

Research Security & Intellectual Property Hot Topics

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Moderator:

Robert Hardy, Director of Research Security and Intellectual Property Management, COGR

Panelists:

Alexandra Albinak, Associate Vice Provost for Research Administration, Johns Hopkins University

Allen A. DiPalma, Director, Trade Compliance, University of Pittsburgh

Elizabeth Peloso, Associate Vice Provost, Research Services, University of Pennsylvania

Jennifer Ponting, Executive Director of Sponsored Programs, University of Chicago

Kenneth Porter, Director, University of Maryland College Park

Fred Reinhart, Senior Advisor for Technology Transfer, UMass Amherst

John Ritter, Director, Technology Licensing and Intellectual Property, Princeton University

Jarrett Cummings, Senior Advisor, Policy and Government Relations, Educause (Q&A)

Allen A. DiPalma
Director, Trade Compliance
University of Pittsburgh



Advance Notice of Proposed Rulemaking (ANPRM): Foundational Technologies

- Export Control Reform Act (ECRA) of 2018 requires Commerce to identify and control the export of emerging and foundational technologies.
- November 2018: Commerce (BIS) publishes ANPRM for Emerging Technologies. COGR partnered with multiple associations on a [response \(01/10/19\)](#) to this ANRPM.
- August 2020: Commerce (BIS) publishes ANPRM for Foundational Technologies.
- Emerging vs. Foundational: what is the difference?

Advance Notice of Proposed Rulemaking (ANPRM): Foundational Technologies (contd.)

Foundational Technology Issues for Academia:

1. Likely to include items already in widespread use, including those classified as EAR99!
2. Process of identification: inclusion of academics
3. New controls: preference for a scalpel vs. a sledgehammer
4. Possible chilling effect on innovation
5. Don't touch our exemptions (FRE, Public info)!!!
6. We have a voice- please comment!

**Fred Reinhart, Senior Advisor for Technology
Transfer
UMass Amherst**

**John Ritter, Director, Technology Licensing and
Intellectual Property
Princeton University**

**Ken Porter, Director
University of Maryland, College Park**



Letter from 34 Attorneys General re Gilead & Remdesivir

- Highly inaccurate on all fronts
 - Drug created by Gilead with own IP
 - Funding & funding type-not related to B-D
 - Adequate supply Q
 - Affordability Q
- Applicability to B-D march-in
 - None of the four march-in triggers in evidence
- Shows lack of understanding by AGs
 - Bipartisan; steppingstone to governorships

AUTM Response to AG Letter

- Cites huge benefits of B-D with startups, licensing, job creation and economic impact
- Remdesivir not created with federal funds
- NIH and BB&RD: “Pricing not a march-in trigger”
- Pharma & Bio risk >\$2 billion on R&D so inappropriate use of march-in will reduce investment.

Center for American Progress Article & March-in

- Cites increasing high cost of medicine
- Cites drug company monopoly power
- Discusses taxpayer support for drug R&D
- Points to: march-in & USC Section 1498
- Claims “reasonable pricing” and inadequate supply trigger
- Government patent use under Section 1498 avoids march-in problem, compensates IP owner

University Responses to Covid-19

- Many universities signed COVID licensing pledges or principles with some limits (AUTM, MIT/Harvard, e.g.)
- COGR joined AUTM statement but cited other considerations
- Where large investment, patent exclusivity will still be needed; for PPEs may not be necessary
- Recognition of unique situation; things may need to revert to more “standard” approach in a post-COVID world
- USPTO’s lancu says patents have not hindered response to pandemic

Universities must comply with federal reporting rules

- Activists & critics are pushing for intervention, compulsory patent licensing or government seizure of patents
- Most universities may not be up to date with B/D reporting requirements
- If a university or company grantee fails to do proper government reporting, assignment of patents to the federal government **IS A CONSEQUENCE PERMITTED UNDER B-D!**

Jennifer A. Ponting
Executive Director, Sponsored Programs
The University of Chicago



Higher Education Act of 1965: Section 117

- Section 117 of the HEA amended, requires the submission of disclosure reports to the Department of Education containing information about:
 - gifts received from any foreign source;
 - contracts with a foreign entity; and
 - any ownership interests in or control over the institution by a foreign entity.
- Specifically, all Title IV domestic institutions are required to report contracts with or gifts from the same foreign source that, alone or combined, have a value of \$250,000 or more for a calendar year; and/or if the institution is owned or controlled by a foreign source.

Timeline: Higher Education Act of 1965



New Portal & Requirements

- DoEd announced their new reporting system on June 22, 2020
 - Required to be used for the July 31 reporting deadline
 - Reports provided to the Agency prior to June 22 did not need to be re-submitted using the new system
- Required institutions to provide more information about their foreign financial ties than what was previously mandated
- Time consuming to use the Portal
 - Compounded by the timing of the portal launch date and the reporting deadline

Now What?

