The Alliance for U.S. Startups and Inventors for Jobs
Comments to
National Institute for Standards & Technology

Proposed Rule:
"Rights to Federally Funded Inventions and Licensing of Government Owned Inventions"

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April 1, 2021

The Alliance of U.S. Startups and Inventors for Jobs ('USIJ")[1] supports the National Institute of Standards ("NIST") proposed rule entitled "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions." Preliminarily, we endorse fully AUTM's position on the proposed rule (http://bit.ly/AUTMNISTBD), including AUTM's suggestion for removal of the words "exclusively" and "of the contractor" from the current language so that the intent is not even marginally susceptible of misinterpretation.

In general, the proposed rule addresses various revisions and clarifications to the University and Small Business Patent Procedures Act of 1980, Public Law 96-517 (as amended), codified at 35 U.S.C. 200 *et seq.*, commonly known as the "Bayh-Dole Act." Section 203 provides for "march in" rights in certain specifically defined circumstances to allow a funding agency to intercede and require that owner of a federally funded invention grant licenses or additional licenses to ensure that such inventions are actually made available to the public and not licensed in a way that blocks that end result.

Much of criticism of the current treatment of these "march in" rights comes from or on behalf of persons that would prefer to pay less the for the drugs made available by licensees of inventions that were initiated or contributed to by federal funding to university and/or nonprofit organizations. Of course, people would like to pay less for life enhancing drugs (as well as most of the other products they purchase), but the utilization history of government funded scientific research before and after the 1980 passage of the Bayh-Dole Act provides a powerful demonstration of the hard reality – allowing a government agency to control the price of a new drug or a new device after a private company has invested millions of dollars and years of human effort would be the death knell of our pharmaceutical and medical device industries as we have come to know them.

The current U.S. pharmaceutical industry is really the poster child for the impact that the Bayh-Dole Act has had on drug development. From 1945 to 1980, despite enormous investment by NIH in basic medical research, that research did not translate into a single pharmaceutical product that ever was commercialized. As demonstrated by the AUTM paper, since the enactment of the Bayh-Dole Act,

[1] USIJ is an association of inventors, startups, venture capital investors and entrepreneurs whose efforts to bring new companies and new technologies into being are entirely dependent upon a reliable system of patent protection. USIJ was formed in 2014 to help foster the need for strong and enforceable patents and to promote investment and innovation in patent-intensive industries that are critical to U.S. economic leadership.

Americans have enjoyed more than 25,000 new life-enhancing drugs, brought into being by the public-private partnerships that the Act unleashed. We have seen terrifying diseases (AIDS, many types of cancer, many autoimmune diseases, and some types of blindness, to name but a few) made treatable and in some cases even curable. Those products, although based on federally funded initial research, did not come about purely as a result of the research funded by the government, as some assert; these products would never have reached the market at all without the investment of vast amounts of human effort and capital by private organizations and their investors. Figure 1 of AUTM's paper, referred to above, shows why this is true. The initial funding of scientific research amounts to a small fraction of the total cost of getting a new drug to market, even for a drug that ultimately is successful. The risk of failure is high for a variety of reasons shown in Figure 1 – scientific risk, obsolescence and technology risk, difficulties in scaling laboratory production to commercial production, approval by appropriate federal agencies, etc. – thus making the overall spend up 100 times the amount spent on initial research.

Investors and entrepreneurs with an enormous appetite for risk will undertake the years and cost of getting a new drug to market primarily because they perceive the monetary gain is likely to justify doing so. Even though motivated to some extent by a desire to make a contribution to humanity, few of such individuals are capable or willing to absorb the private costs needed to succeed. If Bayh-Dole were reinterpreted to construe its language the way that consumer advocates are requesting, it would add a layer of uncertainty to an already high-risk endeavor that few if any investors would find acceptable. It is simply not reasonable to expect the private sector to continue investing multiple millions of dollars and years of dedicated and focused effort if the end product is to be saddled with the potential of governmental pricing demands that will be driven largely by political considerations.

If government policy makers want to bring desirable products to the population, they can do that easily by funding the purchase directly, as is being done today with the COVID vaccines. Any other course is likely to result in no products to distribute at any price. When an agency of the U.S. government purchases anything from a private contractor, it already has ample power to influence the price. More would have extremely unfortunate consequences.