



March 27, 2015

Library of Congress
Copyright Office
101 Independence Avenue, SE
Washington, DC 20559-6000

RE: In the matter of Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies Under 17 U.S.C. 1201—Sixth Triennial DMCA Rulemaking – Proposed Class 27

To the Librarian of Congress and the Register of Copyrights:

The Intellectual Property Owners Association (“IPO”) respectfully submits these comments in connection with the sixth triennial rulemaking proceeding under the Digital Millennium Copyright Act (“DMCA”), in opposition to the exemption for proposed class 27 covering “Software—Networked Medical Devices.”

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO’s membership includes more than 200 companies and more than 12,000 individuals who are involved in the association, either through their companies or through other classes of membership.

1. Introduction and Summary

IPO opposes an exemption for proposed class 27. None of the statutory criteria under section 1201(a)(1)(C) weigh in favor of granting the exemption. Proponents have indicated that the exemption is necessary for “safety, security, or effectiveness research.”¹ Medical device manufacturers regularly provide access to the software for such purposes. Any alleged research need is purely speculative.

The proposed exemption permitting unregulated access to the software would permit infringement of copyright in the software. Permitting unregulated access to the software also raises concerns regarding the safety and security of the networked medical devices. The exemption creates a patient safety risk by allowing access and control of a patient’s networked medical device by individuals that are neither health care providers nor the medical device manufacturer. The FDA has agreed that access should be limited.²

¹ http://copyright.gov/1201/2015/comments-020615/InitialComments_longform_Coalition_of_Medical_Device_Researchers_Class27.pdf

² <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/ucm373213.htm>

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Milbank Tweed

Executive Director
Herbert C. Wamsley

Proponents are required to demonstrate how they will be adversely affected in their ability to make non-infringing uses of the software absent an exemption. This showing in support of the exemption must not be merely speculative or theoretical. Proponents must meet this burden with respect to each networked medical device and establish that the section 1201(a)(1)(C) criteria require granting the exemption. Proponents have not met this burden.

2. There is no necessity for the exemption.

Proponents argue that patients need access to their data, but there is no evidence patients have been unable to get their data from their healthcare providers. There are no reports of a section 1201 action ever being threatened or brought against any medical device researcher. There is no evidence that any research has been stopped by a section 1201 action.

Moreover, there is no showing that research concerning networked medical devices is not occurring. The Food and Drug Administration recently sponsored a workshop among industry, academic and government leaders entitled “Collaborative Approaches for Medical Device and Healthcare Cybersecurity.”³ This workshop highlighted the “collaboration among all stakeholders within the healthcare and public health community in order to address current cybersecurity gaps and challenges”⁴ for networked medical devices. Similarly, the Archimedes Institute at the University of Michigan has been active in conducting device cybersecurity research in partnership with many industry leaders.⁵ One company is reported to have hired three separate security firms to conduct research after an initial demonstration of a patient getting access to an insulin pump.⁶

3. The scope of the exemption requested is very broad.

According to the Federal Register notice, proposed class 27 “would allow circumvention of TPMs protecting computer programs in medical devices designed for attachment to or implantation in patients and in their corresponding monitoring devices, as well as the outputs generated through those programs.” The exemption would encompass devices such as pacemakers, implantable cardioverter defibrillators, insulin pumps, and continuous glucose monitors, among others. In fact, the class is defined broadly as all “medical devices designed for attachment to or implantation in patients and their corresponding monitoring devices.” This broad class of medical devices, includes, but is not limited to, the devices listed above, and also deep brain stimulators, spinal cord stimulators, vagal nerve stimulators, sacral nerve stimulators, implantable drug pumps, left ventricular assist devices, ambulatory cardiac monitors, ambulatory gastric monitors, wireless capsule endoscopy, and others. In view of the vast array of products that could be accessed through the exemption, the public risk is impossible to quantify.

4. FDA’s views must be obtained on this proposed exemption.

The FDA is charged with ensuring food and medicines, including devices, are safe and effective, and as noted above, the agency has taken a keen interest in cyber security. Before even

³ See <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM419427.pdf>

⁴ *Id.*

⁵ See <http://www.secure-medicine.org/>.

⁶ See <http://www.bloomberg.com/news/articles/2012-02-29/mcafee-hacker-says-medtronic-insulin-pumps-vulnerable-to-attack>.

considering granting this broad exemption, the Librarian of Congress and Register of Copyrights should solicit and consider the FDA's views. The requested exemption implicates life-saving medical technologies, which takes this particular request far beyond a typical copyright exemption request.

5. The exemption would risk HIPAA violation.

The U.S. Congress has expressed a strong public policy to maintain the confidentiality of patient-identifiable health information (PHI) through enactment of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA requires health care providers to maintain strict controls on access to PHI, and to ensure that anyone to whom they provide such information, e.g., the device manufacturers, does so as well. Here, the information would be accessible to anyone who could connect to the networked medical device, regardless of whether the patient had given permission for that connection. Any exemption which allowed circumvention and subsequent unauthorized access to patient information, such as for general testing of the device, would risk HIPAA violation.

We thank you for considering IPO's comments and would welcome any further dialogue or opportunity to provide additional information to assist your efforts on this important issue.

Sincerely,



Herbert C. Wamsley
Executive Director