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

[ ] Check here if multimedia evidence is being provided in connection with this comment

Item 1.Commenter Information

This proposal is respectfully submitted by Public Knowledge. Public Knowledge is a nonprofit organization dedicated to representing the public interest in digital policy debates. Public Knowledge promotes freedom of expression, an open internet, and access to affordable communications tools and creative works.

Interested parties are encouraged to contact Michael Weinberg (mweinberg@PublicKnowledge.org) or Sherwin Siy (ssiy@PublicKnowledge.org) as Public Knowledge's authorized representatives in this matter. Public Knowledge's contact information is as follows:

Public Knowledge
1818 N St. NW
Suite 410
Washington, DC 20036
(202) 861-0020

Item 2. Proposed Class Addressed

This comment addresses Proposed Class 27: Software—networked medical devices.

Item 3. Overview

The anticircumvention provisions of the DMCA should not act as a barrier to the ability of users and researchers of networked medical devices to test, diagnose, and better use those devices. Patients and researchers should likewise be able to access the data generated by those devices, without any repercussions springing from the operation of copyright law.

Item 4. Technological Protection Measure(s) and Method(s) of Circumvention

A number of barriers to data and software access can colorably be classified as technological protection measures controlling access to the software on medical devices. Such possible TPMs include encryption on the software or of the signal produced; specially designed cables, plugs, or ports designed to frustrate access; proprietary or deliberately obscure formats for data; or even the simple denial of an programming or user interface to access the software.

While proponents, Public Knowledge, the Librarian, or the Register may disagree about the characterization of any or all of these features as "technological protection measures" under the terms of section 1201(a)(1), it is within the Library's power to permit

exemptions of them *to the extent* that a court may later consider them TPMs. We urge the Library and the Office to do so in the interest of removing any potential uncertainty regarding these activities.

Similarly, methods of circumvention will be widely varied, and unlikely to have consequences beyond those that can be anticipated by their qualitative description at this stage.

Item 5. Asserted Noninfringing Use(s)

Data is Unprotected by Copyright; However, an Exemption Should Be Prophylactically Granted for Copyrighted Software Access in the Furtherance of Accessing the Non-copyrighted Data

The data output by the devices itself is not subject to copyright protection. To the extent that copyright holders or other parties with an interest in restricting access to this data and the software on the medical devices might assert the 1201(a)(1) prohibition, the Office and Library should clarify that, should a court determine that accessing the non-copyrighted data requires accessing a copyrighted work in the form of the software that processes it, circumvention for the purpose of that access and use is exempted.

Accessing Software For the Purposes of Safety, Security, and Effectiveness Research is Noninfringing

Patient access for the purpose of accessing and transmitting data should not implicate the section 106 rights of the copyright holder. To the extent that RAM copies or other temporary copies are necessary, these should be deemed lawful as either: (1) failing to meet the statutory definition of a "reproduction,"[1] (2) under the doctrine of *de minimis non curat lex*, (3) under the limitation of the essential-step rule,[2] or as a fair use.

Fair use should also cover more lasting reproductions or adaptations of any copyrighted software involved. Research is one of the paradigmatic fair uses explicitly contemplated in the text of section 107. To the extent that any user may not be deemed as engaging in "research" but is simply pursuing the safety, security, or effectiveness of his device, those purposes should categorically also be considered fair, based upon the literal lifesaving purpose of the use.

The effect on the market for the original works also weighs in favor of fair use. Any reproductions or adaptations made in the course of pursuing the proposed uses will not compete with unsold copies of the software—to the extent that the software is ever sold at all.

[1] *See Cartoon Network, LLP, v. CSC Holdings, Inc.*, 536 F.3d 121, 127-30 (2d Cir. 2008) (holding that instances of a work lasting no more than a transitory duration were not sufficiently fixed as to meet the statutory requirement of a copy).
[2] 17 U.S.C. § 117(a)(1).

The Exemption Should Not Differentiate Between Types of Users

Various types of users have cause to access software controlling medical devices. Beyond patients themselves, healthcare providers may need to access data to better diagnose and treat patients in ways unanticipated by the device manufacturers. Family members, guardians, and friends of patients also have cause to access the data, in order to provide care and support for loved ones. For example, a schoolchild with a glucose monitor could easily benefit from the school nurse, a parent, or a guardian having access to the data, so that those equipped with necessary medication in case of an emergency can react fastest.

