software Foundation's 2017 Award for the Advancement of Free Software as well as an O'Reilly Open Source Award.

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ITEM B. PROPOSED CLASS ADDRESSED

These comments address Proposed Class 9: Literary Works—Medical Device Data.

¹ Hugo Campos, *The Heart of the Matter*, Slate (Mar. 24, 2015), <https://perma.cc/4QKM-C632>.

² Karen Sandler et al., *Killed by Code: Software Transparency in Implantable Medical Devices*, Software Freedom Center (Jul. 21, 2010), <https://perma.cc/5XX2-MYZJ>.

ITEM C. OVERVIEW

The Coalition proposes the following language for the exemption (the “Proposed Expansion”):

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.

This language reflects four differences from the current language of the exemption.³ First, it omits the phrase “that are wholly or partially implanted in the body” from the language of the exemption. Second, “by a patient” is replaced with “by or on behalf of a patient.” Third it does not contain the requirement that patients circumvent TPMs through passive monitoring of wireless transmissions alone. Fourth it contains no language requiring consideration of other applicable laws, which are irrelevant to the exemption process.

ITEM D. TECHNOLOGICAL PROTECTION MEASURE(S) AND METHOD(S) OF CIRCUMVENTION

Medical device manufacturers use a variety of technological protection measures (“TPM”s) to control access to the data from their devices, often in combination. Each of these methods may be used both in systems that transmit data wirelessly and those that use other methods, including older devices relying on separate memory cards.⁴ These TPMs include at least:

Encryption of data during transmission. The Copyright Office has previously stated that encryption is a form of TPM.⁵ Encryption is accomplished by using an algorithm to mix up data into an unreadable form.⁶ If one has the corresponding “key” to the algorithm, one can decrypt the information.⁷ Without the corresponding key, reading encrypted data requires reverse engineering, which is sometimes accomplished by feeding a program data and observing the corresponding changes in the encrypted outputs.⁸ The FDA’s proposed update to its cybersecurity guidelines for medical devices specifically recommends manufacturers encrypt data during transfer and implement authentication protocols at endpoints.⁹ Although FDA guidance documents are nonbinding, conforming with the guidelines can “facilitate an efficient premarket review process” for new devices.¹⁰ Moreover, manufacturers regulated by the FDA largely follow these guidelines in order to expedite approval of new devices.¹¹ As such, it is

³ See 37 C.F.R. § 201.40(b)(4).

⁴ Kingshuk De, *Rise and fall of Sleepyhead: How Community Backed CPAP Hacking Got Jeopardized*, Piunikaweb (Feb. 2019), <https://perma.cc/2UY5-R7QJ>.

⁵ U.S. Copyright Office, *Section 1201 of Title 17: A Report of the Register of Copyrights*, 10 (2017), <https://perma.cc/RZS3-J77H>.

⁶ Privacy Guy, *What is Encryption & How Does it Work?*, Internet Privacy Guy (Nov. 27, 2017), <https://perma.cc/DK5V-V5AQ>.

⁷ *Id.*

⁸ Cem Kaner, *The Problem of Reverse Engineering*, 2 (1998), <https://perma.cc/Z3ZH-K9KX>.

⁹ Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Food and Drug Administration, 15 (Oct. 2018), <https://perma.cc/LX9H-7N9F>.

¹⁰ *Id.*

¹¹ K.M. Lewis, *Informal Guidance and the FDA*, 66 Food & Drug L.J. 507, 541–42 (2011).

highly probable that manufacturers will increase their use of encryption once the updated guidelines are finalized, which will likely occur within the next three years. Already, wearable hearing aids contain encryption securing wireless transmissions.¹² And encryption is likely to reach even more devices, including personal electrocardiogram machines and blood glucose monitors.

Access to data through a proprietary reader. Proprietary file formats are readable only by specific programs and devices.¹³ This is because proprietary file formats often use “scrambling” encryption, in which the decryption key is hardwired into another program or device.¹⁴ As an example, Continuous Positive Airway Pressure (“CPAP”) machines, which patients use to treat sleep apnea, often store data in proprietary file formats on Secure Digital (“SD”) cards (some newer models transfer data wirelessly via Bluetooth or an internal modem to cloud platforms).¹⁵ Only manufacture-specific tools can read the data, and such tools are not generally accessible to patients.¹⁶ Without those tools, reading the data in these proprietary formats reportedly requires circumventing TPMs, at least in some circumstances.¹⁷ Some of the obstacles to reading the data include anti-tamper software and checksummed data.¹⁸ To avoid these obstacles, one must compare data to known data, often by flipping settings in machine menus or by using commercial software with known data sets.¹⁹

ITEM E. ASSERTED ADVERSE EFFECTS ON NONINFRINGING USES

I. The Proposed Expansion Covers Works That May Be Protected by Copyright

The works within the proposed class consist of “compilations of data generated by medical devices or by their corresponding personal monitoring systems.” As was undisputed in the 2015 proceeding that resulted in the current exemption, much of this data is not copyrightable, but some parties assert that some such data may contain copyrightable elements as a compilation.²⁰

The characteristics of data outputs vary greatly between different systems. Data can be transmitted in streams of real-time data or as batch reports transmitted from the device on a set

¹² Signia (Jan. 23, 2018), <https://perma.cc/Z8HE-87ZM>.

