



Petition to Renew a Current Exemption Under 17 U.S.C. § 1201

9th Triennial Rulemaking

Please submit a separate petition for each current exemption for which renewal is sought.

NOTE: Use this form if you want to renew a current exemption without modification. If you are seeking to engage in activities not currently permitted by an existing exemption, including those that would require the expansion of a current exemption, you must submit a petition for a new exemption using the form available at copyright.gov/1201/2024/new-petition.pdf.

If you are seeking to expand a current exemption, we recommend that you submit both a petition to renew the current exemption without modification using this form, and, separately, a petition for a new exemption that identifies the current exemption and addresses only those issues relevant to the proposed expansion of that exemption.

ITEM A. PETITIONERS AND CONTACT INFORMATION

Please identify the petitioners and provide a means to contact the petitioners and/or their representatives, if any. The “petitioner” is the individual or entity seeking renewal.

Petitioner:

Coalition of Medical Device Patients and Researchers

Hugo Campos
hugoc@gmail.com

Karen M. Sandler
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Jay Radcliffe
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Representative:

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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 website and use by Copyright Office staff for purposes of the rulemaking proceeding conducted pursuant to 17 U.S.C. § 1201(a)(1). NOTE: No other advisory statement will be given in connection with this application. Please keep this statement and refer to it if we communicate with you regarding this petition.

ITEM B. IDENTIFY WHICH CURRENT EXEMPTION PETITIONERS SEEK TO RENEW

Check the appropriate box below that corresponds with the current temporary exemption (see **37 C.F.R. § 201.40**) the petitioners seek to renew. Please check only one box. If renewal of more than one exemption is sought, a separate petition must be submitted for each one.

Motion Pictures (including television programs and videos):

- Excerpts for use in documentary filmmaking or other films where use is in parody or for a biographical or historically significant nature
- Excerpts for use in noncommercial videos
- Excerpts for use in nonfiction multimedia e-books
- Excerpts for educational purposes by college and university faculty, students, or employees acting at the direction of faculty, or K–12 educators and students
- Excerpts for educational purposes by faculty and employees acting at the direction of faculty in massive open online courses (“MOOCs”)
- Excerpts for educational purposes in digital and literacy programs offered by libraries, museums, and other nonprofits
- For the provision of captioning and/or audio description by disability services offices or similar units at educational institutions for students, faculty, or staff with disabilities
- For the preservation or the creation of a replacement copy of the motion picture by libraries, archives, or museums
- For text and data mining by a researcher affiliated with a nonprofit institution of higher education, or by student or staff at the direction of such researcher, for the purpose of scholarly research and teaching

Literary Works:

- Literary works distributed electronically for text and data mining by a researcher affiliated with a nonprofit institution of higher education, or by student or staff at the direction of such researcher, for the purpose of scholarly research and teaching
- Literary works or previously published musical works that have been fixed in the form of text or notation whose technological protection measures interfere with assistive technologies
- Literary works consisting of compilations of data generated by medical devices or their personal corresponding monitoring systems, to access personal data

Computer Programs and Video Games:

- Computer programs that operate wireless devices, to allow connection to an alternative wireless network (“unlocking”)
- Computer programs that operate smartphones and portable all-purpose mobile computing devices to allow the device to interoperate with or to remove software applications (“jailbreaking”)
- Computer programs that operate smart televisions to allow the device to interoperate with software applications on the television for purposes other than gaining unauthorized access to copyrighted works (“jailbreaking”)
- Computer programs that operate voice assistant devices to allow the device to interoperate with or to remove software applications for purposes other than gaining unauthorized access to copyrighted works (“jailbreaking”)
- Computer programs that operate routers and dedicated network devices to allow the device to interoperate with software applications on the device for purposes other than gaining unauthorized access to copyrighted works (“jailbreaking”)
- Computer programs that control motorized land vehicles, marine vessels, or mechanized agricultural vehicles or vessels for purposes of diagnosis, repair, or modification of the vehicle, including to access diagnostic data
- Computer programs that control devices designed primarily for use by consumers for diagnosis, maintenance, or repair of the device or system
- Computer programs that control medical devices or systems, and related data files, for diagnosis, maintenance, or repair of the device or system
- Computer programs for purposes of good-faith security research
- Video games for which outside server support has been discontinued, to allow individual play by gamers and preservation of games by libraries, archives, and museums (as well as necessary jailbreaking of console computer code for preservation uses only), and discontinued video games that never required server support, for preservation by libraries, archives, and museums
- Computer programs other than video games, for the preservation of computer programs and computer program-dependent materials by libraries, archives, and museums
- Computer programs that operate 3D printers, to allow use of alternative material
- Computer programs for purpose of investigating potential infringement of free and open source computer programs
- Video games in the form of computer programs for purpose of allowing an individual with a physical disability to use alternative software or hardware input methods

ITEM C. EXPLANATION OF NEED FOR RENEWAL

Provide a brief explanation summarizing the continuing need and justification for renewing the exemption. The Office anticipates that petitioners will provide a paragraph or two detailing this information, but there is no page limit. While it is permissible to attach supporting documentary evidence as exhibits to this petition, it is not necessary. Below is a hypothetical example of the kind of explanation that the Office would regard as sufficient to support renewal of the unlocking exemption. The Office notes, however, that explanations can take many forms and may differ significantly based on the individual making the declaration and the exemption at issue.

