LAW ELEVATED

To Repair or Not to Repair:

The Shakespearean Question of 2021

AUGUST 19, 2021

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Preview

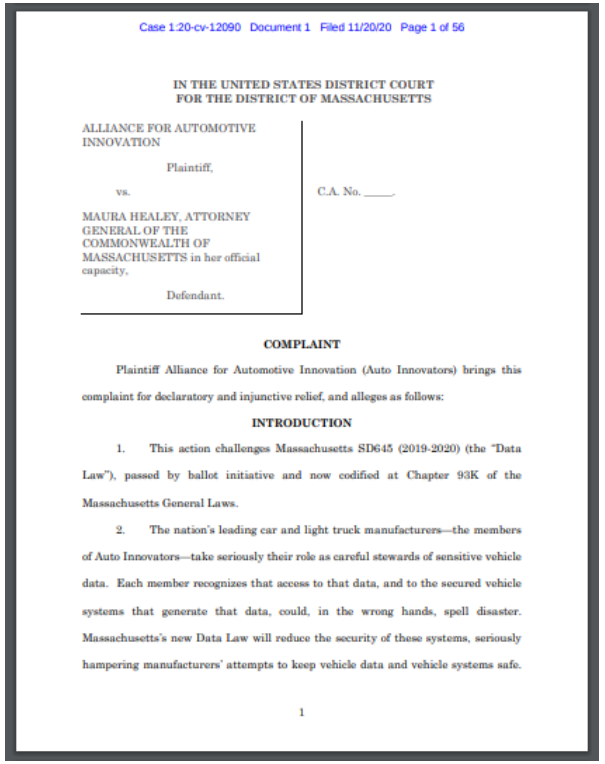
- Right to Repair Legislation
- Current Litigation Landscape
- Medical Device Right to Repair Legislation
- Potential Impact on Medical Device Manufacturers

Right to Repair Legislation

- Electronic Consumer Products
- "The Repair Organization"
- Model Legislation
    - Requirements
    - Limitations
        - Not required to divulge trade secrets "except as necessary to provide documentation, parts, and tools on fair and reasonable terms."

Current Litigation Landscape

- Massachusetts Motor Vehicle Owners' Right to Repair Act
  - Requires automotive manufacturers to make diagnostic and repair information available to independent repair facilities.
  - New expansion includes access to telematics systems.
- *Alliance for Automotive Innovation v. Healey*, case number: 1:20-cv-12090, U.S. District Court, District of Massachusetts



Case 1:20-cv-12090 Document 1 Filed 11/20/20 Page 1 of 56

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ALLIANCE FOR AUTOMOTIVE INNOVATION

Plaintiff,

vs.

MAURA HEALEY, ATTORNEY GENERAL OF THE COMMONWEALTH OF MASSACHUSETTS in her official capacity,

Defendant.

C.A. No. ____.

COMPLAINT

Plaintiff Alliance for Automotive Innovation (Auto Innovators) brings this complaint for declaratory and injunctive relief, and alleges as follows:

INTRODUCTION

1. This action challenges Massachusetts SD645 (2019-2020) (the "Data Law"), passed by ballot initiative and now codified at Chapter 93K of the Massachusetts General Laws.

2. The nation's leading car and light truck manufacturers—the members of Auto Innovators—take seriously their role as careful stewards of sensitive vehicle data. Each member recognizes that access to that data, and to the secured vehicle systems that generate that data, could, in the wrong hands, spell disaster. Massachusetts's new Data Law will reduce the security of these systems, seriously hampering manufacturers' attempts to keep vehicle data and vehicle systems safe.