¹³ Paul Skidmore, *Intro to CAD File Formats – Proprietary vs. Non-Proprietary*, Cad Crowd (Nov. 20, 2018), <https://perma.cc/JZ62-WE89>.

¹⁴ Frederick W. Dingley & Alex Berrio Matamoros, *What is Digital Rights Management?*, Library Staff Publications 6, (2016), <https://perma.cc/8YDA-3HJD>.

¹⁵ Kingshuk De, <https://perma.cc/2UY5-R7QJ>, *supra*.

¹⁶ *Id.*; ResMed, *ResScan*, <https://perma.cc/K4V5-FCTB> (last visited Dec. 9, 2020) (restricting purchase of product to download, analyze, and store CPAP therapy data to licensed physicians).

¹⁷ Cory Doctorow, *Thousands of sleep apnea sufferers rely on a lone Australian CPAP hacker to stay healthy*, Boingboing (Nov. 16, 2018), <https://perma.cc/2FLT-9B43>.

¹⁸ Cathryn Virginia, *I’m Possibly Alive Because it Exists: Why Sleep Apnea Patients Rely on a CPAP Machine Hacker*, Vice (Nov. 2018), <https://perma.cc/VUB2-D5CM>.

¹⁹ *Id.*

²⁰ U.S. Copyright, *Section 1201 Rulemaking: Sixth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention*, 384 (2015), <https://perma.cc/G4DG-YSRC> (hereinafter “*Section 1201 Rulemaking: Sixth Triennial Proceeding*”).

schedule or as prompted by a device reader.²¹ There is no consensus on the copyright eligibility of the data outputs of a computer program. Although current case law supports the idea that many data outputs are not copyright eligible,²² there is a possibility that a court in the future will determine a specific data output is arranged with the requisite originality to receive some copyright protection as a compilation.²³ Even if most data outputs are held to be non-copyrightable, patients seeking to access their medical data will likely be unable to determine the exact type of data configuration until they have circumvented a TPM. Accordingly, because some data outputs may be given thin copyright protection in the future, and patients have no way of determining the copyright eligibility of the data they wish to access before circumventing TPMs protecting that data, the Copyright Office should consider this proposed expansion as if some data outputs are eligible for copyright protection.

II. The Uses in the Proposed Expansion at Issue are Noninfringing

There are two broad categories of noninfringing uses that support the proposed exemption to circumvent TPMs in medical devices: (a) patients' use of output data to detect anomalies, to adjust devices, and to adjust their medical regimens; and (b) researchers' use of aggregated patient data to study device effectiveness, treatments, and genetic factors. As discussed above, the data outputs from medical devices are largely not copyrightable. However, to the extent that the data outputs are copyrightable, patient and researcher use of the data constitutes fair use.

Patients Use Their Personal Medical Data to Manage Their Health and Support Research

There are a number of illnesses for which patients need access to data outputs from their medical devices to enhance their treatment and overall health. For example, sleep apnea is a condition in which breathing starts and stops repeatedly during sleep.²⁴ It occurs most often when muscles in the upper airway relax, causing the airway to narrow or close.²⁵ This narrowing of the airway reduces blood oxygen levels and can lead to high blood pressure, heart problems, liver problems, and even Type 2 diabetes.²⁶ Sleep disorders affect 35% to 40% of adults in the United States, and sleep apnea is associated with "increased utilization of health care resources and excess morbidity and mortality."²⁷

As mentioned above, patients who suffer from sleep apnea use CPAP machines, which are non-implantable devices that, utilizing a pump, tube, and mask, push air into the patient's airway to

²¹ Eran Levy, *Batch, Stream, and Micro-batch Processing: A Cheat Sheet*, Upsolver (Sep. 5, 2019), <https://perma.cc/3TMG-E9Q7>.

²² See, e.g., *Design Data Co. v. Unigate Enterprise, Inc.*, 847 F.3d 1169, 1173 (9th Cir. 2017) (suggesting that copyright protection may extend to the output of a computer program if the user's role in creating the output is so marginal that the output reflects the program's contents).

²³ *Feist Publications, Inc. v. Rural Telephone Service Co.*, 499 U.S. 340, 344 (1991) ("[F]acts are not copyrightable, compilations of facts generally are.").

²⁴ *Sleep apnea*, Mayo Clinic (July 28, 2020), <https://perma.cc/4K4T-N3V8>.

²⁵ *Id.*

²⁶ *Id.*

²⁷ Jaspal Singh, et al., *American Academy of Sleep Medicine (AASM) Position Paper for the Use of the Telemedicine for the Diagnosis and Treatment of Sleep Disorders*, 11 J. Clin. Sleep Med. 1187 (Oct. 2015), <https://perma.cc/3FLB-CSSS>.

prevent collapse during sleep.²⁸ Not only do CPAP machines prevent airway collapse, but they also collect data while patients sleep. This data includes air pressure, air leak-rate, time spent sleeping, and apnea-hypopnea index (“API”) (determined by tracking the number of collapses and near-collapses of the airway per hour).²⁹ CPAP machines often display a rudimentary form of this data to patients.³⁰ Patients can use this data to adjust their CPAP machine settings.

