



December 19, 2018 Compliance
Webinar

Critical Considerations for Bayh-Dole Compliance



AGENDA

Attendees will learn:

- How to be compliant under the recently promulgated regulations
- Why early attention to compliance is more important than ever
- Recent actions regarding Bayh-Dole Compliance
- Upcoming regulations that will impact your compliance actions & burden
- Who is filing petitions requesting the government to take title to inventions
- What are the differing agency views on US manufacturing requirements
- Why complete reporting of all required data is critical
- How to set up data gathering to support reporting



Our Speakers

Nikki Borman, CEO Borman & Company, LLC

Robert Sahr, Choate, Hall and Stewart LLP



Bayh Dole Reporting Changes: Seven months in

- What's Been Learned From the Mouths of Agencies
- Requirements are Standard; Implementation Varies
- Edison Reporting vs. the Rest
- What To Know About Timing



Implications for the TTO

- Current and Desired State
- New Challenges Abound
- Where Are the Gaps?
- Staffing
- Attention at the Top
- Resources



Roles and Responsibilities

- Perception of Compliance
- Resourcing Compliance
- Collaboration Across Institution (s)
- Value of Compliance.



Roles and Responsibilities-Going Forward

- Challenges presented by the New World Order
- Here's What Can Fall Through The Cracks
- Here's What We Recommend
 - Best Practices
 - Structure
 - Teaming
 - Training
 - Timeline



An Overlooked Requirement

- Mandate Staff Training Across All TTO Levels
 - Technical Training
 - Continued Education
 - Teaming Practice
 - Standard Action/Actors in Compliance
- This is Something Your TTO ***Can and Should Do Now***
- In Fact, Review Your Training Overall; who gets it and what should it be
 - TLO, Administrative, Researchers others that hold a piece of the compliance chain



Heads-up Administration!

- What's Important:
 - The foundation of ***Technology Transfer Rights*** rests upon compliance
 - This was the agreement between federal funding agencies and recipients of federal funding
 - The value of compliance needs to be elevated on par with licensing, patenting and products on the market
 - Failure to honor the *Agreement* with the Federal Funding Agencies puts rights in peril, in the same manner that licensees who are not compliant with Technology Licensing Agreements put their rights at peril.



Heads-up Administration!

- Getting Attention and Resources
 - Develop Standard Reports Regarding **Bayh-Dole** risk technology Technology
- What to Track and Measure
 - How to get the information
 - Who to collaborate with
 - How to report internally and to Edison
 - Unintended consequences of catching up
 - Things will get deeper in the short term
 - You will catch up: although compliance is ongoing
- Recent Requests and Difficulties



Heightened Scrutiny for Bayh Dole Compliance



Bayh-Dole Compliance

§401.14 (c) Invention Disclosure, Election of Title

(c)(1) disclose each subject invention to the Federal Agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters

(c)(2) elect in writing whether or not to retain title to any such invention by notifying the Federal agency within two years (may be shortened)



Forfeiture of Title

§401.14 (d) Conditions When the Government May Obtain Title

The contractor will convey to the Federal agency, upon written request, title to any subject invention—

(1) If the contractor **fails to disclose or elect title to the subject invention within the times specified in paragraph (c)** of this clause, or elects not to retain title



Compliance

NIH Notice Number: NOT-OD-16-066 (2016)

- This Notice is issued to remind ALL awardee institutions that the HHS 568 must be filed by a grantee or contractor at the conclusion of a grant or contract. It requires the reporting of all subject inventions that were made under an applicable NIH funding agreement.
- Additionally, all subject inventions that were made under an applicable funding agreement and reported on the HHS 568 must be reported in iEdison. **Failure to report (on the HHS 568 AND in iEdison) all inventions funded in whole or in part by NIH may result in your organization's loss of rights in the invention or other actions as appropriate.**

- DoD has equivalent DD Form 882



Campbell Plastics v. Army, 389 F.3d 1243 (Fed. Cir. 2004)

- Army demanded title to invention (protective mask) developed pursuant to contract
- Campbell Plastics provided progress reports, but did not list invention on DD Form 882
- Court of Appeals: “While it is at least debatable whether the various progress reports and drawings Campbell Plastics submitted to the Army together convey a clear understanding of [the invention], we think the contract requirement of a single, easily identified form on which to disclose inventions is sound and needs to be strictly enforced.”



