UNITED STATES COPYRIGHT OFFICE

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

8th 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 **https://www.copyright.gov/1201/2021/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:
Hugo Campos, Member of the Coalition of Medical Device Patients and Researchers
hugooc@gmail.com
(415) 794-1567

Representative:
Jef Pearlman
Director, Intellectual Property & Technology Law Clinic
USC Gould School of Law
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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 educational purposes by college and university or K-12 faculty and students
- ○ Excerpts for educational purposes by faculty in massive open online courses ("MOOCs")
- ○ Excerpts for educational purposes in digital and literacy programs offered by libraries, museums, and other nonprofits
- ○ Excerpts for use in nonfiction multimedia e-books
- ○ 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
- ○ For the provision of captioning and/or audio description by disability services offices or similar units at educational institutions for students with disabilities

Literary Works:

- ○ Literary works distributed electronically (*i.e.*, e-books), for use with assistive technologies for persons who are blind, visually impaired, or have print disabilities
- ◉ Literary works consisting of compilations of data generated by implanted medical devices and corresponding personal monitoring systems, to access personal data

Computer Programs and Video Games:

- ○ Computer programs that operate cellphones, tablets, mobile hotspots, or wearable devices (*e.g.*, smartwatches), to allow connection of a new or used device to an alternative wireless network ("unlocking")
- ○ Computer programs that operate smartphones, tablets and other all-purpose mobile computing devices, smart TVs, or voice assistant devices to allow the device to interoperate with or to remove software applications ("jailbreaking")
- ○ Computer programs that control motorized land vehicles, including farm equipment, for purposes of diagnosis, repair, or modification of the vehicle, including to access diagnostic data
- ○ Computer programs that control smartphones, home appliances, or home systems, for diagnosis, maintenance, or repair of the device or system
- ○ Computer programs for purposes of good-faith security research
- ○ Computer programs other than video games, for the preservation of computer programs and computer program-dependent materials by libraries, archives, and museums
- ○ 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 that operate 3D printers, to allow use of alternative feedstock

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 may 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.

I am a member 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, 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 Triennial Proceeding (2018), we successfully petitioned to renew the exemption. Along with coalition members Karen Sandler and Jay Radcliffe, I now seek to renew the exemption again.

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 implanted or attached to them. It is imperative that this use is continued without the chilling effect of potential liability under § 1201.

I have personal knowledge of the need for this exemption, as medical data being communicated from my own personal medical device has, in the past, been off limits to me. Specifically, as I have written about, I have at times been unable to access the data generated by my implanted defibrillator. Hugo Campos, The Heart of the Matter, Slate (March 2015), https://perma.cc/4QKM-C632.

Furthermore, as stated in the record for the Final Rule to the Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, the Food and Drug Administration (FDA), a federal regulatory agency, has encouraged the implementation of technological protective measures on the data outputs of medical devices. The FDA has since issued new draft guidance that will ultimately replace the guidance we discussed in the 2015, and which was drafted with the current exemption in place. See FDA, Content of Premark Submission for Management of Cybersecurity in Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff, https://www.fda.gov/media/119933/download. That draft guidance continues to encourage the use of encryption and other security measures to restrict access to data. See id. at 15 ("Ensure capability of secure data transfer to and from the device, and when appropriate, use methods for encryption and authentication of the end points with which data is being transferred."). 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.

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.

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 C. Explanation of Need For Renewal *(cont'd)*

Finally, as observed by the Register, many instances of personal medical device data outputs do not constitute works that would be protectable by copyright; and in the few instances that they do, the limited nature of the exemption would not significantly undermine the value of those works.

Petitioners also note that while this exemption for data access is necessary, it is not sufficient. Though it is outside the scope of this petition, we also support the petition for an exemption for good-faith security research, which is critical to ensure our medical devices are secure from vulnerabilities. At a later date, we also intend to seek expansion of the existing exemptions to cover non-implantable devices and ensure the ability of patients and technologists to test the safety and efficacy of the medical devices they rely on.

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 2021 – October 2024), 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 https://www.copyright.gov/1201/2018) 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:

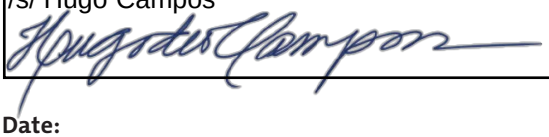
If the petitioner is an entity, this declaration must be signed by an individual at the organization having appropriate personal knowledge.

Hugo Campos, Member of the Coalition of Medical Device Patients and Researchers

Signature:

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

/s/ Hugo Campos



Date:

July 22, 2020