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Transforming Ideas into Opportunities

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The New Bayh-Dole Rules: What They Are, What They Mean



Webinar Panel

- **Paul Zielinski**, Director of the Technology Partnership Office
National Institute of Standards and Technology (NIST)
- **Bob Hardy**, Director of Contracts and Intellectual Property
Council on Governmental Relations (COGR)
- **Valerie McDevitt**, Associate Vice President for Technology Transfer and
Business Partnerships, University of South Florida
- **Mike Waring**, Executive Director of Federal Relations, University of
Michigan, and Chair of AUTM's Public Policy Advisory Committee



Updating Bayh-Dole Regulations

Paul Zielinski

Director, Technology Partnerships Office
National Institute of Standards and Technology



Background



**PRESIDENT'S
MANAGEMENT
AGENDA**

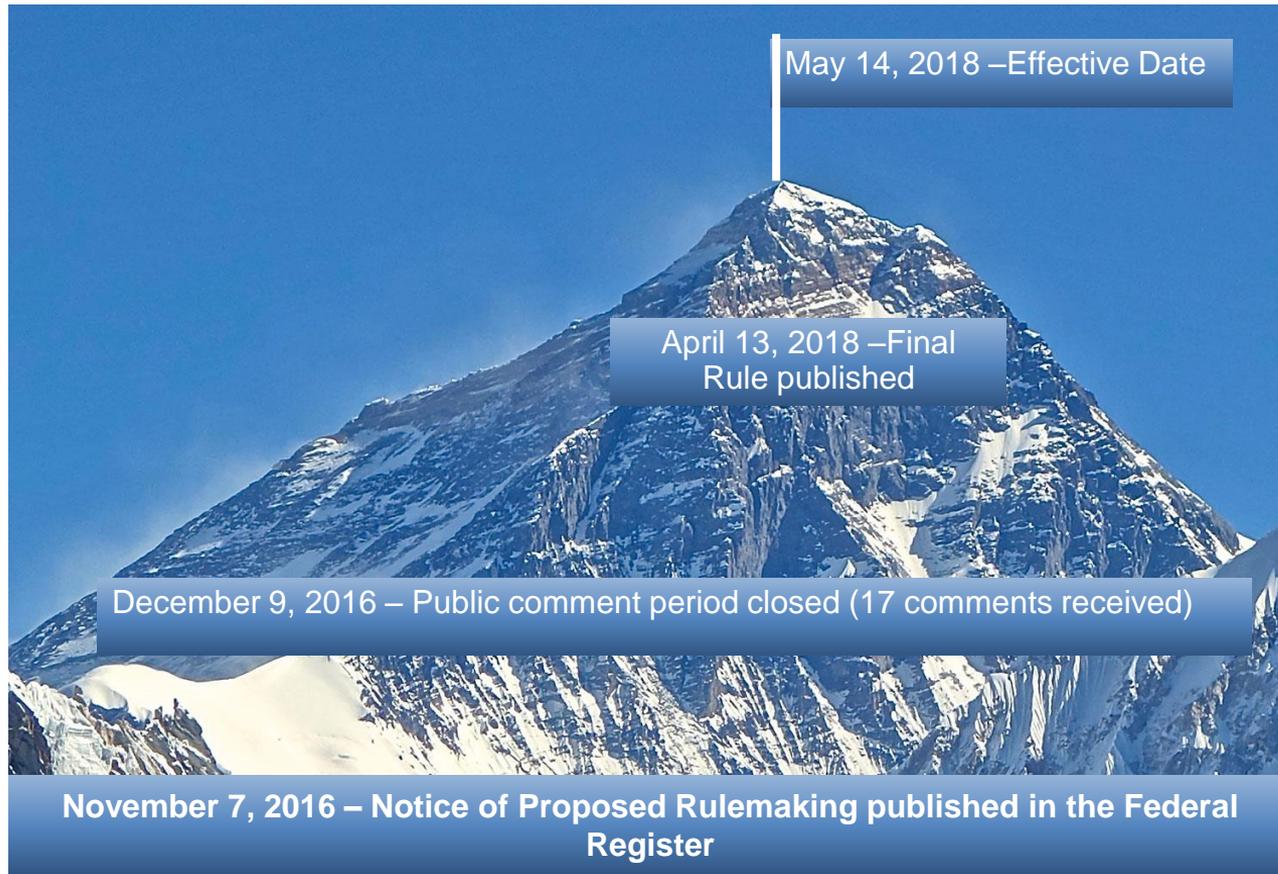
NIST



Goals

- America Invents Act timelines, definitions, and royalty payment requirements were in conflict with regulatory provisions in Bayh-Dole
- Certain scenarios were not contemplated in original Bayh-Dole Act
- Codification of EO 12591 in regulation
- Turns out we numbered sections of the original regulation wrong...

Timeline



Looking Ahead

**President's
Management Agenda**
Cross Agency Priority Goal
**14 Improve Transfer of
Federally-Funded
Technologies from Lab-to-
Market**
Performance.gov

NIST ROI Initiative
Comment period ends July 30
Public meetings:
San Jose CA (May 17)
Denver CO (May 21)
Chicago IL (May 31),
Gaithersburg MD (June 14)
nist.gov/tpo/roi

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The Bottom Line

- Does not change basic Bayh-Dole regime
- Specifically incorporates large businesses
- A number of the changes are significant and will have impact on TTOs
- **Note:** Bayh-Dole regs also contain provisions on CRADAs and licensing of government-owned inventions as well as agency-specific requirements pertaining to DOE. We will not further consider as they are of limited relevance to most AUTM members.

Assignments

- From a compliance standpoint biggest change is to extend the employee written agreement requirement to include assignments to the contractor of the entire right, title and interest in each subject invention (401.14(f)(2))
- Responds to *Stanford v. Roche* decision
- Previously no clear *regulatory* requirement for assignments

Time Period Changes

- Changes in certain prescribed time periods of greatest operational significance
- Previously contractors had to notify agencies 30 days prior to the statutory deadline of any decision not to continue patent prosecution, pay maintenance or other fees, or defend a patent (e.g. IPRs, reexaminations, etc.).
- Now 60 days (401.14(f)(3)) (Proposal was 120)
- Note: applies only to non-provisional applications; status of abandoned provisionals unclear under the new rules

Time Period Changes—Continued

- Another significant change is to require filing of a non-provisional application within 10 mos. of filing a provisional (401.14(c)(3))
- Automatic one-year extension upon request to funding agency unless agency notifies the contractor within 60 days of receiving request
- Not in original proposal

More Time Period Changes (And Not)

- Also no time limit now for agency to request title when contractor fails to disclose or elect title to an invention (previously agencies had 60 days to do so—(401.14(d)(1))
- But proposal for agencies to shorten two-year time frame for contractor election of title (401.14 (c)(2)) “if necessary to protect the Government’s interest” was not adopted

Other Changes

- Detailed new language on federal co-inventor situations (401.10)
- Small business preference concerns now to be reviewed by funding agencies rather than Commerce (401.14(k)(4))
- New provision added permitting alternatives to Bayh-Dole rights when agencies contract for services with a non-profit that does not promote commercialization (401.3(a)(6))

What Else?

- Many changes reflect or recognize America Invents Act
- “Initial patent application” definition expanded to include first provisional or non-provisional U.S. or PCT application (401.2(n))
- Changes do not address invention reporting, but NIST notes in Preamble that it is working with NIH to update and improve iEdison
- ROI outcome may lead to further changes

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View from a Tech Transfer Office

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Q&A





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Thank You For Joining Us!