September 14, 2017

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
S-230 The Capitol
Washington, D.C. 20510

Dear Mr. Majority Leader:

We write to express our profound concern regarding possible amendments to the National Defense Authorization Act that would undermine the Bayh-Dole Act and jeopardize the certainty of intellectual property rights and exclusive licensing by private-sector entities that take on the great costs and significant risk of commercializing Defense Department-funded research when these private firms succeed at turning a pharmaceutical discovery into a viable medication.

Proposed amendments to the Senate's National Defense Authorization Act would require the Department of Defense to withdraw the exclusive license from innovator companies when certain products exceed foreign-government-controlled prices. The effects of these proposals would be to devalue companies' intellectual property and to exercise the equivalent of eminent domain on their significant R&D investment in the associated products. This will have a chilling effect on companies that might otherwise seek an exclusive license on a DOD patent, deprive the American people of the practical commercial benefit of any potentially resulting drug products, and jeopardize existing American jobs and economic contributions, as well as new jobs that future exclusive licensing would have created. Notably, these provisions directly conflict with current law under the Bayh-Dole Act and will therefore sow confusion while simultaneously undermining investment and innovation.

Congress wisely employed the private-property-right basis of our patent system with the Bayh-Dole Act. This bipartisan law has for 36 years enabled private-sector entities to put federally funded research discoveries to practical commercial use. Bayh-Dole has given taxpayers practical benefit for their tax dollars spent on basic, theoretical research in universities and government labs. This law has done so precisely by securing ownership of resulting patents and enabling private entities' exclusive licensing of federally owned patents.

Prior to Bayh-Dole, U.S. taxpayers funded basic research, the U.S. government retained the IP rights to all discoveries, and few benefited practically from the discoveries. By 1980, when this law was enacted, the federal government held 28,000 patents from the research it had funded. Yet, less than 5 percent of those patents was commercialized.

Extensive evidence shows the tangible benefits the public derives from private exclusivity of high-value patents. In the case of the Bayh-Dole Act alone, patents owned by universities and exclusively licensed from universities and federal agencies have in the past two decades added $1.3 trillion to U.S. industrial output and nearly $600 billion to our economy. Some 11,000 companies have been founded and 80,000 patented inventions have been created over the past 20 years, thanks to Bayh-Dole.

Bayh-Dole contains a narrow safeguard known as "march-in rights," which the proposed NDAA amendments would radically distort. March-in is permitted when a licensee does not try to commercialize the patent, or public health and safety needs are unmet.

Commercialized product price is not a statutory ground, and federal agencies on several occasions have declined to exercise march-in on such a basis.

Undermining Bayh-Dole would poison the well that fuels the innovation ecosystem, which discovers, develops, and commercializes new inventions that benefit American citizens individually and our nation generally, beginning with pharmaceutical patents. We oppose proposals such as those offered by Senators Sanders and King and would oppose similar proposals, should they be considered. We urge the Senate to consider carefully the critical importance of preserving exclusivity in patent licensing and how the United States and the American people would suffer if such a breathtaking attack on IP and property rights were enacted. Thank you for considering our input.

Respectfully,

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