

September 12, 2024

The Honorable Bill Cassidy
Ranking Member
Senate Committee on Health, Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Ranking Member Cassidy:

One of the most pressing issues facing our nation is the need to bring down health care costs. As you well know, that is an extremely complex problem. This issue is outside the purview of the Bayh-Dole Coalition, which focuses on preserving and explaining the landmark Bayh-Dole Act that makes the United States the unquestioned leader in turning federally funded inventions into useful products, improving and protecting lives here and around the world.

However, we are concerned that in the debate over health care costs, misleading claims are often made that the government can “march-in” under Bayh-Dole to allow copiers to produce products critics claim are “unreasonably priced” or that the government can simply take privately owned inventions under the so-called authorities of Section 1498.

Because the Senate HELP Committee will be holding a hearing on September 24, 2024, about the costs of specific drugs, these claims may again be made. Both assertions are false. Neither statute works that way:

- March-in rights are narrowly tailored to situations when good faith efforts are not being made to commercialize a federally funded invention or, in rare cases, when the developer cannot meet national health or safety needs. In those circumstances, the government can force a university to issue a license to other developers. However, the law does not allow the government to “march in” just because someone feels a successfully commercialized product is not “reasonably priced,” a completely arbitrary and undefined term.¹

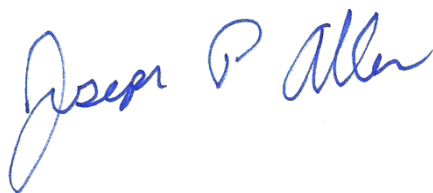
¹ <https://bayhdolecoalition.org/wp-content/uploads/2023/02/BDC-Issue-Brief-March-in-Rights.pdf>

- Section 1498 was enacted to provide a remedy for patent owners when a patented invention is “used or manufactured by or for the United States” without a license, such as in times when the nation is at war. Later amendments to the law allowed patent owners to receive compensation for the actions of federal contractors. In such cases, the patent owner can sue the government to recoup “reasonable and entire compensation” for this infringement. Thus, Section 1498 was enacted to protect patent owners when the government needs a product for its own use. That does not extend to use by the general public. Section 1498 is not a license for the government to take privately funded inventions whenever it chooses.²

Attached are two background papers on march-in rights and Section 1498, explaining how these laws have worked for many decades. Perhaps this information will be helpful in steering the hearing into a meaningful conversation about the real problems of our healthcare system and away from the highly misleading theory that the solution is having the government seize privately owned inventions. Rather than being a magical sword cutting the Gordian knot of healthcare costs, such actions would be a dagger to the heart of American innovation.

Please let me know if the Bayh-Dole Coalition can answer any questions or provide more information.

Sincerely,



Joseph P. Allen
Executive Director
Bayh-Dole Coalition

² <https://www.wlf.org/wp-content/uploads/2022/05/5202022BradenKresh.LBweb.pdf>