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Medical Device Right to Repair Legislation

- Impact of COVID-19
- Critical Medical Infrastructure Right-to-Repair Act of 2020
  - Require manufacturers to provide, on fair and reasonable terms, access to information and tools to diagnose, maintain, or repair medical equipment.
  - Allow owners or lessees of medical equipment to repair or maintain medical infrastructure.
- Arguments for/against

Medical Infrastructure Right to Repair Act

116TH CONGRESS
2D SESSION

S. _____

To amend title 17, United States Code, to address circumvention of copyright protection systems with respect to the maintenance or repair of critical medical infrastructure, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. WYDEN introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend title 17, United States Code, to address circumvention of copyright protection systems with respect to the maintenance or repair of critical medical infrastructure, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Critical Medical Infrastructure Right-to-Repair Act of 2020".

SEC. 2. DEFINITIONS.

In this Act—

(1) the term "commerce" has the meaning given the term in section 4 of the Federal Trade Commission Act (15 U.S.C. 44);

(2) the terms "covered emergency", "covered service provider", "critical medical infrastructure", "repair", and "service material" have the meanings given those terms in section 123(a) of title 17, United States Code, as added by section 3(a)(1) of this Act;

(3) the term "covered healthcare provider" has the meaning given the term in section 1201(l)(1) of title 17, United States Code, as added by section 3(a)(2) of this Act;

(4) the term "critical medical infrastructure contract" means a contract relating to the purchase, leasing, licensing, repair, or maintenance (including periodic maintenance) of critical medical infrastructure;

(5) the term "service provider" means any person engaged in the diagnosis of problems with respect to, or the service, maintenance, or repair of, critical medical infrastructure; and

(6) the term "trade secret" has the meaning given the term in section 1839 of title 18, United States Code.

Medical Infrastructure Right to Repair Act

"(l) REPAIR OF CRITICAL MEDICAL INFRASTRUCTURE RELATING TO COVID–19.—

"(1) DEFINITIONS.—For purposes of this subsection—

"(A) the terms 'covered emergency', 'critical medical infrastructure', and 'repair' have the meanings given those terms in section 123(a); and

"(B) the term 'covered healthcare provider' means—

"(i) a healthcare provider who is the owner, lessee, or licensee of critical medical infrastructure; or

"(ii) the agent of a person described in clause (i).

"(2) PERMISSIBLE CIRCUMVENTION.—Notwithstanding the provisions of subsection (a)(1)(A), it is not a violation of that subsection for a covered healthcare provider to circumvent a technological measure that effectively controls access to a work protected under this title, if—

"(A) the purpose of the act of circumvention is to repair or maintain critical medical infrastructure with respect to that covered healthcare provider; and

"(B) the repair or maintenance described in subparagraph (A) is part of preparation for, or a response to, the covered emergency.

"(3) ENABLING CIRCUMVENTION.—Notwithstanding the provisions of subsections (a)(2) and (b), it is not a violation of either such provision for a covered healthcare provider to manufacture, import, offer to the public, provide, or otherwise traffic in technological means to circumvent a technological measure that effectively controls access to a work protected under this title, or to circumvent protection afforded by a technological measure that effectively controls access to a work protected under this title, if that action by that covered healthcare provider enables a repair or maintenance permitted under paragraph (2).

"(4) RULES OF CONSTRUCTION.—Nothing in this subsection may be construed to—

"(A) exempt a covered healthcare provider from compliance with any other applicable law or regulation relating to the repair or maintenance of critical medical infrastructure, except as explicitly provided in this subsection; or

"(B) prevent the Librarian of Congress from determining, under the applicable sub-

Medical Infrastructure Right to Repair Act

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"(B) the term 'covered healthcare provider' has the meaning given the term in section 1201(l) of title 17.

"(2) NON-INFRINGEMENT.—It shall not be an act of infringement with respect to a patent for design obtained under section 171 for a covered healthcare provider to fabricate a part on a non-commercial basis, and as needed, for the repair or maintenance of critical medical infrastructure with respect to that covered healthcare provider, if the repair or maintenance is part of a response to the covered emergency.

"(3) RULE OF CONSTRUCTION.—Nothing in this subsection may be construed to exempt a covered healthcare provider from compliance with any other applicable law or regulation relating to a part or critical medical infrastructure described in paragraph (2).".

SEC. 5. CONTRACTS.