However, even if a CPAP machine displays reassuring values to the user, there are concerns that algorithms in CPAP machines overestimate and underestimate patients’ APIs.³¹ Algorithms vary between vendors, and there are “no specific guidelines or standards for capturing, measuring, or scoring” the data that CPAP machines track. Inaccurate API readings risk that patients may not make proper air pressure or mask adjustments to treat their sleep apnea.³² However, manual analysis of data outputs from CPAP machines can reveal false positives and false negatives that algorithms either use or fail to use in calculating patients’ APIs.³³

Unfortunately, as mentioned above, CPAP output data is not readily available to patients nor researchers due to TPMs and restrictions on sales of data management software by CPAP machine manufacturers.³⁴ Thus, patients and researchers must rely on free open-source software to circumvent TPMs on CPAP machine SD cards—rather than passively monitor wireless transmissions emitted from CPAP machines.

“SleepyHead” was an free open-source software, developed by a sleep apnea patient, for accessing data in CPAP machines.³⁵ Patients and researchers alike could use SleepyHead to view data outputs stored on the SD cards in CPAP machines.³⁶ SleepyHead takes data stored on the CPAP machine SD cards and presents it in flow waveforms.³⁷ These are graphical representations of all leaks, all pressure changes, and all occurrences of four different types of sleep apnea events (central apneas, constructive apneas, unclassified apneas, and hypopneas).³⁸ Based on this information, patients are able to make informed changes in their CPAP machine

²⁸ John Donovan, *How to Sleep Easier With Your CPAP Machine*, WebMD (2015), <https://perma.cc/RFH5-SBB6>.

²⁹ David Repasky, *What Do These Readings on My CPAP Machine Mean? (AHI, Leak, Pressure, Usage)*, cpap.com (Oct. 2018), <https://perma.cc/LQL3-G9FH>; *Sleep Data Privacy Concerns: How to Keep Your Information Safe*, Sistemma, <https://perma.cc/LGA2-PGE4>.

³⁰ Robert J. Thomas & Matt T. Bianchi, *Urgent Need to Improve PAP Management: The Devil Is in Two (Fixable) Details*, 13 J. Clin. Sleep Med. 5 (May 2017), <https://perma.cc/B5JU-8ANU>; Repasky, <https://perma.cc/LQL3-G9FH>, *supra*.

³¹ Thomas & Bianchi, <https://perma.cc/B5JU-8ANU>, *supra*.

³² *Id.*

³³ *Id.*

³⁴ Kingshuk De, <https://perma.cc/2UY5-R7QJ>, *supra*; ResMed, *ResScan*, <https://perma.cc/K4V5-FCTB> (restricting purchase of product to download, analyze, and store CPAP therapy data to licensed physicians), *supra*.

³⁵ *SleepyHead*, SourceForge (April 26, 2018), <https://perma.cc/QMW4-SFEL>; Kingshuk De, <https://perma.cc/2UY5-R7QJ> (noting that the developer “himself suffer[s] from the disorder”), *supra*.

³⁶ Thomas & Bianchi, <https://perma.cc/B5JU-8ANU>, *supra*.

³⁷ *Id.*

³⁸ Amin Reviews, *How to Use SleepyHead to See Information from Your CPAP Machine*, YouTube (Dec. 2017), <https://perma.cc/LG9U-JKWN>.

settings that improve their sleep and energy—changes they could not make with rudimentary data displayed on their machine—that sometimes prove lifesaving.³⁹

After development of SleepyHead ceased,⁴⁰ another free open-source software emerged for accessing CPAP machine data outputs. This software, Open Source CPAP Analysis Reporter (“OSCAR”), displays data in a similar manner as SleepyHead.⁴¹

Patients’ Use of Data Outputs Constitutes Fair Use

As the Register concluded when this exemption was proposed in 2015, to the extent medical device data receives copyright protection, patients’ use of data outputs from medical devices such as CPAP machines to enhance their treatment constitutes fair use.⁴² The Proposed Expansion is no different than the original one with respect to fair use. All four factors remain the same, regardless of the manner of acquiring the data or the identity of the individual who performs the act on behalf of the patient.

Courts consider four factors in the fair use analysis: (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.⁴³

When evaluating the purpose and character of the use, courts consider whether a defendant's use is (a) commercial and (b) transformative.⁴⁴ First, patients’ use of data that they are unable to access through commercial means is noncommercial. For example, patients who use SleepyHead or OSCAR do not “stand[] to profit . . . without paying the customary price.”⁴⁵ That is, although patients benefit from using SleepyHead and OSCAR, patients cannot pay the customary price for similar software because manufacturers do not allow patients to buy their software products.⁴⁶ Moreover, medical professionals often do not give detailed analyses of patient data, and there is a substantial shortage of sleep apnea specialists across the United States.⁴⁷

³⁹ John Bishop, *Want to see all the data stored on your CPAP machine’s SD Card?*, Mayo Clinic Connect (Nov. 2018), <https://perma.cc/LCV4-UGGU>; Virginia, <https://perma.cc/VUB2-D5CM>, *supra*.

⁴⁰ Mark Watkins, *SleepyHead*, <https://perma.cc/LQ6Y-VGTS>.

