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July 21, 2022

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The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra,

On behalf of the members of the Licensing Executives Society, USA & Canada, Inc. (“LES”), we write to express concern regarding a letter you recently received from 100 congressional lawmakers, urging you to take action to lower prescription drug prices under various legal theories. The letter proposes action that would instead hinder innovation in healthcare by undermining intellectual property protection, both at home and globally.

LES is an independent, non-profit, non-partisan, professional association devoted to turning inventions and intellectual property rights into useful commercial products through education, networking, standards development, and certification. It is the leading professional organization devoted to the industry of technology licensing, *i.e.*, the use of agreements to exchange intellectual property rights (patents, trade secrets, know-how, trademarks, and copyrights) to bring the fruits of innovation from lab to market.

The authors of the Congressional letter misconstrue the language, legislative history, and intent of both the Bayh-Dole Act of 1980, and 28 U.S.C. Section 1498. They urge you to overturn decades of executive branch interpretation and judicial precedent in pursuit of goals that are shortsighted at best, but which, in the long term, would be disastrous to American innovation. Their proposal would undermine the creation of public – private partnerships such as those that, under existing interpretation, have produced thousands of lifesaving and life-changing products.

Prior to Bayh-Dole, the federal government retained the rights to inventions derived of federally funded research at universities, other non-profits, and small businesses. With good intent, but flawed reasoning, the government made that research generally available, and did not protect it by patent, or would not exclusively license it.¹ Government support of basic research is essential to enlarging our store of knowledge, but neither government nor academia is suited

¹ <https://bayhdolecoalition.org/wp-content/uploads/2021/02/Memo-To-Foster-Innovation-Biden-Administration-Must-Protect-Bayh-Dole.pdf>

to applying that knowledge to practical purposes in the development of commercial products. In the absence of intellectual property protection, the private sector found it unduly risky to make that investment. It would be an investment that others could readily exploit – creating the so-called “free-rider” problem.² Meritorious inventions were left on the academic shelf, undeveloped and unused; and taxpayer money funding that research produced no public benefit.

To stop this waste, Congress passed the Bayh-Dole Act, which gave universities and small companies the right to retain title to inventions they had developed with the support of federal funding, and to procure and license patents on those inventions. For the first time, universities and small businesses -- rather than the government -- could make the decision on whether, when, and how to further develop those inventions using intellectual property protection and licensing.

In enabling universities to derive revenue from licensing, Bayh-Dole created a virtuous cycle. Academic institutions are incentivized to move valuable, government funded innovation from lab to market through license agreements with the private sector; the academic institutions derive revenue from those license agreements that rewards the academic inventors and funds additional research; and that additional research produces more inventions, more license agreements, and more and better products, further improving quality of life. As a result, America’s higher education institutions have become immensely powerful economic engines: they fund more ground-breaking research, attract and retain the world’s best and brightest researchers, spin out more innovative products, and forge valuable relationships with the private sector to support still more research, picking up where government funding left off.³

This virtuous cycle has been enormously successful pushing back the frontiers of science, to great public benefit. Universities now have many resources beyond the public coffers to fund research, and to foster development of that research into useful products. The results speak for themselves. Bayh-Dole is singularly responsible for an immense range of transformative products and services, from quantum computing and firefighting drones to a once-a-day pill for HIV, high-definition television, and Google's original search algorithm.⁴

Under Bayh-Dole, the government retains certain rights. In carefully defined, limited, and exceptional circumstances, the government may “march-in” on a license agreement. If, for example, a company were to license federally funded technology from an academic institution, but then failed to make a good faith effort to develop it into a product, the government could

² See, e.g., Gruber, Jonathan and Johnson, Simon: Jumpstarting America: How Breakthrough Science Can Revive Economic Growth and the American Dream, esp’ly Chap. 4, “The Limits of Private Research & Development (explaining the free-rider problem); and Chap. 5, “Pushing Frontiers and Promoting Growth,” Public Affairs, Hachette Book Group (2019); and Science - the Endless Frontier, A Report to the President by Vannevar Bush, Director of the Office of Scientific Research and Development, July 1945, U.S. Government Printing Office, Washington (1945), esp’ly Chap. 3 (“It is important that the patent system continue to serve the country in the manner intended by the Constitution, for it has been a vital element in the industrial vigor which has distinguished this nation.”).

