July 8, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary, Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Kennedy:

I write on behalf of the Bayh-Dole Coalition, a group of innovation-oriented organizations and individuals committed to celebrating and protecting the historic Bayh-Dole Act and the nationwide technology transfer system it helped create. We want to express our grave concern about a request recently made to your department by Knowledge Ecology International (KEI).

In its letter dated June 13, 2025, KEI calls on the Department of Health and Human Services to authorize the production of generic versions of enzalutamide, commonly known by the brand name Xtandi, by exercising its purported powers under 35 U.S.C. § 202 (part of the Bayh-Dole Act) and 28 U.S.C. § 1498. Though framed as a simple procedural matter that would reduce drug spending for patients in government-sponsored health programs, this request is both legally unfounded and potentially destructive to the foundations of America's innovation system.

It is worth noting the unusual timing of the request. As KEI acknowledges in its letter, the first patent on Xtandi will expire less than a year from now, in May 2026. All three of Xtandi's relevant patents will have expired by fall 2027. Generic manufacturers have already begun notifying the FDA of their intent to launch competitors once Xtandi's patents expire, which will act as a natural mechanism for lowering prices. Moreover, Xtandi has been selected for Medicare price negotiation under the Inflation Reduction Act, meaning that the Centers for Medicare & Medicaid Services will be able to set a "maximum fair price" for the drug beginning in 2027.

In other words, the extreme measures KEI recommends would, at most, speed the introduction of generic enzalutamide by about a year — and likely less, considering the time and resources required to produce, manufacture, and market a new generic drug. The marginal benefits for patients and taxpayers would be negligible.

Unfortunately, that does not mean KEI's request is harmless. In fact, it distorts the purpose and scope of both statutes it cites. And, if implemented, it stands to do serious damage to the longstanding economic incentives that drive American innovation.

Pursuant to the Bayh-Dole Act, the federal government does indeed have the power to assert its license to a patented invention that resulted from taxpayer funding. But this power cannot be exercised for just any reason. Government agencies can only assert their license to a patented invention under 35 U.S.C. § 202(c)(4) when doing so is necessary to meet their mission needs and obligations. Licensing a patent on a medication to a third-party producer in order to lower prices for patients insured under federal insurance programs such as Medicare and Medicaid would clearly fall outside the narrow scope of this provision.

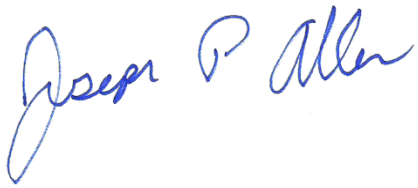
Similarly, 28 U.S.C. § 1498 has a limited scope that does not apply here. This statute essentially allows patent owners to recover "reasonable and entire compensation" should a patent be infringed "by or for the United States" by either the federal government or one of its contractors. Historically, it has been invoked exceedingly rarely, usually for purposes such as military procurement. Authorizing the production of cheap medicines for Medicare and Medicaid patients clearly would not qualify as "use or manufacture by or for the United States" as defined by this statute.

If the federal government adopts KEI's willful and gross misinterpretation of these two laws, it would threaten the entire U.S. innovation economy. Patents provide the financial incentive and legal surety required to spur private investment into unproven, early-stage research. The success of the Bayh-Dole Act, which enabled federally funded research institutions to own and license patents on their discoveries, exemplifies this: Since 1996, academic technology transfer through Bayh-Dole has contributed nearly $2 trillion to the United States' gross domestic product and supported roughly 6.5 million jobs across the economy.

However, if the government endorses interpretations of Bayh-Dole and § 1498 that allow it to override patent rights for capricious and legally dubious reasons, it will undermine that innovation incentive. Investors will hesitate to support breakthrough research, understanding that if the government decides to license the patent to a competitor, their ability to earn a return will collapse. This uncertainty wouldn't only harm innovation in medicine, either. Because products in all sectors — from energy to artificial intelligence — would similarly be vulnerable to government appropriation, high-tech investment across our economy could crater.

KEI's petition may appear narrow and technical, but its consequences would ripple far beyond this single drug. It would weaken confidence in patent rights, destabilize technology transfer partnerships, and compromise the very system that enables the development of breakthroughs like Xtandi in the first place.

I urge you to reject this request in the strongest terms, and I would be happy to provide any further information you may require.



Sincerely,

Joseph P. Allen
Executive Director
Bayh-Dole Coalition