

**Comments of the Union for Affordable Cancer Treatment:
National Institute of Standards and Technology Request for Comments on Proposed
Regulations regarding “Rights to Federally Funded Inventions and Licensing of
Government Owned Inventions”**

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The Union for Affordable Cancer Treatment (UACT) is a union of people affected by cancer, their family members and friends, people who take care of people with cancer, health care professionals and cancer researchers committed to increasing access to effective cancer treatment and care. UACT is particularly concerned about the rapidly escalating cost of cancer medication and seeks to fight for cancer treatment and care to be affordable and available, everywhere, for everyone who needs it. Our work is described on our web page at <https://cancerunion.org/>.

UACT was party to a march-in request to the NIH and the US army over the price of the prostate cancer drug enzalutamide, invented at UCLA, and now marketed globally by Astellas under the trade name Xtandi.

UACT has also contested the grant of overly broad exclusive licenses on cancer drugs and cell therapies, by the NIH.

UACT offers comments in opposition to two elements of the NIST proposals to amend the regulations of the Bayh-Dole Act, on the grounds that these provisions will weaken and enfeeble the public’s rights in inventions that receive federal funds.

1. UACT opposes the proposal to modify 37 C.F.R. § 401.6 to exclude prices as a standalone ground for march-in requests

UACT opposes the proposal by NIST to add language in 37 C.F.R. § 401.6 stating that march-in authority “shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.” The law now defines “practical application” to include an obligation to make the benefits of inventions “available to the public on reasonable terms.” For UACT members, this means, the price of a cancer drug or a cell or gene therapy, or a diagnostic test, should be reasonable. What NIST is proposing is to redefine and twist the language from the statute so that it can only be used to ensure that drug companies benefit from the reasonable terms condition. This stands the intent of the statute on its head, making the right holder, including a drug company with a monopoly on a taxpayer funded invention, the protected party.

Some parties have argued that the intent of the statute, which was first enacted in 1980, could be inferred by a 2002 letter published in the Washington Post from former Senators Bayh and Dole, both then working for years as Washington, DC lobbyists. The 2002 Bayh and Dole letter to the editor was in response to a guest editorial by two academics, Peter Arno and Michael Davis, who had earlier published a law review article highlighting the importance of the obligation in the definition of practical obligation, to make the benefits of inventions “available to the public on reasonable terms.” Any suggestion that the interpretation of legislative intent should rely on the ex-post claims of these Senators-turned-lobbyists can have no legal merit, for all of the obvious reasons.

2. UACT opposes the NIST proposal to modify 37 C.F.R. § 404.11 to eliminate the standing of patients to challenge an exclusive license.

UACT has opposed the NIH granting of exclusive licenses where the grant of the exclusive license is contrary to the intent and plain language of the Bayh-Dole Act limitations on the granting of exclusive rights in federally owned patents (35 USC 209). In some cases, the NIH will have an invention that benefits from the government owned inventions, where there is no reason for an exclusive license, or where the rights need to be limited, as is required by law. Examples include cases where the developer is spending very little on clinical trials, and already has the benefits of 12 years of exclusive rights in test data and/or 7 years of orphan drug regulatory exclusivity and/or a big incentive from the priority review voucher. The persons or entities that are inclined to challenge the grant of exclusive monopoly rights are patients, patient groups or other advocates. NIST again wants to make the Bayh-Dole Act protect only commercial competitors, if and only if they want to challenge the terms of an exclusive license. Most companies have no interest in limiting what is a gravy train for companies, getting exclusive licenses on the cheap and maximizing profits from the monopoly. This proposal is insulting to the public that pays the salaries of the government employees.

Annex: The government’s rights in patents from 2010 to 2020

There is a lot at stake in this proposal. Today the fundamental patents on CRISPR, many key cell and gene therapy patents, and more generally more than 8 thousand new patents per year are subject to the Bayh-Dole framework, which gives the public the right to march-in when the benefits of inventions are not “available to the public on reasonable terms”

From 2010 to 2020, the USPTO issued 146,358 patents that included the word “cancer” in the patent. Of these patents, 20,717 declared on the patent either an assignment to the United States of America or in a separate field that the U.S. government had rights in the patent, pursuant to a funding agreement. In other words, 14.2 percent of all patents that include the word “cancer” in the patent declared government rights. Other relevant search terms provide similar results. For example, when looking at patents over the same time period that have the Current US Classification (CCL) 435, for “molecular biology and microbiology”, 15.3 percent declare government rights. For patents that mention “chimeric antigen receptor”, 21.2 percent

declare government rights. Moreover, these percentages understate the number of relevant patents, because patent holders routinely under-report federal funding and government rights, or report them late as certificates of correction, which are not included in these queries. (<http://patft.uspto.gov/netahtml/PTO/search-adv.htm>)

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