The Librarian is not confined to granting exemptions to owners of copies of the copyrighted works; section 1201(a)(1)(B) applies to *any* user of a work who is adversely affected by the prohibition.

Third Parties May Engage in Circumvention

As noted above, section 1201(a)(1)(B) permits the Librarian to grant exemptions to *any* user adversely affected by the prohibition. The bans on trafficking in circumvention devices and services in 1201(a)(2) and 1201(b) do not occupy the field of third party users.

Also as indicated above, researchers other than the individual patient may wish to circumvent in order to conduct research and collect data; parents, guardians, or other healthcare providers may wish to individually circumvent for their own purposes of providing care. This circumvention serves the needs of the parent, guardian, or healthcare provider, and does not itself constitute a "service" to the patient.

Third parties should also be able to offer the proposed circumvention to the extent that they act on behalf of the patient. A comparable model can be found within the Unlocking Consumer Choice and Wireless Competition Act,[3] which, without altering the text of section 1201, specified that family members of the device owner, or third parties acting at the direction of the device owner, could circumvent on the owner's behalf.

Safety And Security Repercussions Are Irrelevant to the Evaluation of the Exemption Request

While concerns about the safety of permitting circumvention of copyright access protections are appreciated, they are irrelevant to this inquiry. Those who would seek to cause deliberate harm to the owners of medical devices are not waiting for an exemption in order to act. Fear of liability under chapter 12 of title 17 is likely not at the forefront of such actors' minds. The presence or absence of a copyright exemption does not affect the presence or absence of any security vulnerability that might be present and exploited by a bad actor. On the contrary, however, the absence of an exemption could prevent a security researcher from discovering such a vulnerability before it can be exploited.

[3] Pub. L. No. 113–144, 128 Stat. 1751 (2014).

This proceeding is also not the forum to assess worries about the safety of patients who might inadvertently cause harm to themselves through circumvention. The balance between public health and patient autonomy can be a complex one, and it is not within the competence of this proceeding or its participants to decide it. The Digital Millennium Copyright Act is not the last—or indeed any—bulwark of patient safety, and its potential as a complication in such matters should be removed to make way for any relevant discussions that may occur in the appropriate forums.

The Only Relevant Question Regarding the Lawfulness of the Proposed Use is Whether or Not it Infringes Copyright

The Library and the Office should disregard the extent to which any proposed uses may infringe contracts, laws, or regulations that are not the exclusive rights granted to authors in section 106.

The lawfulness requirement of proposed exemptions is merely that they be "noninfringing," not that they comply with all potential legal restrictions.[4] Such a limitation is necessary to ensure that the rulemaking process, created by Congress, have any meaningful effect. This is true for at least four reasons.

First, allowing unrelated matters of law to bar circumvention for noninfringing uses runs the risk of categorically denying exemptions in any field that is subject to a sufficiently complex set of contracts or regulations.

A finding that a proposed use *may* be barred by regulations unrelated to copyright should not act as a bar to granting an exemption under section 1201(a)(2). To the extent that the proposed use would violate the unrelated rules, nothing in section 1201 supersedes or obviates those rules. Exemption proponents would be free to petition the relevant agencies, offices, or legislative bodies—or advocate for legal changes in court—in order to make use of the exemption granted through this proceeding. Otherwise, allowing unrelated rules to block assessment of the merits of the copyright and circumvention claims could easily lead to a circular stagnation, as each rulemaking authority awaits word from others to proceed. Progress for any sufficiently complex regulated system would be impossible, regardless of the individual merits of an exemption under each separate regime.

Furthermore, the Library and Office should not assess the lawfulness of a proposed use based upon the presence or absence of contractual limitations on that use. It is trivial for any party to create contracts that purport to prohibit circumvention, or uses that might flow from it that do not in themselves infringe copyright. Should the Library and Office assume that any breach of an agreement would bar the granting of an exemption, the entire section and rulemaking process runs the risk of being rendered a nullity by the inclusion of appropriate terms of service by rightsholders or other affected parties. Unless the Library and Office are willing to either presume that contractual obligations will

[4] 17 U.S.C. § 1201(a)(1)(C).

eventually render this rulemaking moot, or to assess the contractual limitations on each instance of a use of given class of works, as well as the contractual limitations anticipated within the next three years, its determinations should not be affected by such extraneous factors.