Department of Education appears very focused on Foreign Reporting and Foreign Influence Activity

- On August 3, 2020, Congress issued request for information to six Universities citing jurisdiction over Section 117 of the Higher Education Act
- In August 2020: Issued *Notice of 20 U.S.C. § 1011f Investigation and Record Request* to two Universities
 - Focus of records requests were dominated by PRC – related activities
- COGR provided detailed feedback and requested information from DoEd specifically on the new portal
 - No response from DoEd
- A joint letter from State and DoEd was sent to University Presidents on October 9, 2020.
 - More focus on PRC and specifically Confucius Institute U.S. Center (CIUS)
 - Included as an attachment a previous communication from State Department issued in August
- NSF OIG investigatory subpoenas



NEWSFLASH

DoEd has released a report titled: “Institutional Compliance with Section 117 of the Higher Education Act of 1965”

<https://www2.ed.gov/policy/highered/leg/institutional-compliance-section-117.pdf>

Questions?

Alexandra Albinak
Associate Vice Provost for
Research Administration
Johns Hopkins University



NDAA Section 889

- Section 889 of the National Defense Authorization Act (NDAA) FY19 became effective August 13, 2020.
- The statutory prohibitions of Section 889 are implemented through contracting prohibitions in the Federal Acquisition Regulations (FAR) (52.204-24, 25 and 26) and separately in a prohibition on use of grant funds through the updated Uniform Guidance (UG) (200.216).

FAR 52.204.24, .25 and .26

- 52.204-25(b)(1) Federal Government **may not**:
 - Procure from a contractor equipment, systems or services that uses covered technology as a substantial/essential component unless an exception applies or the equipment or services are covered by a waiver.
- 52.204-25(b)(2) Federal Government **may not**:
 - Enter into a contract or extending a contract with a contractor that uses any equipment, systems, or services as a substantial/essential component unless an exception applies or are covered by a waiver.
 - ***Regardless of whether such use is in performance of the Federal contract.***
- Exceptions include services that connect to facilities of a third-party (e.g. backhaul, roaming) and telecommunications equipment that cannot route or redirect user data traffic or permit visibility into data...

FAR 52.204.24, .25 and .26

- Prior to executing a contract with these FAR clauses, institutions must conduct a “reasonable inquiry” to assure that the university would not violate this prohibition by “using” such telecommunications products or services.
- Reasonable inquiry is defined as an inquiry designed to identify information in the institution’s possession about the identity of the producer or provider, but excludes the need to include an internal or third-party audit.
- The FAR requirement 52. 204-25(b)(2) (use) is limited to prime contractors and specifically does not apply to subcontractors.
 - See 52.204-24(e).

FAR 52.204.24 Representation

- Similar to Existing: The Offeror represents that it _ will, _ will not provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract, or other contractual arrangements.
- Addition: After conducting a reasonable inquiry, for the purposes of this representation, the Offeror represents that it _ does, _ does not use covered telecommunications equipment or services or use any equipment, system or service that uses covered telecommunications equipment or services.
- Starting October 26th, institutions will no longer be required to complete the certifications if they have answered **both** “ **will not** ” provide covered telecommunications equipment or services to the Government and, based on a reasonable inquiry, “ **does not** ” use covered telecommunications equipment or services.

FAR 52.204.25

- If an institution identifies covered equipment and believes it could be considered a substantial or essential component, and does not fall within an exception:
 - Report the information to the contracting officers within one business day.
 - Within 10 days following, provide additional information available, including mitigation plans, efforts to prevent, etc.
- Agencies are responsible for obtaining a waiver where needed/allowed.
- Several agencies have obtained blanket waivers for a period time to allow contractors to come into compliance.
 - DOD
 - USAID

NDAAs Grants Applicability

- Section 200.216 prohibits non-Federal entities **from obligating or expending** loan or grant funds to:
 - Procure or obtain,
 - Extend or renew a contract to procure or obtain; or
 - Enter into a contract (or extend or renew a contract) to procure or obtain, equipment, services, or systems that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as a critical technology as part of any system.
- Applies to both domestic and foreign subrecipients.

Uniform Guidance

- Inconsistency in UG language:
 - The UG II.A. states that Federal award recipients are prohibited from using government funds “to enter into contracts (or extend or renew contracts) with entities that **use** covered telecommunications equipment or services.”
- COGR letter on 9-24-2020 asked that UG II.A be revised so that the prohibition matches the prohibition as intended by the NDAA.
- **WARNING:** Institutions are beginning to see the misinterpreted “use” language in grants.
 - Agencies are working to clarify their grant terms to match 200.216 prohibition.