Consequences of Noncompliance

Practical Considerations

- Typically issues arise during IP diligence
- Failure to disclose or elect title creates a cloud on title
- Deals have been halted until 60 day window expires, or made conditional

New regulations

- Cloud on title is permanent
- Risk of loss lowers value of deal
- Loss of title to even a single patent that covers a commercial product creates potentially devastating FTO issue



Heightened Scrutiny for Bayh-Dole Compliance

Internal

- GAO report noted that federal contractors and grantees were not meeting the reporting requirements associated with the Bayh-Dole Act
- Substantial discrepancies between number of grants awarded invention disclosures received

External

- Multiple recent requests for NIH to exercise march-in rights or take title



Recent Requests

Knowledge Ecology International (KEI)

- | | |
|------|---|
| 2018 | <u>University of Pittsburgh Failure to Disclose Federal Funding for Patents on Vizamyl (INN flutemetamol F 18). May 18, 2018.</u> |
| 2018 | <u>Six organizations ask HHS Secretary Azar to take title of 5 patents on Exondys 51, as remedy to failure by inventors to disclose NIH funding. April 5, 2018.</u> |
| 2018 | <u>James Griffin, Dana-Farber Cancer Institute and Novartis failure to disclose NIH funding for patents on leukemia drug midostaurin (Trade name Rydapt), March 21, 2018.</u> |
| 2018 | <u>Six University of Pennsylvania and Daniel J. Rader patents on Juxtapid (lomitapide) failed to discuss multiple NIH grants, March 19, 2018.</u> |
| 2018 | <u>KEI request that HHS take ownership of US Patent 7,964,580 on sofosbuvir, now held by Gilead, for non-disclosure of NIH grants, March 14, 2018.</u> |
| 2018 | <u>Following KEI request for investigation, Cold Spring Harbor Labs says 7 patents require correction to disclose federal funding, October 20, 2017.</u> |



Recent Requests

Knowledge Ecology International (KEI) (Continued)

- | | |
|------|---|
| 2017 | <u>Fred Hutchinson Cancer Center often fails to disclose federal funding of inventions on initial patent, October 20, 2017.</u> |
| 2017 | <u>Penn "Certificates of Correction" on Federal Funding for 5 CAR T Patents, October 18, 2017.</u> |
| 2017 | <u>KEI finds University of Pennsylvania failed to disclose government rights in five CAR T patents, October 17, 2017. Updated on October 18, 2017 to address Certificates of Corrections on the five patents.</u> |
| 2017 | <u>Spinraza: KEI asks DHHS Office of the Inspector General (OIG) to investigate a failure to disclose federal funding in patents, January 19, 2017</u> |



US Manufacturing Requirement

- **Statutory**

- 35 U.S.C § 204: Preference for US Industry

- No small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall **grant to any person the exclusive right** to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States.
- Requirement may be waived ... upon a showing that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.



US Manufacturing Requirement

DOE view (GAO 15-212 Report to Congress, 2015)

- U.S. Preference provisions generally require small business and nonprofit contractors' exclusive licensees to substantially manufacture federally funded inventions domestically in order to use or sell the inventions in the United States. These requirements apply only to a contractor's exclusive licensee; the contractor that developed the invention faces no limitations on manufacturing location



US Manufacturing Requirement

NIH view

- US Manufacture requirement applies to grantees as well as exclusive licensees



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Transforming Ideas into Opportunities

Take Away Actions



Get Your Ducks in a Row

- Review Organization Structure: Mind the Gaps
- Reassess the Workflow: Map to This New World
- Educate/Train Staff
- Create Collaborative Work Structure Along the Value Chain
- Provide Feedback to Agencies-Now
- Monitor Gov't Actions That Could Impact Your Reporting
- Maintain a sense of humor and accomplishment!



Speakers Today

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