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Technology Transfer in the Crosshairs: How to Help Your University Make Its Case

Welcoming remarks will begin at
11:55 a.m. Eastern Time.

The formal presentation will begin at Noon Eastern

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2

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Technology Transfer in the Crosshairs: How to Help Your University Make Its Case

Moderator:
David Winwood, AUTM President

Speaker:
Mike Waring, AUTM Public Policy Chair

April 21, 2016

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Questions?

We will be taking questions at the conclusion of the presentation.

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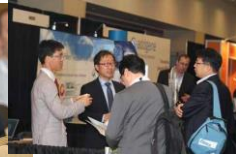www.autm.net/events

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– AUTM Salary Survey
– AUTM Technology Transfer Practice Manual

In-person and Online Networking

– Special Interest Groups (SIGS)
– Online Discussion Groups
– Volunteer committees

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David Winwood, Ph.D., RTTP,
AUTM President

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Michael Waring,

AUTM Public Policy
Committee Chairman

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TECH TRANSFER IN THE CROSSHAIRS

HOW TO HELP YOUR UNIVERSITY MAKE ITS CASE

- **Moderator: David Winwood, AUTM President**

- **Speaker: Mike Waring, AUTM Chair, Public Policy Advisory Committee, and Executive Director of Federal Relations, University of Michigan, Washington DC**

Title here

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Goals of this Webinar

- Update tech transfer directors on latest issues facing us in Washington
- Inform tech transfer offices how they can play a key role in ensuring that their university's voice is heard on those issues
- Questions and answers

13

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Washington and Tech Transfer

- Increasingly, Congress and federal agencies taking much more interest in our world
- Considering legislation and regulations with a direct impact on commercialization
- AUTM's role is to help advise our sister organizations to help respond to that increased scrutiny

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Allies in DC

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How We Collaborate

- Monthly calls
- Meetings in DC and at events around the nation
- Joint letters, amicus briefs
- AUTM data
- Better World Report – videos – other AUTM materials

Informing the Dialogue

- Through its advocacy, AUTM helps our presidential associations earn a "seat at the table" when issues are discussed
- We help advise on impacts of laws and regulations
- Critical role which is increasingly important, given new interest in our activities

Update on DC Issues

Mike Waring
Chairman, Public Policy Advisory Committee

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Busy Time in Washington

- Election year
- Congress bogged down in politics
- Presidential campaigns
- Budgets tight
- More scrutiny on everything

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Numerous Issues Facing
Tech Transfer

- Patent legislation
- NIH March-in Rights and drug pricing
- Regulations that could impact IP generated by federal research investments
- Fundamental misunderstandings about role IP plays in economy

Patent Reform Issues

- History
  - America Invents Act passes in 2011
  - Even before ink is dry, some patent users clamoring for more changes
  - Claims that patent "trolls" are hurting innovation
  - Legislation in last Congress stalled and pulled
  - Supporters renew effort in this Congress

Current Patent Bills

- HR 9 (House Judiciary Committee)
  - Of serious concern to higher ed
  - Fee shifting, joinder, other anti-patent provisions
  - AUTM working with AAU, APLU et al to oppose
  - Voted out of Judiciary Committee but has not come to House floor, thanks to numerous objections, particularly by conservatives
  - *Inter partes* review at PTO a major stumbling block

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Current Patent Bills

- S. 1137 (Senate Judiciary Committee)
  - Similar bill to HR 9
  - Some improvements negotiated with higher ed but further changes sought
  - Approved by committee but similarly stalled by concerns, IPR issues

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Latest Wrinkle

- S. 2733 (Flake/Gardner)
  - Venue provisions pulled out of House bill in attempt to try and move as separate legislation
  - Focused on high number of lawsuits filed in a few district courts (Eastern District of Texas, e.g.)
  - Issue less of a concern for higher ed, but could be vehicle for things we are concerned about
  - Consumer Technology Association supports

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Courts Continue to Act

- U.S. Supreme Court to hear case about IPRs this month – decision in June
- Venue issue also being addressed
- Many of the reasons legislation was proposed are being addressed by judicial system
- Fewer lawsuits being filed
- Need for legislation unclear

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Cuozzo Speed v. Lee

- Fight over how USPTO has used IPRs to consider patent validity
- Claims construction standard too broad
- Well beyond intent of American Invents Act
- A complement to court, not a substitute
- Courts should be able to review IPR decisions

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Sequenom v. Ariosa Diagnostics

- Case deals with patent-eligible subject matter involving biotechnology
- Hopefully will rein in courts' use of "judicial exceptions" to deny patents to certain biologics
- AUTM has signed onto amicus brief

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NIH March-in Rights

- Old issue with renewed focus
- Recent stories about high drug prices generated Dec. letter to HHS/NIH from 50 House Democrats, led by Rep. Doggett (D-TX)

- Lawmakers urged agencies to use march-in authority to rein in drug prices

- In absence of that, urged that agencies create "reasonable guidelines"