⁴¹ *OSCAR, the Open Source CPAP Analysis Reporter: Official Download Page*, SleepFiles, <https://perma.cc/CT8P-YT9P>; *How to Use OSCAR (Open Source CPAP Analysis Reporter)*, Optimize My Sleep (Feb. 2020), <https://perma.cc/8Z39-WNYC>.

⁴² See U.S. Copyright Office, *Section 1201 Rulemaking: Sixth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention*, 394 (Oct. 2015), <https://perma.cc/G4DG-YSRC>.

⁴³ 17 U.S.C. § 107.

⁴⁴ The Fair Use Defense—In General, E-Commerce and Internet Law § 4.10[1] n. 12.

⁴⁵ *Harper & Row Publishers, Inc. v. Nation Enterprises*, 471 U.S. 539, 562 (1985).

⁴⁶ ResMed, *ResScan*, <https://perma.cc/K4V5-FCTB> (last visited Dec. 9, 2020) (restricting purchase of product to download, analyze, and store CPAP therapy data to licensed physicians), *supra*;

⁴⁷ Bishop, <https://perma.cc/LCV4-UGGU>, *supra*.

(patient recounting medical clinic’s “high level” review of his data but also the detailed understanding that SleepyHead software provided him); Singh, et al., <https://perma.cc/3FLB-CSSS> (noting that “parts of the United States are grossly underserved or not served at all” by sleep apnea specialists and that “the specialist gap is expected to widen . . .”), *supra*.

Furthermore, patients use the data from these devices in many transformative ways. Incorporating the data with software like SleepyHead or OSCAR “alter[s] the [original work] with new expression”⁴⁸ The software presents the raw data in graphical representations, thereby using the data as “as raw material, transformed in the creation of . . . new aesthetics, new insights and understandings.”⁴⁹ Specifically, the graphical representations give patients a detailed understanding of their medical data, allowing them to draw conclusions about their health that they would be unable to appreciate otherwise. More generally, patients can also use the data on its own or in conjunction with data from other medical devices to better inform them of their own health, thereby giving the data new significance.

As to the second factor, the output data is far from the “core of intended copyright protection” because it is informational rather than creative.⁵⁰ The thin copyright protection afforded to the data outputs here weighs in favor of fair use.

Although software like SleepyHead and OSCAR allow patients to view all of their data, using an entire work does not preclude a finding of fair use.⁵¹ Moreover, because the intended use is to view detailed data to enhance treatment, all of the data is necessary to accomplish this purpose. Without all of the data, patients would not be able to make accurate assessments of their health. Thus, patients use only the amount necessary for their intended use, so the third factor does not weigh against fair use.⁵²

Finally, viewing the data outputs from medical devices would not have a negative impact on the market for medical software or data outputs. In fact, access to the data outputs would allow patients to make proper adjustments to their machines, which would make their machines more effective in treating medical conditions such as sleep apnea, hearing loss, and diabetes.⁵³ Greater effectiveness of the machines would *increase* the market for medical software and data outputs.

Researchers’ Use of Data Outputs Constitutes Fair Use

Similarly, to the extent that data from medical devices is copyrightable, researchers’ use of data outputs constitutes fair use. Primarily, such use by researchers is transformative because it has a “further purpose” to study device effectiveness and identify genes associated with certain disorders and illnesses.⁵⁴ This purpose is distinct from that of the machines, which is to use the data to estimate rudimentary metrics for individual medical purposes. The Copyright Act itself

⁴⁸ *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 579 (1994).

⁴⁹ *Castle Rock Entertainment, Inc. v. Carol publishing Group, Inc.*, 150 F.3d 132, 141 (2d Cir. 1998).

⁵⁰ *Campbell*, 510 U.S. at 586; *see Dr. Seuss Enterprises, L.P. v. Penguin Books USA, Inc.*, 109 F.3d 1394, 1402 (1997) (noting fair use is easier to establish when the original work is informational).

⁵¹ *Kelly v. Arriba Software Corp.*, 336 F.3d 811, 820 (2003).

⁵² *Id.*

⁵³ Sejal Kuvadia & Luis F. Camacho, *Data Logging – Hearing Aid Behavior in the Real World*, Audiology Online (Jun. 2017), <https://perma.cc/UMC7-65WU> (detailing the benefits of collecting and analyzing hearing-aid data); Sarah Zhang, *People Are Clamoring to Buy Old Insulin Pumps*, The Atlantic (Apr. 29), <https://perma.cc/D8VG-Z2ME> (stating that demand for certain insulin pumps increased after release of free open-source algorithm for analyzing real-time glucose data).

⁵⁴ *Campbell*, 510 U.S. at 579.

suggests use of a copyrighted work for purposes such as “scholarship . . . or research” constitutes fair use.⁵⁵

As noted above, the second factor favors fair use because data outputs have thin copyright protection, if any. Moreover, aggregating data from many patients’ is necessary to “identify rare genetic variants” associated with disorders like sleep apnea, so the third factor does not weigh against fair use.⁵⁶ Further, even if researchers criticize the effectiveness of medical software or data, aggregating data could improve the market for medical software and data. For example, analysis of large sets of data would improve understanding of the factors that contribute to adherence to CPAP treatment.⁵⁷ This knowledge could then be “leveraged to improve adherence” to CPAP treatment, which would increase the value of the underlying software and data.⁵⁸ Thus, the fourth factor further supports that researchers’ use of data outputs constitutes fair use.