Second, to the extent that determining the lawfulness of a proposed use requires assessment of the law beyond questions of copyright infringement or other aspects of Title 17, the Copyright Office and the Library of Congress are poorly placed to answer such questions on its own. The details of antitrust enforcement, false advertising, wireless signal interference, or computer intrusion have neither been delegated to these entities, nor are they expert agencies in these matters.

Third, neither copyrights nor the anticircumvention provisions of the DMCA are to be used as proxy enforcement mechanisms of other interests. The doctrine of copyright misuse "forbids the use of the copyright to secure an exclusive right or limited monopoly not granted by the Copyright Office and which it is contrary to the public policy to grant."[5]

In other words, parties should not be able to extend the exclusive powers granted to them over their works beyond their realm in order to achieve goals unrelated to the public purposes of copyright. While a rightsholder is perfectly free to pursue whatever lawful aims it may have beyond the reach of Title 17, copyright misuse prevents it from attaching the presumptions and remedies associated with copyright law into those areas.

One particularly timely example of copyright misuse has come to the fore in *Omega S.A. v. Costco Wholesale Corp*.[6] In that case, the watch manufacturer Omega attempted to restrict imports of its watches. Unable to use other means to prevent Costco from doing so, Omega began placing a copyrighted symbol on the backs of its watches, in an effort to use territorial restrictions in copyright law, and thus copyright law itself, to improve its market share in its own watch importation and retail sales—despite the fact that the copyrighted work upon which its legal theory hinged had no value and was itself of little commercial concern to any of the parties or to the eventual consumers. Even if Costco had breached a contract in the act of its importation, or if it failed to pay some import duty in shipping the watches, those hypothetical violations would have no bearing upon the fact that Omega was engaged in copyright misuse.

By the same token, access protection measures that serve not to prevent infringing uses of the work serve to impermissibly extend exclusive rights beyond those granted by the scope of copyright and the public policy underlying it. One case in point is the geographical encoding present on many DVDs, which do not themselves effectively control copyright-implicating access to works; their presence does not bar the

[5] *Lasercomb Am., Inc. v. Reynolds*, 911 F.2d 970, 977-779 (4th Cir. 1990); *Practice Management Information Corp. v. Am. Medical Ass'n*, 121 F.3d 516, 520 (9th Cir. 1997).
[6] 2011 U.S. Dist. LEXIS 155893 (E.D. Cal. Nov. 9, 2011), *aff'd* 2015 U.S. App. LEXIS 830 (9th Cir. Jan. 20, 2015).

reproduction, distribution, or public performance of motion pictures so much as it allows for the exact sort of geographical restrictions on arbitrage so disfavored in *Omega*.

Within the context of analyzing the merits of exemption requests in this proceeding, the Library and Office should therefore exercise its authority in such a way that confines the reach of section 1201(a)(1) in such a way so as to not perpetuate attempts at copyright misuse.

Fourth, the language of section 1201(a)(1) limits the application of the circumvention prohibition to measures that control only those types of access that are protected under title 17. In other words, if a form of access is not protected as an exclusive right of the copyright holder under section 106, a protection measure is not covered by the access control provision.

This interpretation protects all legally cognizable acts of access under the law while preventing potentially absurd overinterpretations of section 1201(a). To the extent that "access" affects the interests of a copyright holder, at least one of the section 106 rights will be implicated. In the digital context, RAM and buffer copies will frequently implicate the reproduction right; other types of access will certainly involve more permanent reproductions, adaptations, distributions, public displays, and public performances.

At the same time, recognizing that "under this title" modifies "access" rather than "work" solves an existing conundrum: how, under the terms of section 1201(a), does a padlock (of however much technological sophistication) on a locker full of books not constitute a "technological measure control[ling] access to a work" protected under Title 17? Certainly it was not the intention of Congress to allow prosecutors to include a DMCA violation against any common burglar.