Elizabeth Peloso
Associate Vice Provost for
Research Services
University of Pennsylvania



Foreign Influence Management at the Department of Energy

- DOE O 142.3A Unclassified Foreign Visits and Assignments Program (12/13/2019) update from 1/18/2017
- DOE P 485.1, Foreign Engagements with DOE National Laboratories (12/13/2019)
- DOE O 486.1, Department of Energy Foreign Government Talent Recruitment Programs (6/7/2019)
- DOE O 486.1A, Foreign Government Sponsored or Affiliated Activities (9/24/2020)

485.1 Foreign Engagements with National Laboratories Establishes

- Review criteria for foreign engagements
 - Alignment with U.S. strategic interests
 - Compliant with U.S. laws and regulations
 - Addresses counterintelligence and national security concerns
 - Considers risks (access by sensitive countries to DOE information, Intellectual Property, as well as impact on U.S. competitiveness)
- Restrictions on agreements with foreign countries of risk as identified in the Science and Technology Risk Matrix
- Exemption request process and timeline for restricted engagements

486.1 Department of Energy Foreign Government Talent Recruitment Programs

- Purpose is to ensure continued flow of science and technical information while protecting U.S. competitive and national security interests and DOE program objectives; and limiting unauthorized transfers of scientific and technical information.
- Prohibits DOE employees and DOE contractors from participating in foreign talents recruitment programs from risk countries
- Establishes process for disclosure and review
- Exempts non-DOE contractor employees working under a Cooperative Research and Development Agreement; Strategic Partnership Project; Proprietary or Non-Proprietary User Agreement; Agreement for Commercializing Technology; or financial assistance agreements

486.1A, Foreign Government Sponsored or Affiliated Activities

- Purpose is to
 - Protect U.S. competitive and national security interests
 - Manage conflicts of interest/conflicts of commitment
 - Prevent unauthorized transfer/release of DOE information
- Applies to DOE employees and Contractors
- Does NOT apply to
 - Users conducting research under a DOE facility user agreement
 - DOE sponsored international collaborations

486.1A, Foreign Government Sponsored or Affiliated Activities (continued)

- Talents recruitment program participation in at risk country is prohibited;
- Other activities in risk countries are restricted including
 - Foreign risk country employment
 - Foreign risk country resources
 - Grants
 - Awards
 - Appointments
 - Scholarships
 - Sabbatical
 - travel
 - University directed funding
 - Honoraria

486.1A, What must be disclosed

- Positions and appointments, both domestic and foreign. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).
- Current or pending participation in, or applications to programs, e.g., grant programs, sponsored by foreign governments, instrumentalities, or entities. Associated contracts, upon request by DOE, must be disclosed, in addition to the fact of participation

486.1A, What must be disclosed

- All foreign country of risk entity resources made available, directly or indirectly, to a researcher in support of and/or related to all of their professional R&D efforts, including resources provided directly to the individual rather than through the research institution, and regardless of whether or not they have monetary value (e.g., even if the support received is only in-kind, such as office/laboratory space, equipment, supplies, or employees). This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, gifts, financial support for laboratory personnel, and participation of student and visiting researchers supported by other sources of funding. This further includes compensation, for example, current or promises of future: grants, awards, funding, scholarship, appointment, sabbatical, travel, university directed funding, and honoraria

486.1A, Exemptions for restricted activities

- Foreign activities must be disclosed to the head of the field element
- Activities must be suspended pending review and approval of the activity
- DOE must return with approval/denial decision within 30 days
- Contractors must report quarterly on activities

Robert Hardy
Director, Research Security &
Intellectual Property
Management
COGR



Cybersecurity and the CMMC

- Association letter to DOD 9/1 on need for fundamental research exemption from the CMMC program
- Expresses need for dialogue with DOD
- Flow downs from DOD primes singled out as particular concern

9/29 DOD Interim Rule *Assessing Contractor Implementation of Cybersecurity Requirements*

- All DOD contractors must obtain at least a Level 1 CMMC certification
- Level 1 is compliance with FAR Basic Safeguarding Requirements
- Rule states that contractors must implement FAR requirements immediately (if they've not already done so)
- FAR requirements apply to *Federal Contract Information* (FCI)
- FCI defined as information not intended for public release
- CMMC requirements based on NIST SP 800-171 security requirements for controlled unclassified information (CUI)

Fundamental Research and DOD Interim Rule

- Fundamental research is intended to lead to publication and dissemination of results, so FAR FCI requirements not applicable
- NIST requirements implemented thru DFARS 7012 clause that applies to safeguarding covered defense information (DOD CUI category)
- Fundamental research by definition cannot involve covered defense information, so 7012 clause is self-cancelling
- CMMC framework established by interim rule does not fit fundamental research
- Results in conceptual problem with seriously adverse consequences

Joint Association Comments

- Draft association comments make these points; also ask for clarity on no 800-171 self-assessment requirement for fundamental research
- Some understanding at DOD that CMMC will compromise achievement of DOD fundamental research objectives
- End game unclear but existential threat to ability to conduct fundamental research (and could spill over to other agencies)
- Encourage institutions to submit their own comments; volume matters!
- Institutions need to acknowledge importance of assuring appropriate cybersecurity, but a balance is needed

New DFARS Requirements in Interim Rule

- DFARS 204.7501 states that DOD contractors must achieve a CMMC certification and contracts cannot be awarded without a current one
- New DFARS 7021 clause implements the requirement for contracts and subcontracts
- Basic level CMMC includes restrictions on physical access and posting of public information antithetical to the open fundamental research environment
- Jeopardizes necessary sharing of findings and results essential to research progress