Notwithstanding any other provision of law or regulation, a provision of a critical medical infrastructure contract is null and void if that provision of the critical medical infrastructure contract prohibits or restricts the ability of a covered healthcare provider that is a party to the contract to, in response to the covered emergency, repair

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of access means at no charge, except that if the applicable service provider requests documentation in physical printed form, the term "fair and reasonable terms" includes a charge imposed by the manufacturer for the reasonable actual costs of preparing and sending the documentation.

(b) DUTY TO DISCLOSE INFORMATION.—The manufacturer of a piece of critical medical infrastructure sold, leased, or otherwise introduced into commerce in the United States shall provide owners, lessees, or service providers with respect to that piece of infrastructure with access to, on fair and reasonable terms, service materials that are required to—

(1) diagnose problems with respect to that critical medical infrastructure; and

(2) service, maintain, or repair that critical medical infrastructure.

(c) DUTY TO MAKE TOOLS AVAILABLE.—The manufacturer of critical medical infrastructure sold, leased, or otherwise introduced into commerce in the United States shall—

(1) offer for sale to the owner or lessee of the critical medical infrastructure, and to all service providers with respect to the critical medical infrastructure, on fair and reasonable terms, any tool (includ-

Medical Infrastructure Right to Repair Act

ing software) for the diagnosis, service, maintenance, or repair of the critical medical infrastructure; and

(2) provide all information that enables aftermarket tool companies to manufacture tools with the same functional characteristics as those tools made available by the manufacturers to authorized dealers.

(d) EQUIPMENT.—The manufacturer of critical medical infrastructure sold, leased, or otherwise introduced into commerce in the United States shall offer for sale to the owner or lessee of the critical medical infrastructure, and to all service providers with respect to the critical medical infrastructure, on fair and reasonable terms, all equipment for diagnosis of problems with respect to, service, maintenance, or repair of the critical medical infrastructure.

(e) PROTECTION OF TRADE SECRETS.—

(1) IN GENERAL.—Subject to paragraph (2), a manufacturer of critical medical infrastructure may not be required to publicly disclose information that, if made public, would divulge methods or processes entitled to protection as trade secrets under chapter 90 of title 18, United States Code.

(2) PROVISION OF INFORMATION TO DEALERS OR SERVICE PROVIDERS.—A manufacturer of critical medical infrastructure may not withhold information

under paragraph (1) on the ground that disclosing the information would divulge methods or processes entitled to protection as trade secrets under chapter 90 of title 18, United States Code, if that information is provided directly or indirectly to authorized dealers or service providers.

(f) ENFORCEMENT BY THE FEDERAL TRADE COMMISSION.—

(1) UNFAIR OR DECEPTIVE ACTS OR PRACTICES.—A violation of this section, or a regulation promulgated under this section, shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

(2) POWERS OF COMMISSION.—The Federal Trade Commission (referred to in this subsection as the "Commission") shall enforce this section and any regulation promulgated under this section in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section. Any person who violates this section or a regulation pro-

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Potential Impacts on Medical Device Manufacturers

- Safety Concerns
- Quality Concerns
- Litigation
- Cybersecurity

Takeaways

- Awareness
- Advocacy
- Ask Questions
- Community Engagement

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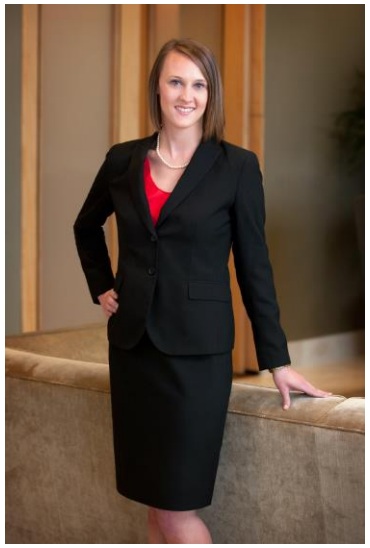
Questions?



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Thank You!