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Mind the Gap: Fixing Problems with Chain of Title From Inventor to University

Moderator:

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Speakers:

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About the panel:

Michael A. Gollin, Partner, Venable LLP, magollin@venable.com

Michael Gollin is a patent attorney with almost three decades experience in intellectual property law. He chairs Venable's Life Sciences group, teaches business and law classes, and publishes frequently. He was counsel on an *amicus* brief for Sen. Bayh in *Stanford v. Roche*.

Janna Tom, Assistant Director, Policy, University of California, Janna.Tom@ucop.edu

Janna Tom has worked in the intellectual property policy unit for more than 20 years at the University of California Office of the President.

Bryce Pilz, University of Michigan, bpilz@umich.edu

Bryce Pilz is Associate General Counsel in the Office of General Counsel where he has served since 2006, working on patent and copyright transactional and litigation matters involving software, medical devices, and engineering technologies. He has litigation experience and also teaches at the law school.

Kevin Marks, Roche Molecular Diagnostics, kevin.marks@roche.com

Kevin A. Marks is Vice President and General Counsel and is responsible for legal and patent functions. He previously was VP and General Counsel for Roche Palo Alto and was also responsible for overseeing the Environmental Health & Safety and Quality Assurance functions.

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Agenda

- Chain of title basics
- Stanford v. Roche background and holding
- Implementing new practices
 - UM and UC
- Results of Survey on Implications of Stanford
 v. Roche
 - Who's doing what?
 - Open discussion

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Chain of title basics

- "Nemo dat quod non habet"
 - "You can't give what you don't have"
- Chain of title is only as good as its weakest link
- A --> B --> C --> D
 - faculty to university to licensee to customer
- Stanford University v. Roche Molecular Systems
 - University title to faculty invention superseded by faculty-industry agreement

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Chain of title significance

- Doctrine of supremacy of present conveyance
 - FilmTec line of cases
- Special problems to avoid or fix
 - multi-institution inventions (exclusivity?)
 - inventorship problems (now and post-AIA)
 - Licensing (valuation and warranties)
 - litigation
- Differences in university and industry strategies



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Stanford v. Roche Factual Background

1988	Holodniy joins Stanford, signing employment agreement: "agrees to assign" patent rights"
1989	Holodniy visits Cetus, signing VCA: "hereby assigns" inventions created "as consequence of work at Cetus." Spends 9 mos. at Cetus.
1991	Stanford researchers invent diagnostic test using NIH funding
1991	Roche acquires Cetus
1992	Stanford applies for patent on diagnostic test
1995	Holodniy assigns rights to Stanford: "hereby assigns." Stanford notifies NIH it elects to retain title.
2000	Stanford and Roche enter negotiations for a license to Stanford's patent rights
2005	Stanford sues Roche for patent infringement



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Procedural Background

District Court

- Under Bayh-Dole Act, Holodniy had no rights to assign to Cetus/Roche
- Patents invalid

Federal Circuit

- Holodniy's agreement with Cetus assigned his rights to Cetus/Roche
- Bayh-Dole Act did not automatically void an inventor's rights in federally funded inventions
- Therefore, Stanford lacked standing for failure to join the jointowner
- Remanded on invalidity question

Supreme Court • Granted cert on Bayh-Dole question



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Amicus Briefs

Stanford	Roche
AAU	IPO
Birch Bayh	Pharm. Research and Mfg. Of America
John Sutton	Intel, Eli Lilly, J&J, Pfizer, etc.
U.S.	BIO
Alexander Shukh	AAUP, IEEE, and IP Advocate
Bayhdole25, Inc.	AIPLA ("neutral")
National Venture Capital Assoc.	



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Supreme Court

- Bayh-Dole Act does not automatically vest title to federally funded inventions in contractors or allow them to take title unilaterally
- Bayh-Dole Act does not depart from premise that rights belong to inventor and only addresses rights as between government and contractor



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Supreme Court (more)

Roberts Majority

- Bayh-Dole does not automatically displace inventor's rights
- FN2: "Because the Federal Circuit's interpretation of the relevant assignment agreements is not an issue on which we granted certiorari, we have no occasion to pass on the validity of the lower court's construction of those agreements."

