

Legislative and Regulatory Update

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COGR

UIDP Contracting Forum

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Strengthening
University-Industry
Partnerships





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Who We Are

- Nonprofit 501 c 3 association of leading research-intensive universities and affiliated medical centers and nonprofit research institutes
- 216 member institutions in 48 states & D.C.
 - 82 Privates | 134 Publics | 22 Affiliate Academic Hospitals and Research Institutes
 - 134 Carnegie Research I Institutions
 - 30+ Hispanic Serving Institution (HSI)
 - \$49 Billion+ in combined federal expenditures (2022 NSF HERD Survey)
- 96% of eligible institutions among top 100 & 84% of eligible institutions among the top 200 institutions as measured in federal research expenditures are COGR members (2022 NSF HERD Survey)



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What We Do

- Advocate directly with federal agencies in areas of research administration, financial oversight, compliance, and ethics, intellectual property, and research security
- Work closely and coordinate with AAU, APLU, AAMC, FASEB, and other higher education associations that lobby on pending legislation
- Provide expertise, commentary, and analysis to higher education associations and government officials about pending federal policies, guidance, and legislation
- Provide guidance and analysis on topics of interest to COGR members in the form of white papers, readiness guides, webinars, written updates, and more
- Promote effective compliance practices
- Provide opportunities to engage directly with federal officials, the research university community, and institutional colleagues on key and timely issues

COGR Members: Leaders in Innovation

- ➔ **More than 1200 NEW Issued Patents**
- ➔ **Over 4000 NEW Patent Applications**
- ➔ **200+ NEW Start Ups**

*2021 AUTM Licensing Survey,
based on data from 132 COGR
member institutions*

National Academy
of Inventions “Top
100” in U.S.
Universities Granted
U.S. Utility Patents
Report = **96/98 are
COGR Members***

** 2 institutions listed are not yet COGR member eligible*



Derived from AUTM report titled *AUTM US Licensing Activity Survey: 2021, A Survey Report of Technology Licensing (and Related) Activity for US Academic and Nonprofit Institutions and Technology Investment Firms* can also be referenced by its abbreviated title, *AUTM US Licensing Activity Survey: 2021*, editors John Miner, Stephen Susalka, Paul Stark and Jordana Bieze Foster.



[8.30.23-Top-100-U.S.pdf](#)
academyofinventors.org





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Funding Outlook for FY24— Status Quo or Mostly Dismal?

- CHIPS and Science Act authorized + \$50B over 5 years but most of the money not yet appropriated.
- Agencies most impacted are NSF, NIST, and the DOE Office of Science programs, many with key responsibilities for technology transfer and commercialization like the Technology, Innovation and Partnerships (TIP) Directorate at NSF.
- Modest funding increases provided NSF and DOE in FY'23, but far below CHIPS and Science levels. Based on last year's funding we are already \$3B behind on the commitment Congress made in C&S. Under levels drafted by the House and Senate for FY24, the deficit will grow to more than \$7B behind in FY24.

Funding Outlook – Continued

- Currently the government is funded at flat levels based on FY23.
- Stopgap funding measure passed 1/18 maintains a two-step or “laddered” approach to funding, setting a March 1 deadline for Congress to pass the FY24 Agriculture-FDA, Energy and Water, Military Construction-VA, and Transportation-HUD bills and a March 8 deadline for the remaining eight appropriations bills
- Controversial funding issues still to be resolved in FY24 include additional funding to address the wars in Ukraine and Israel, and border security, while a subset of the House GOP is also keen to cut additional non-defense discretionary spending (which includes all science and research funding).

- DETERRENT Act
 - Lowers Section 117 reporting threshold
 - Increases information required to be reported
 - Changes reporting requirement to annual
 - Required designation of a Section 117 Compliance Officer
 - **Prohibits contracting with foreign country or entity of concern**
 - Requires institutional policy and database for foreign gifts and contracts to individual staff (not limited to countries of concern)
 - Requires disclosure of “investments of concern”
 - New penalties for compliance violations

- More on DETERRENT Act:
 - Passed the House 246 to 170. [31 Democrats](#) joined all Republicans to vote in favor of the legislation.
 - Senate timeline and engagement: Senate HELP Committee and chairman Sanders do not expect the bill to be a priority or move quickly through the Senate like it did in the House.
 - Sections 117a-d are problematic; definition of a contract in 117a is very broad so that all collaborations and academic exchange programs could be at risk with foreign countries of concern.
- Inquiries/Investigations/Reports expected to continue e.g.:
 - Senate E&C / House Select Committee on the CCP – [UCLA Inquiry](#)
 - House Ed & Workforce – [Harvard Antisemitism Investigation](#)
 - House Select Committee on the CCP -- [Report with 150 policy recommendations](#)
 - House Foreign Affairs Committee – [BIS Report](#)

- PREVAIL Act (H.R. 4370; S. 2220)—PTAB reform
 - Full Senate Judiciary Comm. hearing expected Feb./March
- [Reforming the Patent Trial and Appeal Bo... | United States Senate Committee on the Judiciary](#)—last year’s Hearing
- ICIE Act (H.R. 6684)—GAO Review of IP Disclosure/Reporting Process
 - Senate version to be introduced (Coons/Tillis)
- Patent Eligibility Restoration Act (S. 2140)—101 reform
 - Hearing may be scheduled soon
- PARA Act (H.R. 5475)—no U.S. patent to national security threat entities
 - Has not gone forward- <https://www.congress.gov/bill/118th-congress/house-bill/5475?s=1&r=26>

March-In(g)—Backwards?