III. Adverse Effects Summary

Preventing Circumvention Adversely Affects Patient Health and Medical Research

The use of TPMs in medical devices restricts patient access to their own medical data, adversely affecting patient treatment and medical research into chronic illnesses in America. Many medical devices prevent patient access to the raw data those devices collect.⁵⁹

For example, without access to their own medical data, patients must rely on doctors to access the readings from CPAP machines. However, a shortage of sleep specialists in the medical profession means many patients suffering from sleep apnea receive treatment from primary care physicians who lack training in sleep medicine.⁶⁰ Additionally, doctors frequently look at CPAP data to determine compliance for insurance purposes rather than to more effectively shape patient treatment, often looking at data averages over time instead of readings from individual nights.⁶¹ This results in ineffective treatment for many patients who are left struggling with their sleep disorders and feeling dismissed by their doctors.⁶²

CPAPs are not the only medical devices restricting patient access to data through proprietary software. Wearable Cardioverter-Defibrillators (“WCD”s) are an emerging therapeutic option for patients who have had an Implantable Cardioverter-Defibrillator (“ICD”) removed due to infection, or are waiting for a heart transplant.⁶³ The device uses a transmitter to send data to the patient’s physician, either through a daily or weekly remote transmission.⁶⁴ Like CPAP

⁵⁵ 17 U.S.C. § 107.

⁵⁶ Rohit Budhiraja et al., *The Role of Big Data in The Management of Sleep Disordered Breathing*, 11 *Sleep Med. Clinic* 241 (Jun. 2016), <https://perma.cc/DD7N-UQ4X>.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ Doctorow, <https://perma.cc/2FLT-9B43>, *supra*.

⁶⁰ Kingshuk De, <https://perma.cc/2UY5-R7QJ>, *supra*.

⁶¹ Virginia, <https://perma.cc/VUB2-D5CM>, *supra*.

⁶² *Id.*

⁶³ Peter Magnusson et al., *The Wearable Cardioverter-Defibrillator*, *Intechopen* (Dec. 19, 2019), <https://perma.cc/YNN7-6JU9>.

⁶⁴ *Id.*

machines, the software required to monitor patient data is available only to physicians—not to patients themselves.⁶⁵

Proprietary systems are also used to limit access to data from hearing aids.⁶⁶ Many wearable hearing aids log data about patient usage which can be used to troubleshoot programs used by the hearing aid or otherwise better adjust the hearing aid to the patient’s regular environment.⁶⁷ The specific types of data recorded by the device vary by manufacturer, but many record things like daily use time, time spent in different acoustic environments, average volume control, manual corrections made by the patient, etc.⁶⁸ This data is then wirelessly transmitted by hearing aids to a corresponding proprietary programming system.⁶⁹ These systems are accessible to physicians but are not available to patients.⁷⁰ Although the extent to which encryption is used in hearing aid software is unclear, manufacturers have stated that, in accordance with FDA guidelines, hearing aids do contain encryption and “secure wireless technology.”⁷¹ Thus, any logged data that is wirelessly transmitted is likely encrypted. To the extent that these devices or proprietary formats use encryption or other TPMs, patients are unable to lawfully access their own medical data.

Although physicians have substantially more medical expertise compared to the patients they treat, a patient has more comprehensive experience with their body and physical health over time. This experience puts patients in the best position to make certain executive choices regarding their health and treatment. Access to medical data would enable patients to better understand their own bodies and help them to discuss informed changes to treatment with their physicians.

Additionally, by preventing access to patient data, TPMs also restricts the data available to medical researchers. For example, the copious amounts of data recorded by CPAP machines are largely unavailable to researchers in the sleep medicine field.⁷² Allowing patients access to that data would then enable opportunities to aggregate patient-volunteered CPAP readings into large data sets which could then be used to study sleep disorders.⁷³

Moreover, if patients are unable to circumvent TPMs that are currently present—or likely to arise in the next three years—in other non-implantable medical devices, they would be unable to make holistic assessments of their health. For example, nonimplantable electrocardiogram machines help patients evaluate their cardiovascular health.⁷⁴ Because sleep apnea is associated with cardiovascular disease, combining data from CPAP machines and electrocardiogram

⁶⁵ LifeVest Network, <https://perma.cc/KQD2-G3Y6> (last visited Dec. 9, 2020).

⁶⁶ *Manufacturers Explain How Their Data Logging Systems Work*, 60 Hearing J. 22, 22-23 (Oct. 2007), <https://perma.cc/PJ5R-D9KS>.

⁶⁷ Gustav H. Mueller, *Data Logging: It’s Popular, but how can this feature be used to help patients?*, 60 Hearing J. 19, <https://perma.cc/87PX-UL86>.

⁶⁸ *Manufacturers Explain How Their Data Logging Systems Work*, <https://perma.cc/PJ5R-D9KS>, *supra*.

⁶⁹ *Connex 8.5.15*, Signia, <https://perma.cc/NF9Y-6S9P> (last visited Dec. 14, 2020).

⁷⁰ Mandy Mroz, *New hearing aid technology*, Healthy Hearing (Jun. 5, 2020), <https://perma.cc/K255-DFMX>.

