



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.

TriMedx Holdings, LLC
Attn: Laura Sahm
5451 Lakeview Parkway Drive South
Indianapolis, Indiana 46268
laura.sahm@trimedx.com
317-696-1604

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.

TRIMEDX is a third-party independent service organization with customers ranging from small rural hospitals to major metropolitan health systems, with a goal of providing timely and cost-efficient clinical engineering and medical device repair and maintenance that enables the continuity of patient care at our customer facilities. To provide such services, TRIMEDX must be able to access and utilize both medical devices themselves and any related service materials which includes software or computer programs that provide information on the maintenance and repair of such devices, and often enables the application of repair maintenance and repair procedures. Unfortunately, original equipment manufacturers (OEMs) often preclude and/or make such access difficult.

Restrictions by OEMs can take many forms, including denial of access to service manuals and diagnostic/calibration software, and restrictions on availability of parts, specialized tools, and training. By their very nature, these OEM restrictions are anti-competitive, intended to protect a manufacturer's revenue and not public safety or interest as some have claimed. In its 2021 "Nixing the Fix" report, the Federal Trade Commission (FTC) recognized that manufacturers across multiple industries restrict repairs on their own devices, noting there is "scant evidence to support manufacturers' justifications for repair restrictions."

The exemption to the DMCA by the Library of Congress allows TRIMEDX and other third-party servicers to overcome, and in some cases, avoid the anti-competitive tactics of the OEMs, while ensuring third-party service organizations have the necessary access to medical devices and information to repair and maintain the equipment on behalf of hospital customers. This contributes to the ultimate goal of allowing equipment owners the right to choose who services their medical devices. Not extending this exemption could directly impact that.

Perhaps nowhere is this access more important than when it comes to cybersecurity: 53% of medical devices have known critical vulnerabilities*, and for the past 12 years, health care delivery organizations (HDOs) have the highest cost per breach at +\$10M with a record number of breaches in 2021.** Nearly one quarter of surveyed HDOs stated cyberattack victims experienced increased mortality rates following a data breach, and more than half reported inferior patient outcomes due to longer hospital stays and delayed procedures.*** At its core, cybersecurity in healthcare is a patient safety issue. Being able to quickly and adequately access devices and associated information about the repair and maintenance of a medical device can allow organizations like TRIMEDX to most quickly and effectively assist OEMs in decreasing the cyber-vulnerability of medical equipment and improve their safety and effectiveness.

Finally, the FDA has previously stated that it believes third-party service organizations, like TRIMEDX, can offer healthcare providers high quality, safe, and effective medical device servicing. Not only are there no concerns with the quality of TRIMEDX ' s work, TRIMEDX and other third-party servicers are essential to maintaining medical devices in the United States, as the OEMs do not have the bandwidth to manage it all. Unlike OEMs, who are remote and can be slow to respond to rural sites, organizations like TRIMEDX are onsite at hospitals and can repair a device immediately.

Based on the above, TRIMEDX requests the exemption under 17 U.S.C. § 1201(a)(1) that allows circumvention of technological measures applied to software programs and data files in medical device for the purpose of diagnosis, maintenance, or repair of such a device to continue.

*<https://www.cynerio.com/blog/cynerio-research-finds-critical-medical-device-risks-continue-to-threaten-hospital-security-and-patient-safety>

**<https://www.idtheftcenter.org/post/identity-theft-resource-center-2021-annual-data-breach-report-sets-new-record-for-number-of-compromises/> <https://www.ibm.com/security/data-breach>

***<https://www.proofpoint.com/sites/default/files/threat-reports/pfpt-us-tr-cyber-insecurity-healthcare-ponemon-report.pdf>

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

[Empty box for explanation of need for renewal]

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.

Laura Sahm
TriMedx Holdings, LLC

Signature:

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

/s/ Laura Sahm

Date:

July 7, 2023