We are members of a coalition of medical device patients and researchers who research, 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, in the Sixth Triennial Proceeding (2015), we requested and were granted an exemption for Class 27: Software Networked and Personal Medical Devices. In the Seventh Triennial Proceeding (2018), we successfully petitioned to renew the exemption. In the Eighth Proceeding (2021), we successfully petitioned for renewal and to expand the exemption to remove its prior limitation to implanted devices and passive wireless monitoring, as well as to explicitly permit third-party assistance.

The Coalition now seeks to renew the current, expanded exemption. We have personal knowledge that the need for this exemption continues to exist and have no reason to believe the need will be reduced over the next three years. We are well versed in the issues and commentary surrounding the previously approved exemption and renewal. The exemption is vital to patients' ability to monitor the data output of medical devices that monitor and maintain their health. It is imperative that this use can continue without the chilling effect of potential liability under § 1201. Each coalition member has personal knowledge of the need for this exemption.

Medical data being communicated from Coalition member Hugo Campos's own personal medical device has, in the past, been off limits to him. Specifically, as he has written about, he has at times been unable to access the data generated by his implanted defibrillator. Hugo Campos, *The Heart of the Matter*, Slate (March 2015), <https://perma.cc/4QKM-C632>. From his personal experience, these types of limitations continue to exist and affect patients.

Even when the DRM does not completely prevent access to implanted medical device data, it often prevents access in real-time, which presents a similar problem. Delayed access to data prevents patients from monitoring their medical status in the moment, on their own schedule, and responding appropriately. For example, people with a Continuous Glucose Monitor for diabetes may face delays as long as three hours when trying to access their data. These delays can be even longer and more dangerous: during the past three years, Coalition member Karen Sandler has experienced an issue where she could not get her defibrillator interrogated by an authorized representative within a three day window, potentially putting her health at serious risk.

Furthermore, medical monitoring devices tend to have long lifetimes. For instance, Ms. Sandler's implanted defibrillator dates from before the previous triennial and is likely to remain implanted and functional for another decade or more.

Finally, and as discussed by both Petitioners and the Copyright Office in previous triennials, the Food and Drug Administration (FDA), a federal regulatory agency, has and continues to encourage the implementation of technological protective measures on the data outputs of medical devices. Because device manufacturers will likely continue to adhere to the FDA's updated guidance, the exemption for personal medical data will continue to be necessary.

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ITEM C. EXPLANATION OF NEED FOR RENEWAL (CONT'D)

Patients need to access the data output from their medical devices to manage their own health and react to data in real-time. This use will not meaningfully burden the ability of rights holders to obtain value from their works. The exemption for Literary works consisting of compilations of data generated by medical devices that are wholly or partially implanted in the body or by their corresponding personal monitoring systems, where such circumvention is undertaken by a patient for the sole purpose of lawfully accessing the data generated by his or her own device or monitoring system, is justified as a matter of copyright and beneficial to public and personal health. A renewal would give affected individuals the access to information they need to make personal decisions and lifestyle choices that are related to their health.

ITEM D. DECLARATION AND SIGNATURE

The declaration is a sworn statement made under penalty of perjury and must be signed by one of the petitioners named above.

I declare under penalty of perjury under the laws of the United States of America that the following is true and correct:

1. Based on my own personal knowledge and experience, I have a good faith belief that but for the above-selected exemption's continuation during the next triennial period (October 2024–October 2027), technological measures controlling access to relevant copyrighted works are likely to diminish the ability of relevant users to make noninfringing uses of these works, and such users are likely to rely upon the above-selected exemption during the next triennial period.
2. To the best of my knowledge, there has not been any material change in the facts, law, or other circumstances set forth in the prior rulemaking record (available at copyright.gov/1201/2021) that originally demonstrated the need for the above-selected exemption, such that renewal of the exemption would not be justified.
3. To the best of my knowledge, the explanation provided in Item C above is true and correct and supports the above statements.

Name/Organization:

If the petitioner is an entity, this declaration must be signed by an individual at the organization having appropriate personal knowledge.

Coalition of Medical Device Patients and Researchers

Signature:

This declaration may be signed electronically (e.g., "/s/ John Smith").

/s/ Karen M. Sandler

Date:

July 7, 2023