⁷¹ Signia (Jan. 23, 2018), <https://perma.cc/Z8HE-87ZM>.

⁷² Budhiraja et al., <https://perma.cc/DD7N-UQ4X>, *supra*.

⁷³ *Id.*

⁷⁴ Danielle Moores, *Electrocardiogram*, Healthline (Sep. 2018), <https://perma.cc/H5R9-RCW3>; *KardiaMobile*, AliveCor, <https://perma.cc/G5D9-C8AN>.

machines would improve patients' assessments of their health, help researchers understand the pathophysiology of sleep apnea, and improve sleep apnea treatments.⁷⁵

Limiting Circumvention to Passive Monitoring of Devices Needlessly Prevents Patient Access

The current exemption's language limiting circumvention to passive monitoring of wireless signals sent by a device would prevent many CPAP users from accessing the data from their machines. Although many newer CPAP machine models have wireless capabilities, older models store data only on an SD card.⁷⁶ Uploading data from an SD card is already contemplated by the device manufacturers and thus does not have any negative effects on the machine.⁷⁷

Furthermore, patients should have the ability to choose a circumvention method based on their needs and technical capability. Without an exemption allowing general circumvention, patients are required to circumvent only through passive monitoring and are thus unable to experiment with alternative and perhaps more efficient or effective ways to access their medical data from these devices. A patient may want to write software that reads the data directly from a device rather than intercept data in transit. Giving patients the freedom to access TPM-protected data using methods besides passive monitoring would open new avenues for data access even for devices covered by the existing exemption, allowing the search for and use of better, more efficient, or more easily accessible methods of circumvention, thereby expanding lawful access to personal medical data.

Additionally, requiring patients to circumvent through passive monitoring of wireless transmissions forces patients to enable wireless capabilities to access that data, which makes their data and devices more vulnerable to intrusion from third parties.⁷⁸ For the purposes of copyright law, there is no meaningful difference between passive monitoring and other forms of circumvention. Accordingly, the exemption should not draw such a distinction and instead allow patients to circumvent the TPMs restricting access to their data without arbitrarily limiting the manner in which they do so.

Limiting the Definition of "User" to Individual Patients Restricts Data Access to a Select Class of Technologically Proficient Patients

By defining the eligible class of users for the purposes of Section 1201 to mean the individual patient using the device, the practical application of an exemption to access data from medical devices is incredibly slim. The vast majority of patients likely do not have the technical knowledge required to circumvent a TPM on their own. Furthermore, there is nothing within the statute itself limiting the definition of "user" to encompass solely the owner of a device.⁷⁹

⁷⁵ Budhiraja et al., <https://perma.cc/DD7N-UQ4X>, *supra*.

⁷⁶ Kingshuk De, <https://perma.cc/2UY5-R7QJ>, *supra*.

⁷⁷ Virginia, <https://perma.cc/VUB2-D5CM>, *supra*.

⁷⁸ Patricia A.H. Williams & Andrew J. Woodward, *Cybersecurity vulnerabilities in medical devices: a complex environment and multifaceted problem*, 8 *Medic. Devices: Evidence and Research* 305, 307 (2015), <https://perma.cc/X5AN-U8SS>.

⁷⁹ 17 U.S.C. § 1201(a)(1)(B).

The Copyright Office has structured previous amendments to allow third parties working on behalf of a device owner to assist the device owner in circumventing TPMs. As the Copyright Office noted in the Section 1201 Study’s Final Report, the exemption for assistive technology only requires that the device be lawfully acquired by a person with disabilities; it does not require that person to be the one actually doing the circumventing.⁸⁰ Additionally, in the 2018 Recommendation, the Office recommended allowing circumvention of TPMs restricting wireless devices from connecting to wireless telecommunication networks to be carried out by the owner of a device or another person “at the direction of the owner.”⁸¹

Although the Copyright Office has previously suggested that, outside explicit authorization from Congress, third party assistance cannot be permitted through the exemption process,⁸² this is based on an erroneous understanding of the Unlocking Consumer Choice and Wireless Competition Act (“Unlocking Act”) and Congress’s legislative intent therein. The Unlocking Act was a direct reaction to the Librarian’s failure to renew existing exemptions that allowed consumers to “unlock” phones for use on the wireless network of their choice.⁸³ The Act was intended to reinstate a popular exemption, not limit the scope of other exemptions. A report by the Senate Judiciary Committee explicitly states that the bill “makes no changes to Section 1201 . . . [and] does not alter the authority of the Librarian in future rulemakings.”⁸⁴ Accordingly, language in the Unlocking Act allowing third party circumvention under certain circumstances was intended to outline the specific exemption Congress wished to reinstate and, when combined with the “makes no changes” section, strongly suggests that the Librarian (and therefore the Copyright Office) *already* had the authority to allow unlocking at an owner’s—or patient’s—direction.

The same policy considerations that require a broader definition of user for unlocking circumvention apply here as well; many consumers are likely unable to circumvent TPMs without assistance from a third party due to the substantial technical knowledge required to do so.⁸⁵ Defining “user” to include a third party acting on behalf of a patient would enable patients to access their own data from their own devices without first getting a degree in computer science.

