Conservatives
for
Property Rights

July 9, 2025

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

RE: Opposition to KEI Request to Override Patent Rights on Xtandi

Dear Secretary Kennedy:

On behalf of Conservatives for Property Rights (CPR), I write to oppose the June 13 request by Knowledge Ecology International (KEI) urging the Department of Health and Human Services (HHS) to effectively ignore patents covering enzalutamide (Xtandi). KEI's proposal calls on HHS to invoke 35 U.S.C. § 202 and 28 U.S.C. § 1498 in order to allow generic competitors to enter the market prior to patent expiry. This is not a technical procurement issue. It is a direct attack on patent rights, and it must be rejected.

CPR is a coalition of organizations committed to safeguarding property rights — including the foundational rights in intellectual property. We advocate for a national policy climate that protects and promotes innovation, prosperity, and the constitutional principles of private ownership.

Xtandi will be subject to price controls under the Inflation Reduction Act (IRA) starting in 2027. Its core patents expire in 2026 and 2027. There is no access crisis, no market failure, and no legal basis for this kind of unprecedented government intervention, indeed, expropriation of private property. KEI's request is not about Xtandi — or any one drug. It is about establishing a precedent by which the executive branch could ignore valid patents at will.

The Bayh-Dole Act certainly does not authorize this. It is true that Section 202 gives the government a royalty-free license to directly use inventions discovered under taxpayer-funded research for its own purposes. However, it does not allow HHS to delegate that license to commercial entities or to override a product's patent rights across the entire market. Such misuse runs counter to Bayh-Dole's design of leveraging private patent rights to achieve public benefit from otherwise wasted taxpayer dollars.

Section 1498 provides a way for patent owners to receive "reasonable and entire compensation" if the government or its contractors infringe a patent, but it does not create a right for the federal government to disregard patent rights to allow generic manufacturers to sell a medicine at a lower price in the market. Using it that way would transform what is essentially a narrow eminent domain compensation statute into a de facto price control regime.

The Constitution gives Congress, not HHS, the authority to define and protect patent rights. Allowing agency officials to unilaterally nullify those rights by inserting "authorization and consent" language into contracts, in the way that KEI asserts, undermines the rule of law. It would send a message to inventors that the government may take what it wants, when it wants, without going through the process Congress established. That message would do enormous damage to the innovation economy across every patent-intensive sector, not just life sciences.

Patents are private property. That principle is not malleable. The Founders recognized intellectual property in the Constitution. Congress built an entire legal framework around it. If HHS approves this request, it would tell American inventors that the federal government cannot be trusted to honor its own laws.

It would also invite more petitions. Today, it is Xtandi. Tomorrow it could be another medicine, medical device, or a product in a different sector. The goal is not savings. The goal is to erode the foundation of the U.S. patent system until nothing is left and to set a precedent allowing the government to steal intellectual property from patent owners whenever it wants.

We urge HHS to reject this request outright. There is no need for further study, negotiation, or delay. The facts are clear. The law is clear. The Constitution is clear. This precipitating request contradicts all three.

Sincerely,

James Edwards, Ph.D.
Founder and Executive Director
Conservatives for Property Rights