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National Institute of Standards and Technologies
Rights to Federally Funded Inventions and Licensing of Government Owned Inventions
Docket No.: 201207-0327
Docket ID: NIST-2021-0001-0001
FR Doc # 2020-27581, 86 Fed. Reg. 35

April 1, 2021

Re: Lack of jurisdiction to regulate the Bayh-Dole Act in general
Re: The proposal to exclude "price" from a determination health and safety needs (37 C.F.R. § 401.6 (e))
Re: The proposal to enlarge time for an agency to respond to March-In (37 C.F.R. § 401.6(b))
Re: The proposal to exclude the public from having standing to appeal a grant of a license: (37 C.F.R. § 404.11)

The proposed regulations create at least four serious legal issues for all taxpayers who rely on an invention funded by the U.S. government, such as pharmaceutical drugs. We have direct knowledge of the dangers of misuse and non-use of such inventions when they are needed to alleviate health and safety needs; we filed the Fabrazyme March-In request in 2010 and a petition for re-hearing in 2011 under 35 U.S.C. § 203 (a) (2). (Available at https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf).

In the Fabrazyme March-In case, U.S. patients were refused access to Fabrazyme in preference for overseas customers during a drug shortage. Fabry disease is lethal, but Fabrazyme can be used to treat Fabry disease if infused bi-weekly for life. The drug cost $40,000 per month. The U.S. manufacturer/contractor faced overseas competition from a similar drug which was not approved in the U.S., so the U.S. manufacturer/contractor protected its overseas market by sending more drug overseas while intentionally underserving the U.S. market. Because of the U.S. this business decision to favor overseas markets, Americans suffered and some died without access to a medical invention funded by U.S. taxpayers.

ISSUE 1 (Jurisdiction)

NIST – National institute of Standards and Technology - is a non-regulatory agency and as such cannot issue regulations. Congress was explicit. Congress did not grant NIST the authority to issue Bayh-Dole regulations under the Bayh-Dole Act in 1980 under 35 U.S.C. § 206 or subsequently grant NIST the ability to regulate Bayh-Dole (or itself for that matter) in the NIST Organic Act in 1988 under 15 U.S.C. § 277. Therefore, any regulations NIST promulgates whether deemed "good" or "bad" would be per se unenforceable by the U.S. Courts.

The Department of Commerce was delegated the sole authority to regulate Bayh-Dole - not a sub-agency which the Department chooses. The blanket sub-delegation of Bayh-Dole regulatory authority to NIST finds its only support in a Department order that was not published for notice and comment; *see* Dept. of Commerce Directive DO 30-2A (g). However, the APA requires not an administrative order but rather a substantive legislative authority to promulgate rules under 5 U.S.C. § 553(b)(2).

The Congressional delegation of regulatory power to the Department of Commence itself and not its agencies makes logical sense. Bayh-Dole is part of Title 35 (Patents) and was formerly known as the Patent and Trademark Act Amendments but it has never been part of Title 15 (Commerce and Trade) under which the NIST is created and governed. Bayh-Dole sits at the intersection of patents, health, and commerce, so a sub-agency with a narrow non-regulatory mission, such as NIST, should not be involved in legislative regulation of the Bayh-Dole act given the broad crossover into many areas NIST has no expertise in. The Supreme Court would agree that the proposed regulations would all be unlawfully promulgated. "[T]he exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes." (Chrysler Corp. v. Brown, 441 U.S. 281, 302 (1979)). Emphasis added. The NIST has been limited to being a non-regulatory agency. The Department of Commerce cannot broaden NIST's legislative purpose.

While regulations are still needed to define patent misuse and non-use to alleviate health and safety concerns, NIST does not have such authority; therefore, all of the proposed regulations should be withdrawn and properly re-issued by the Department of Commerce itself.