Expanding the user definition would also allow patients to share their data in a more direct way with family members or friends. Nightscout, an open source software project created by the parents of children with Type 1 diabetes, allows parents to remotely view blood sugar readings from their children’s continuous glucose monitors (“CGM”s).⁸⁶ James Wedding, one of the software engineers involved with the project, stated that the application changed the way he and

⁸⁰ U.S. Copyright Office, *Section 1201 of Title: 17 A Report of the Register of Copyrights*, 61, <https://perma.cc/RZS3-J77H>, *supra*.

⁸¹ U.S. Copyright Office, *Section 1201 Rulemaking: Seventh Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention*, 337 (Oct. 26, 2018), <https://perma.cc/VY6Z-35SN>.

⁸² *Id.*, 59 (Oct. 26, 2018), <https://perma.cc/VY6Z-35SN> (citing *Section 1201 Rulemaking: Sixth Triennial Proceeding*, 247, <https://perma.cc/G4DG-YSRC>).

⁸³ S. Rep. No. 113-212, (2014), <https://perma.cc/GZE8-2NDA>.

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ Welcome to Nightscout, <https://perma.cc/J8B2-BW3Q> (last visited Dec. 11, 2020).

his wife interacted with his child.⁸⁷ Remote monitoring allows parents to leave their child with a babysitter or send them on a school trip without worrying about their health.⁸⁸ It is doubtful a child would have the technological proficiency required to circumvent a TPM without parental assistance. However, the current exemption language does not clearly address whether parents have the ability to circumvent TPMs on their children's devices.

Finally, allowing third parties acting on behalf of patients to circumvent TPMs on patient medical devices comports with established agency law. It is a fundamental principle of agency law that the actions of an agent acting within their actual authority are considered the actions of the principal.⁸⁹ Accordingly, any party acting under the authority of a patient to access the patient's medical device data should be treated as if they were the patient for the purposes of a section 1201 exemption.

The Copyright Office Should Not Consider Policy Concerns Unrelated to Copyright Law

Policy considerations unrelated to the protection of copyright law should not underly any decision about the scope or appropriateness of an exemption. For example, device manufacturers' concerns about the safety and morality of circumventing TPMs are unrelated to copyright law, and the Copyright Office should not consider them or integrate them into the exception. Moreover, even if this exemption is granted, device manufacturers' concerns about unrelated regulatory schemes are irrelevant: this exemption will not prohibit device manufacturers from bringing actions under existing regulations or laws unrelated to copyright.

That is, if a patient accessing their medical data violates FDA regulations, that will continue to be true even if it is no longer a violation of copyright law. Similarly, the presence of an exemption allowing owners to circumvent TPMs in their devices would not eliminate remedies for breach of contract for business models that rely on contractual relationships.⁹⁰ The Copyright Office should therefore remove references to FDA regulations, HIPAA, the CFAA, and other legal requirements from this exemption.

IV. Statutory Factors

(i) the availability for use of copyrighted works

The first factor under section 1201(a)(1)(C) has been interpreted by the Copyright Office to require consideration of whether the availability of the work in its protected format enhances or

⁸⁷ Michelle Boise, *NIGHTSCOUT — THE TECHNOLOGY THAT CHANGED THE WORLD WE KNOW*, Beyond Type 1 (Dec. 7, 2016), <https://perma.cc/4W22-QJKL>.

⁸⁸ *Id.*

⁸⁹ *E.g., United States v. Forbes*, 515 F.2d 676, 680 (D.C. Cir. 1975).

⁹⁰ *ProCD, Inc. v. Zeidenberg*, 86 F.3d 1447, 1450 (7th Cir. 1996) (holding that a user who violated a software program's license was still liable to the manufacturer for breach of contract, agnostic of any applicable infringement claims).

inhibits public use of the work, whether the protected work is available in other formats, and, if so, whether such formats are sufficient to accommodate noninfringing uses.⁹¹

Here, the availability of medical devices in a protected format inhibits public use because it prevents patients from using their personal medical data to adjust treatment, thereby making it more likely that a patient will give up using the device. CPAP machines have notoriously low patient compliance; 46-83% of patients do not adhere to treatment.⁹² Unsurprisingly, studies have shown that patients who are satisfied with their CPAP treatment are more likely to continue using their device.⁹³ Conversely, a study by the Scottish National Sleep Center found that 20% of patients who stopped using their CPAP machine did so due to a lack of benefit from the treatment.⁹⁴ Accordingly, enhancing the effectiveness of CPAP treatment is likely to increase long term use of CPAP machines by patients.

Even though CPAP machines capture extensive amounts of data that can be used to adjust machine settings to provide better treatment, many patients struggle to improve the effectiveness of their devices. A patient's doctor has access to the data from the CPAP machine, but doctors trained in sleep medicine are in short supply.⁹⁵ Many primary care physicians only follow up with patient usage to check compliance for insurance purposes, and do not significantly evaluate the data from the patient's machine.⁹⁶ Christy Lynn, a woman living in rural Arizona, spent months seeking a diagnosis for her persistent tiredness before one doctor recognized her symptoms matched sleep apnea.⁹⁷ But even after starting CPAP treatment, Lynn's symptoms hadn't improved and her doctors were unable to get her Apnoea-Hypopnea Index ("AHI"), the number of times she stopped breathing per night, down.⁹⁸ Using data she accessed by circumventing TPMs on her device, Lynn was able to look at individual nights, unlike her doctors that had only looked at six month averages.⁹⁹ Lynn could then adjust her treatment, which successfully brought down her AHI.¹⁰⁰

There do not appear to be alternative medical devices available to the general public without TPMs. Additionally, because FDA guidelines heavily encourage the use of TPMs to protect

⁹¹ U.S. Copyright Office, *Section 1201 Rulemaking: Fifth Triennial Proceeding Recommendation of the Register of Copyrights*, 152 (Oct. 12, 2012), <https://perma.cc/EW9T-6TLY> (citing Recommendation of the Register of Copyrights in RM 2008-8, Rulemaking on Exemptions from Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 56 (June 11, 2010)).