- NIST Announces Draft Framework for Considering March-In Rights Under Bayh-Dole (88 FR 85593; 12/8/23).
- Framework includes consideration of whether the price or other terms at which the product is offered to the public is reasonable under March-in criterion 1 (failure to achieve practical application).
- Also includes consideration of price under March-in criterion 2 (necessary to alleviate health or safety needs)
- Framework sets forth criteria for agencies to follow in considering march-in requests and includes 8 scenarios as examples.



March-In Implications

- No clear authority under Bayh-Dole to exercise march-in on the basis of price; all such march-in requests previously have been rejected (including by the Biden Administration).
- Aimed at drug pricing but while mostly missing the target will adversely affect the value of university inventions in all tech sectors.
- Framework uses terms such as “reasonable,” “extreme,” “unjustified,” “exploitative” with regard to price; what do they mean and how or by whom can such determinations be made?
- Framework may provide a roadmap for large companies and others to challenge and harass small companies (e.g. SBIR) which hold the majority of university patent licenses



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March-in Implications – Continued

- Framework undermines Administration priorities such as CHIPS and Science Act programs that are premised on industry co-investments and partnerships on which it likely will have a chilling effect.
- There could be national security implications by providing a mechanism for unfriendly entities to undermine U.S. innovation through the use of march-in.
- Bottom line: any exercise of march-in on pricing grounds is likely to make companies hesitant to license federally-funded university inventions if at all. This chilling effect will adversely affect U.S. innovation and Administration priorities in critical technology fields.



Responses

- Many groups requested extension of 2/6 comment deadline
- Most comments received so far “canned” letters supporting reduction of drug prices
- Bayh-Dole Coalition Comments: no legal authority for march-in on pricing grounds, and you’ve wrecked Bayh-Dole
- AUTM Comments: no legal authorization, won’t lower drug prices, devastating effect on innovation
- Joint Higher Ed. Association Comments not yet available but likely will frame responses in terms of the 5 questions asked in the NIST RFI
- COGR comments likely to endorse joint association comments and reiterate points in earlier slides



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March-In Resources

- [Council for Innovation Promotion Issue Brief: The Bayh-Dole Act and March-in Rights](#)
- AUTM Comments planned to be posted 1/23
- [Bayh-Dole Coalition Fireside Chat with David Kappos \(C4IP\) and Kate Hudson \(AAU\) on the march-in framework](#)
- [White House's Drug Patent Plan Undercuts Research and Innovation \(bloomberglaw.com\)](#)
- Higher Ed Association Comments--coming



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Domestic Manufacturing— Another Bayh-Dole Challenge

- Executive Order 14104 (July 2023) Puts More Teeth Into Bayh-Dole domestic manufacturing requirement
- EO directs agencies to consider whether “exceptional circumstances” exist to warrant restricting title to federally funded inventions in certain critical and emerging technologies, or to extend the Bayh-Dole Act domestic manufacturing requirement to non-exclusive licenses and sales of inventions outside the U.S.
- Also directs agencies to encourage more domestic manufacturing in solicitations and funding agreements
- NIST directed to enhance invention utilization reporting and develop guidance for manufacturing waiver requests.



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Domestic Manufacturing Challenges – Continued

- DOE Has Added a “U.S. Competitiveness “ Provision to DOE Awards Making Domestic Manufacturing a Binding Requirement and Extending It to Non-Exclusive Licenses and Foreign Product Sales
- Licensee Ownership Changes Require Notification to DOE
- 10/1/23 NIST Invention Utilization Questions Pose Additional Challenges with Requirement to Report Manufacturing Locations
- “Manufactured Substantially” in U.S. Raises Supply Chain Issues
- Note: Pending Legislation (S. 1956) Would Tighten Statutory Requirements Along Lines of DOE Requirements



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Whither Bayh-Dole?

- Basic Tenets of Bayh-Dole were to Establish a Uniform Federal Regime for and Eliminate Government Micro-Management of Federally-Funded Inventions
- Recent Developments Imply that These Tenets No Longer May Hold
- Government Emphasis on Importance of Innovation in Critical Technologies Makes Timing of These Developments Particularly Ironic



ORI NPRM on Research Misconduct: Items of Note for Smaller Institutions/Start-Ups

Definition of “Small” Institution:

- **Currently under 42 CFR §93.303:** “If an institution is too small to handle research misconduct proceedings, it may file a ‘Small Organization Statement’ with ORI in place of the formal institutional policies and procedures required by §93.301 and §93.304.”
- **NPRM:** This provision remains in place, but the NPRM now includes a definition of “small institution” that states: “A small institution typically has a total of 10 or fewer institutional members.”



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ORI NPRM on Research Misconduct: Items that may Create Significant Burden for Smaller Institutions

- Formalized assessment phase, which if not completed in 30 days, automatically moves to inquiry. Includes formal assessment report that ORI may access.
- Prohibits institutions from considering the defenses of “honest error or difference of opinion” at or before inquiry, thus potentially unnecessarily prolonging review process.
- Focus on institution’s creation of a detailed and comprehensive “institutional record” that encompasses all phases of allegation review including (a) documentation of why records were not sequestered; and (b) transcription of interviews that take place at assessment and inquiry.

Link to [COGR Response Letter](#)

- FAR Case 2021-017 Cyber Threat and Incident Reporting and Information Sharing (88 FR 68055)—October 3, 2023
- May apply whenever a computer or smart phone is used in the performance of the contract (“products or services containing ICT”)
- Unclear if applies to research contracts involving incidental use of ICT in performance of the research
- Comment deadline Feb. 2; COGR/EDUCAUSE to seek clarification
- CMMC rule issued Dec. 26; will require third party assessments of compliance with NIST security requirements for CUI
- Pending for 4 years; comments due Feb. 26

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