³ <https://members.lesusacanada.org/news/news.asp?id=411231>

⁴ <https://bayhdolecoalition.org/wp-content/uploads/2021/02/Memo-To-Foster-Innovation-Biden-Administration-Must-Protect-Bayh-Dole.pdf>

“march-in,” requiring the academic institution to license it to others who would make that effort, or to do so itself if the academic institution refused. This was intended to remedy a situation where the public would otherwise be completely deprived of the benefits of the invention.

The letter also misconstrues 28 U.S.C. Section 1498(a), which grants patent owners a remedy against the federal government when the government is found to have committed patent infringement. Contrary to the characterization of the letter, this is not a compulsory license giving the federal government a “right” to infringe or to relicense the patent. It is instead a waiver of sovereign immunity to ensure that the patent owner can be made whole even when the infringer is the sovereign.⁵

Neither Bayh-Dole’s march-in provision nor Section 1498(a) create a mechanism for the government to impose price controls; nor have they ever been construed to provide such authority.⁶ The authors of the letter are urging you to relicense patents on drugs that have been successfully developed, and are, in fact, *commercially available*. Presumably, they would have you relicense to those who would sell those drugs at a cost they find more acceptable. This would be an unprecedented move founded on flawed legal theories, and would undoubtedly be struck down by the courts.

It would also be ineffective. Section 1498(a) provides that the patent owner shall have a remedy “against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture...” Even if the government were to relicense a patent for purposes of price controls, it would nonetheless be obligated to pay the patent owner what it otherwise would have made on those sales in the U.S. market – in the absence of infringement. Thus, the government would incur substantial liability for infringement, and the so-called price controls would have none of the intended effect.

While we sympathize with lawmakers over the rising costs of healthcare, we urge you to reject this request as ill reasoned, ineffective, and counterproductive to improved healthcare. The best and cheapest route to improved healthcare is through innovation.⁷ Short-term tactics such as price controls will only diminish investment in innovation, and delay development of new and useful knowledge.

The letter proposes that the government deliberately usurp intellectual property rights whenever a patented product is deemed unduly expensive. Though the target here is biopharmaceuticals, the logic of the argument extends to all patented products that, by chance, receive any amount of federal funding. Such a widespread taking of private rights would bring a swift halt to private-

⁵Judge Mary Ellen Coster Williams and Diane E. Ghrist, “Intellectual Property Suits in the United States Court of Federal Claims” (“The government has expressly waived its sovereign immunity and consented to be sued for patent infringement under 28 U.S.C. § 1498(a)”). <https://www.uscfc.uscourts.gov/node/2927>

⁶ https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=ik_inline_manual_11

⁷ *Science – the Endless Frontier*, Summary of the Report (“Progress in the war against disease depends upon a flow of new scientific knowledge. New products, new industries, and more jobs require continuous additions to knowledge of the laws of nature, and the application of that knowledge to practical purposes.”).

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sector development of federally funded basic research, and would kill the virtuous cycle that produces many valuable products and alternative sources of funding for America's universities. As a result, the pace of innovation will slacken, and patients awaiting new therapies will be denied.

We are also deeply concerned about U.S. support for global initiatives weakening intellectual property protection and undermining innovation. In June, the World Trade Organization, with support from the U.S., implemented a waiver of patent-related obligations under TRIPS for COVID-19 vaccines. While perhaps well intentioned, this waiver will do nothing to arrest the pandemic, but it will discourage investment in future innovation. In combination with the flawed interpretation proposed for Bayh-Dole and Section 1498(a), it is an assault on innovation and intellectual property rights, and needlessly raises the risk on investment in much needed improvements in healthcare. We urge you to reject such approaches, and instead, to use your voice within the Biden-Harris Administration to support pro-innovation policies that will produce more and better vaccines and therapies, and improve quality of life for all.

Respectfully,

Scott Williams
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Licensing Executives Society (USA and
Canada), Inc.

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