⁹² Terri E. Weaver & Ronald R. Grunstein, *Adherence to Continuous Positive Airway Pressure Therapy*, 5 Proc. Am. Thoracic Soc'y 173 (2008), <https://perma.cc/LZN4-UPKP>.

⁹³ Norman Wolkove et al., *Long-term compliance with continuous positive airway pressure in patients with obstructive sleep apnea*, 15 Can. Respiratory J. 365, 368 (2008), <https://perma.cc/6VZP-TYSF>.

⁹⁴ Nigel McArdle et al., *Long-term Use of CPAP Therapy for Sleep Apnea/Hypopnea Syndrome*, 159 Am. J. Respiratory Critical Care Med. 1108, 1110 (1999), <https://perma.cc/9RRM-NGAN>.

⁹⁵ Barbara Phillips et al., *What Is the Future of Sleep Medicine in the United States?*, 192 Am. J. Respiratory and Critical Care 915, 915 (2015), <https://perma.cc/5XLS-RPRX>.

⁹⁶ Kristina Weaver, *Primary Care Physician vs. Sleep Specialist: Who Knows Best?*, AAST (Feb. 22, 2018), <https://perma.cc/CSM7-KSVG>; Virginia, <https://perma.cc/VUB2-D5CM>, *supra*.

⁹⁷ Virginia, <https://perma.cc/VUB2-D5CM>, *supra*.

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

patient data in medical devices, manufacturers are unlikely to create equivalent devices without TPMs in the future.

(ii) the availability for use of works for nonprofit archival, preservation, and educational purposes

As discussed above, identical medical devices are not available with or without TPMs, and FDA guidelines point to increasing use of encryption and other access controls within medical device software moving forward. Thus, any educational use of data from a medical device will likely require circumventing TPMs.

(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

Allowing patients to circumvent TPMs to access medical data from their devices will increase the availability of reliable self-reported patient data, which will in turn encourage additional observational studies on chronic illnesses such as sleep apnea. The use of self-reported patient data to conduct studies has been widely discussed among the medical community.¹⁰¹ Self-reported patient data is a cheaper method of data collection than alternatives but has validity problems due to the possibility of patient misrepresentation or embellishment.¹⁰² However, patient data obtained from medical devices do not have the same credibility issues as patient surveys. Already, some medical researchers use patient data gleaned from personal medical devices to study the efficacy of these devices.¹⁰³

Currently, nonprofit organizations have been able to aggregate patient volunteered data obtained from implanted medical devices such as continuous glucose monitors.¹⁰⁴ These organizations are then able to share that data with research groups who use the data sets to refine or expand upon existing treatments.¹⁰⁵ By contrast, limitations on available patient data have stymied research into broad issues within the field of sleep medicine.¹⁰⁶ Although CPAP machines track a significant amount of data, that data is primarily used to ensure patient compliance for insurance purposes and then subsequently discarded.¹⁰⁷ Granting patients the right to access that data would provide a feasible path for widespread data collection and preservation across a wider range of individuals than the data sets gathered from a few clinical centers.¹⁰⁸

¹⁰¹ BMJ, *Self-report versus observation*, Injury Prevention (Jun. 14, 2015), <https://perma.cc/YT78-6L94>.

¹⁰² Jeanne M. Ferrante et al., *Self-report versus Medical Records for Assessing Cancer-Preventative Services Delivery*, 17 Cancer Epidemiology Biomarkers & Prevention 2987, 2988 (Nov. 2008), <https://perma.cc/V8FZ-89JF>.

¹⁰³ Thomas & Bianchi, <https://perma.cc/B5JU-8ANU>, *supra*.

¹⁰⁴ Tidepool, <https://perma.cc/G9W4-XSJK> (last visited Dec. 10, 2020).

¹⁰⁵ *Id.*

¹⁰⁶ Budhiraja et al., <https://perma.cc/DD7N-UQ4X>, *supra*.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

(iv) the effect of circumvention of technological measures on the market for or value of copyrighted works

Circumvention of TPMs on medical devices to gain access to patient data will have no negative effect on the value of the software operating these medical devices or the data they produce because, as discussed under the first statutory factor, patients will still purchase medical devices irrespective of their access to data and may even be more likely to do so if the data is readily accessible. Rather, for the reasons stated above, it is more likely that patient access to data will increase patient satisfaction with their medical devices and in turn increase the value and market for the software within those medical devices.

Conclusion

For the above reasons, the Coalition respectfully requests that the Register recommend granting the proposed exemption language, thereby allowing patients to access their own medical data without fear of liability under the DMCA.