Federal March
In Provisions &
NIST Draft
Framework

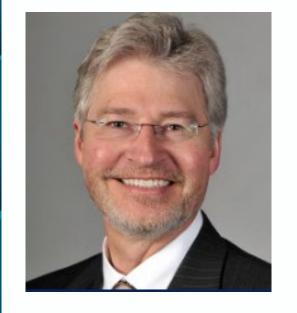
February 29, 2024

A Conversation with Experts in Policy, Research, Inventions,
Technology Transfer, and
Commercialization of University
Inventions



Moderator:

Todd Sherer, Associate Vice President of Research & Executive Director of Technology Transfer, Emory University



Walter Copan, Vice President for Research & Technology Transfer, Colorado School of Mines

Meet the Panel



Kirsten Leute, Partner, University Relations at Osage University Partners.



Dennis Liotta, Professor in Chemistry, Pharmacology & Chemical Biology, Emory University



How Did We Get Here?

- On 1/4/21, NIST <u>proposed additional changes</u> to the 37 CFR 401 regulations implementing the BD Act (86 FR 35). These changes included a controversial provision that march-in rights <u>should not be</u> exercised exclusively based on a contractor's business decision regarding pricing of commercial goods/services. Read <u>COGR Multi-Association Response</u>
- In July 2021, an <u>executive order</u> directed NIST to <u>reconsider</u> finalizing this or any similar provisions.
- On 12/8/23 NIST released its <u>draft interagency guidance</u> framework that <u>includes pricing as a criterion</u> for exercising march-in rights and forcing additional licenses. Read <u>COGR & Multi-Association Response Letters</u>



Poll Question #1

How familiar are you with the Draft NIST March-in Framework?

- a. I'm pretty familiar I know what's in it and I'm concerned!
- b. Somewhat familiar I know the gist, but unsure of what the potential impact is
- c. I've heard of it, but not really my area.
- d. Not very familiar.
- e. Other Tell us in the chat!



Poll Question #2

Did your institution submit comments on the NIST framework RFI?

- a. Yes
- b. No
- c. Not sure



The NIST Draft Framework Will Chill Investment in Federally Funded Inventions

- ➤ 12/8/23 NIST Releases <u>Draft Interagency Guidance Framework</u> that includes pricing with 60 day comment period that ended on 2/6/24.
- More than 100 universities and organizations, <u>including COGR</u>, submitted letters expressing concern about the new Framework. Other associations representing manufacturing, therapeutics, patient advocacy also expressed concern in their comments. A bipartisan letter opposing the framework was submitted by congress.
- In 43 years, no agency has exercised its right to march-in. Several agencies have considered march-in previously but have either declined to exercise it or worked with the parties to find an alternative solution to achieve the desired objectives. The NIH has denied every petition to march-in based upon pricing that has been submitted.
- The Bayh-Dole Act does allow the federal government to march in under certain circumstances and to require that additional licenses be granted if warranted. The Act makes no reference to pricing that should be dictated by the government and this omission was intentional. It was recognized by the bills drafters that the government should not meddle in the business of developing new products and setting their prices.



Poll Question #3

Do you think the pricing provisions introduced in the framework will have an impact on the institution's ability to license inventions arising from federal funding?

- a. Yes
- b. No
- c. Not sure