ISSUE 2 (Price and March-In: 37 C.F.R. § 401.6 (e))

Notwithstanding NIST's lack of Congressional authority to regulate, the exclusion of "price" as a "sole" element for determining a need for March-In under the Bayh-Dole Act exceeds any Constitutional authority. The Supreme Court forbids "the unauthorized assumption by an agency of major policy decisions properly made by Congress." *American Ship Building Co. v. NLRB*, 380 U.S. 300, 318 (1965). Excluding pricing as a sole basis for March-In affects individual rights and remedies originally established under the Bayh-Dole Act. The cost of Fabrazyme is so far beyond average American's ability to pay for it, an uninsured patient would not be able to access the medication. The price creates a death sentence, as do other hyper expensive drugs.

When excessive pricing causes the deaths of Americans from otherwise treatable disease, pricing creates substantive health and safety concerns that March-In can alleviate in a Congressionally approved manner. Indeed, licensees still must pay reasonable fees for the license so March-In is not a forfeiture and thus March-In increases (not decreases) market access to the taxpayer funded invention, which is the whole point of the Bayh-Dole Act. If Congress had wished the rights and remedies to be narrowed to exclude price, it would have said so. NIST is improperly stepping into the role of the Legislature by policy setting for the role of pricing under the Bayh-Dole Act. Therefore, the proposed regulation (§401.6 (e)) regarding "price" should be withdrawn.

ISSUE 3 (Enlarging Time for March-In response: 37 C.F.R. § 401.6(b))

Enlarging the time for an agency to respond to the manufacturer/contractor from 60 days to 120 day after a March-In inquiry serves no purpose in a March-In proceeding. As in the Fabrazyme case, any additional time to respond unnecessarily lengthens a health deprivation to Americans. If the invention is for a satellite navigation system, two months may not be a long time; but for a patient relying on access to a cancer drug, two months can mean the difference between life and death. The manufacturer/contractor always has a right to appeal, so there is no issue with due process.

NIST does not cite a compelling reason to enlarge the time to respond to a March-In request. The longer a manufacturer/contractor engages in patent non-use or misuse, the more likely it will be that Americans will be deprived of a life-saving patented invention such as a pharmaceutical drug. Therefore, the proposed regulation (§ 401.6(b)) enlarging time should be withdrawn in order to alleviate the health and safety effects of patent misuse and non-use on the American public.

Issue 4 (Standing to Appeal Exclusive Licenses: 37 C.F.R. § 404.11)

We join Kathyrn Ardizzone and Knowledge Ecology International in opposing denial of public standing to appeal grants of government licenses under proposed rule 37 C.F.R. § 404.11. We also add that when the government grants exclusive license to manufacturer/contractors, as was the case in Fabrazyme, drug shortages become likely. Some technologies are dangerous if they are single-sourced relative to other technologies (pharmaceuticals versus satellite navigation systems). A sole supplier of a pharmaceutical invention is dangerous to the global market and to the individuals relying on the government funded invention.

A second source of critical medications via a non-exclusive license is often necessary to prevent a disruption of medical supplies whether the cause is a natural disaster - as in the case of Hurricane Maria shuttering 50 drug companies in Puerto Rico - or as in the case of Fabrazyme where the sole manufacturing plant in the world was contaminated. The Department of Defense already requires non-exclusive licenses for second sources related to national security technology and even private computer companies require more than one manufacturer for patented microchips.

It is better to anticipate a problem from market disruptions than it is to suffer the consequences. Therefore, it is the public who is best granted standing because they are the parties who have a real threat of immediate physical injury from granting an exclusive license for a life-sustaining or life-saving technology— not the competitors in a marketplace. Alleviating health and safety needs are expressly referenced in the Bayh-Dole Act at 35 U.S.C. § 203 (a) (2). Therefore, the proposed regulation (§ 404.11) that narrows standing to challenge exclusive licenses should be withdrawn so as to alleviate the health and safety issues that Congress was expressly concerned.

For additional information on this or other issues with the proposed regulations, Dr. Black can be contacted via email at drallenblack@gmail.com and Mr. Carik can be contacted at joseph.carik@gmail.com