Use the Bayh-Dole Act to lower drug prices for government healthcare programs

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As drug prices have increased, there is also greater pressure to find ways to ensure access to medicines. An existing provision of the Bayh-Dole Act could help to lower costs for qualifying drugs in federal programs such as Medicare and Medicaid.

The Bayh-Dole Act of 1980 permits the ownership of patents resulting from federally-funded research to remain with the inventors and their employers. Government research grantees and their institutions now earn billions from royalties and equity interests that result from the sale or exclusive licensing of these patents.[1] In recent years, controversy has arisen when drugs covered by these patents have been sold at excessively high prices, since taxpayers have already contributed to the drugs' discovery, as part of the more than $30 billion annually the US government spends on biomedical research.

In discussing ways to reduce drug costs, legislators and public-health advocates have largely overlooked a provision in the Bayh-Dole Act that could help. Section 202 requires research grantees that obtain patents claiming federally funded inventions to confer a nonexclusive, royalty-free license back to the US government, which permits the government to practice the invention or to have it practiced on the government's behalf. When advocating for the enactment of the Bayh-Dole Act, former Senator Birch Bayh (D-IN) stated that this license allows the government to "use for itself and the public good inventions arising out of research that the Federal Government helps to support."[2] This use could include that for government healthcare programs such as Medicare and Medicaid.

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To our knowledge, the government has never exercised its right to have a prescription drug manufactured on its behalf. One reason may be that, although many drugs have their origins in federally funded research, pharmaceutical companies obtain other patents covering these drugs during their development into FDA-approved products. The government's license does not extend to such privately funded patents, which limits the situations in which the government could use its license.

Still, Section 202 could be useful in some cases. Earlier this year, two consumer-interest organizations, Knowledge Ecology International and Union for Affordable Cancer Treatment, filed a petition requesting the government to use Section 202 to authorize the production of a generic version of the prostate cancer drug enzalutamide (Xtandi), because the drug's list price in the US is two to three times higher than it is in Europe and Australia. All patents currently registered with the US Food and Drug Administration (FDA) covering enzalutamide are licensed to the US government under Section 202. As this article went to press, the US Department of Health and Human Services had not yet ruled on the petition. But the government has received an offer from a generic manufacturer to supply enzalutamide for government programs at $3 per pill, as compared to the $42.38 per pill the government now pays—a potential annual savings of over $57,000 per patient.

A potential obstacle to the exercise of the government's Section 202 license is the patent certification requirements of the Hatch-Waxman Act of 1984. Hatch-Waxman requires a manufacturer that is seeking approval to sell a generic copy of a new drug such as enzalutamide to certify that any patents on the drug are invalid or will not be infringed. This requirement may seem to prevent a generic manufacturer that has no basis for substantively challenging enzalutamide's patents from obtaining FDA approval before the patents expire. But because of the government's Section 202 license, we believe that a generic manufacturer could certify that the patents will not be infringed because approval is being sought for the sole purpose of producing enzalutamide for sale to the government.

Any suit claiming infringement of the enzalutamide patents despite such a certification should be dismissed by a federal court, because the law[3] prohibits the court from interfering with the right of a government supplier to bid on or participate in the sale of products to the government, irrespective of the existence of patents.[4] The only available course of action for acts of patent infringement by or for the government is to initiate a suit in the US Court of Federal Claims—but the Section 202 license would provide the government with a complete defense. In addition to its patents, enzalutamide is protected under Hatch-Waxman by a five-year exclusivity for new chemical entities that expires on 31 August 2017, but an application for generic approval containing a certification of noninfringement may be filed 1 year before the exclusivity expires. There are other drugs, such as the anti-HIV medication emtricitabine (Emtriva), subject to a Section 202 license for which a similar patent certification could be filed immediately.

Some will argue that by exercising its license, the government would undermine the value of commercial rights and adversely affect the willingness of the pharmaceutical industry to invest in the commercialization of federally funded research discoveries. But many manufacturers have reduced their investment in internal drug discovery research and become increasingly dependent on licensing ideas emerging from public funding. There is no reason to believe that they will abandon their essential relationship with academia simply because profits are reduced somewhat by the operation of the Section 202 license.

The economic benefits that result from federally funded biomedical research should be more equitably shared with the public, and the section 202 license can help accomplish that goal for certain drugs. In the long run, Congress should consider ways to amend the Bayh-Dole Act to achieve this outcome more broadly. Until then, the government should utilize its Section 202 license to achieve lower drug prices for public programs whenever possible.

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1. Watanabe, T. UCLA will get hundreds of millions for rights to prostate cancer drug. *LA Times* (4 March 2016).
2. http://bayhdolecentral.com/JoeAllen_part3/statment.on.s.414.pdf.
3. 28 U.S.C. § 1498(a) (2015).
4. Gore v. Garlock, 842 F.2d 1275, 1282 (Fed. Cir. 1988).