- Later, two petitions about specific drugs were sent
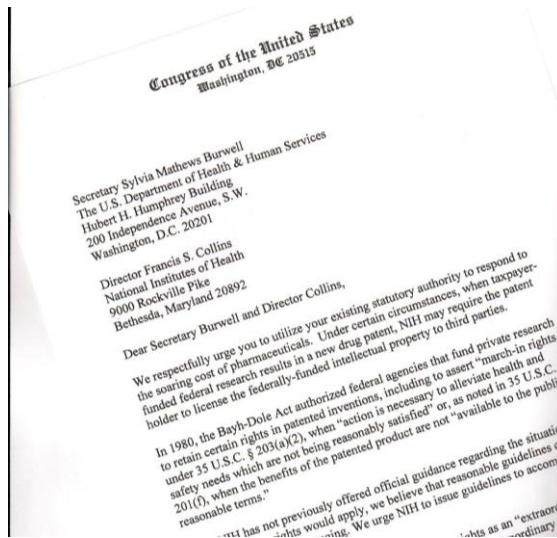
NIH/HHS Reject Request

- Agencies say Bayh-Dole not designed to control drug prices, but to ensure companies do not sit on new therapeutics

- In late March, 12 House and Senate members rewrote, asking that agencies hold open public hearing on one such drug, Xtandi, developed at UCLA to treat prostate cancer

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Difficult Issue

- PhRMA and BIO working to counter concerns
- Universities not the "culprit"
- Drug prices have become campaign issue
- Sen. Sanders one of the signers of the March letter

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Open Licensing

- Proposed rule at Department of Education would require open licensing of software developed with federal grants
- Similar language at Department of Labor
- Associations have weighed in with concerns
- Working with library interests, hoping D of Ed will modify

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OMB Open Source Issue

- Office of Management and Budget looking at draft "open source" policy announcement
- Would affect custom-designed software
- Possible pilot program would require at least 20% be open sourced
- OMB asking questions – associations responding

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NIST Looking at Bayh-Dole

- Learned recently of potential effort by NIST to re-interpret Bayh-Dole
- Another example of agency unaware of other activities, such as NIH march-in requests

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Similar Threads

- Outright attacks on patents
- Misunderstanding of how IP plays important role in developing technologies for public
- If not careful, government may take away incentives for companies to risk capital to develop new ideas, products

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Tech Transfer Office Role

- <u>You</u> are the experts
  - You see early-stage technologies
  - You deal with faculty, inventors, capital markets
  - You understand cost of patenting, need to have exclusive rights to develop new ideas
  - You have examples of projects that have come to fruition and some that have not

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Working with Your
University Leadership

- Need to have unified view of role of tech transfer on your campus
- AAU and APLU presidents both had task forces last year reiterate notion that tech transfer occurs not to enrich university, but to serve the "public good"

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Know Your
Federal Relations Officer

- This person needs your expertise
- If you have in-house counsel, needs their reading on legislation or proposed rules
- This person needs your examples, your success stories
- This person is your key contact on all of these issues

First Rule of Thumb

- Explain to policymakers <u>how your business works</u>
  - Unless they see how ideas develop, become patents, get funding and support, they will never understand why we care about patents, IP
  - Need to understand relationship to capital markets, where risks must be taken to advance new technologies

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Allies

- Your spin-off companies
- The local chamber of commerce
- Economic Development authorities
- All politics is "local"
- Stress jobs, local impact

You Have Resources

- Annual reports
- Innovation Fairs or other activities
- Press releases about new companies or deals with existing ones
- All of these can be used

AUTM Has Resources

- Better World Report

http://www.betterworldproject.org/

https://www.youtube.com/watch?v=ygX5zcU5vdg

Video to explain what Tech Transfer Is

Info-graphic on Value of Tech Transfer to America
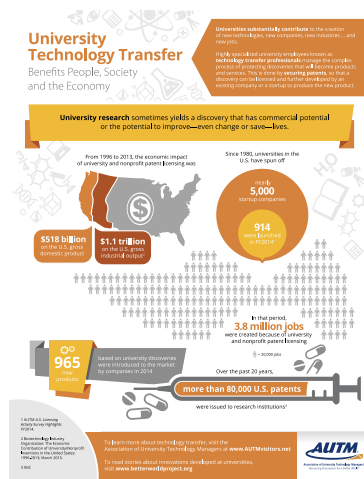
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What You Can Do

- Make sure you have relationship with federal relations, general counsel
- Volunteer to assist with information, tours, etc.
- Make people aware of information you have, especially local
- Your role is not to lobby, but to be there to help

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QUESTIONS AND ANSWERS

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Discussion
and Q&A

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Basics of Technology Transfer for Licensing Professionals
Basic Patenting 101
Copyright Law and Content/Software Licensing
Equity Based License Agreements
Financial Conflicts of Interest
Marketing: Whether By Traditional or Social Media, the Value
Need to Know Basics of Technology Transfer for Support Staff
Negotiation of License Agreements
Nuts and Bolts for Compliance Under Federal Funding Awards
The Basics of Open Source Licensing
Tips for Managing MTAs
Triage
Valuation of Inventions and Patents
(More Added Monthly)

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Register now for AUTM's next webinar

- **IP Basics for Software Innovations**
- **Tuesday, April 26**

- **Nexus Between Research Administrators & Tech Transfer**
- **Thursday, May 19**

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AUTM Eastern Region Meeting
Sept. 29 – 30
The Westin Philadelphia
Philadelphia, PA USA

AUTM Central Region Meeting
July 18 – 20
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Saskatoon, Canada

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**Interested? Please contact
Melinda Briggs – mbriggs@autm.net**

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**March 12 – 15
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