However, if it is the access that is protected under title 17, then the mere act of unlocking or breaking down a door doesn't meet the copyright-specific criteria of section 1201(a). Just as the mere acts of reading a paperback or privately listening to a recorded album access those works without implicating any section 106 rights, the access gained by the defeat of a control mechanism will not trigger section 1201 unless that access is itself covered by title 17.

Each of these various considerations by itself should suffice to indicate why breaches or infringements that are not infringements of copyright should not be determining factors in whether or not an exemption should be granted. Instead, the Library and Office can easily convey the limitations of their exemption grants—just as they do not create blanket immunity from copyright infringement liability or the trafficking provisions of section 1201(a)(2) and 1201(b), they clearly lack the authority to gainsay other areas of law.

Making that distinction clear can allow exemption requests to proceed in a way that reduces uncertainty for all concerned stakeholders.

Item 6. Asserted Adverse Effects

As an initial matter, the language of the statute in assessing adverse effects is clear: the Library and the Office are to determine whether persons are likely to be "adversely affected…in their ability to make noninfringing uses" of copyrighted works.[7] In other words, proponents must show how the prohibition prevents, or creates a likelihood of preventing, a lawful use. The "adverse effect" referred to in the statute is the effect of being prohibited by law from engaging in lawful activity, not a calculation of estimated monetary or equitable damages resulting from the prohibition.

The inability of patients and researchers to access networked medical devices creates clear and present harms for them. While the Office has dismissed "mere inconvenience" as an insufficient harm, matters of "mere inconvienience" in each individual instance can, over the duration of a course of treatment, escalate into a grave barrier.

For instance, it would be easy to characterize the inability to access medical data on the device of a patient's choosing as a "mere inconvenience." In conversational terms, and in an individual instance, a teenage patient might consider it merely inconvenient to carry around two different smartphones—one compatible with his implanted medical device, and the other his personal phone. Yet should that convenience lead the patient to leave the compatible device at home on a regular basis, his ability to appropriately manage his condition could become severely compromised. Although by one characterization, the adverse effect is a small matter, the end result is more than inconvenient.

Existing Statutory Exemptions Do Not Sufficiently Cover the Required Uses

Even to the extent that some proposed uses may be covered by the statutory exemptions, nothing prevents the Library and Office from ensuring that all necessary uses are covered. Redundancy, in this case, produces no harm, and may prevent a great deal. The uncertainty around the various specifics of the statutory exemptions[8] can restrict the activities of researchers and patients in a number of ways that stymie useful work.

For instance, granting this exemption would remove the need for proponents to recast each of their activities within the (significantly different) context s contemplated within the statutory exemptions. For example, patients may not be certain of their own status as "researchers" for the purpose of 1201(g), or the status of their activities as "security testing" for the purpose of 1201(j). Section 1201(f) contains a number of specifications that can plausibly be read in a way that excludes many of the proposed uses in this class as well. For instance, the "sole purpose" of the use must be identifying and analyzing the elements of a program necessary to achieve interoperability between two computer

[7] 17 U.S.C. § 1201(a)(1)(B).
[8] Those uncertainties have been raised, and discussed thoughtfully by the Register in past proceedings. We incorporate that discussion by reference here. *See* Maria Pallante, *Section 1201 Rulemaking:Fifth Triennial Proceedingto Determine Exemptions to the Prohibition on Circumvention* 71-72, October 12, 2012, http://copyright.gov/1201/2012/Section_1201_Rulemaking_2012_Recommendation.pdf

programs. Interoperability may be one of several goals of a user; and she may wish for the software to interact with other devices or interfaces that might not be classified as "computer programs."

Even if the Register and Librarian believe that the proposed uses may have significant, substantial, or complete overlap with the statutory exemptions, this should not be a bar to granting the exemption, provided the other criteria have been met. If the overlap is complete, no additional rights have been gained or lost by the grant. In the absence of the exemption, however, a user within this class would have the burden in litigation of proving every one of the rationales used by the Register and Librarian to place their activities within the statutory exemptions in court in order to prevail. Given this balance of potential harms, the potential redundancy of the proposed exemption with statutory exemptions is purposeless.

For the above reasons, the Librarian should grant the proposed exemption.

Sherwin Siy

Public Knowledge
1818 N St. NW, Suite 410
Washington, DC 20036