Sotomayor Concurrence

• Concerns about contract question (Federal Circuit's application of *FilmTec* to agreements in this case

Breyer/Ginsb erg Dissent

- Relies heavily on examples where rights do initially vest with entities other than inventor
- Would have ruled differently on the contract question



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University Reaction

Employment Agreement

- Incorporate present assignment language
- Questions as to whether to have existing employees sign new agreements

Invention Reports

- Incorporate present assignment language
- Incorporate language confirming earlier assignment in employment agreement
- Educate Tech Transfer staff about importance of obtaining signed Invention Reports

Consulting Agreements

- Educate researchers on potential implications of broad language in consulting agreements
- •Questions as to university involvement in reviewing researchers' consulting agreements

Licensing / Sponsored Research Agreements

• Questions as to whether Universities will be asked to provide contractual assurances of title (reps, warrants, indemnification)



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UM Bylaw 3.10

Sec. 3.10. Ownership of Patents, Copyrights, Computer Software, Property Rights, and Other

Unless otherwise provided by action of the Regents:

 Patents and copyrights issued or acquired as the result of or in connection with administration, research, or other educational activities conducted by members of the university staff and supported directly or indirectly (e.g., through the use of university resources or facilities) by funds administered by the university, regardless of the source of such funds, and all royalties or other revenues derived therefrom shall be the property of the university.



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IMPLICATIONS FOR UNIVERSITIES UNIVERSITIES SHOULD:

- Make sure employee assignment agreements include a present conveyance of rights ("I hereby assign"), rather than a promise to assign
 - Record assignments promptly.
- Adapt policies, practices, and training to identify problems that might arise when researchers sign industry agreements that could conflict with their obligation to assign patentable rights to the university (e.g., consulting agreements, visitor agreements, and material transfer agreements).



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IMPLICATIONS FOR UNIVERSITIES

UNIVERSITIES SHOULD:

- Prepare for due diligence by existing and new licensees regarding chain of title for both older and newer inventions.
- Look for possible changes in federal agency grant agreements as they relate to assignment of inventions.



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IMPLICATIONS FOR CORPORATIONS CORPORATIONS SHOULD:

- When licensing, conduct due diligence and seek assurances from university licensors that there are no encumbrances on ownership of the licensed patent rights.
- When accused of infringement by a university, consider attacking the university's standing on grounds of ineffective assignment as in the Stanford case.



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CORPORATIONS SHOULD:

 Look for ways to resolve clouds on title and ownership conflicts that may arise, e.g. through negotiation, mediation, or test cases.



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University of California Process

- No change to the UC Patent Policy
- Updated Patent Acknowledgment form
 - Effective 11/1/11 for new hires at all 10 campuses
 - Added present assignment of rights
 - Clarified/narrowed scope of rights
- Asked 225,000 current employees to sign Amendment
 - All personnel hired before 11/1/11
 - 3 month window for all-electronic process 11/28/11-2/29/12
 - Managed by outside vendor
- Mid-March, establish database showing who has signed new language



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Some Lessons Learned

- In spite of meeting with many systemwide groups, use more communications to both administration and employees - earlier and more often
- Get earlier buy-in by academic/admin leadership
- Regular work group and project manager be nimble
- Know your population to address issues earlier
- Regular reports frequent and deliver to those who will be proactive



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SURVEY ON IMPLICATIONS OF STANFORD v. ROCHE ON ASSIGNMENT PRACTICES

Describe survey

Summarize results

Discuss implications



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Methodology

- Developed questionnaire
 - Moderator and panel
 - Vetted with several universities and revised
- AUTM distributed to OTT directors Feb 2012
- 68 responses (12% response rate)
 - No individual results were saved
- Analysis to follow
 - contact panelists and AUTM VP Metrics and Surveys shawn.hawkins@stjude.org



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1. Which of the following best describes your institution? (choose one)

		Response Percent	Response Count
Public U.S. university		49.3%	33
Private U.S. university		26.9%	18
Non-academic U.S. research institution		19.4%	13
Non-U.S. university	1	1.5%	1
Non-U.S. research institution	•	3.0%	2
Associate member		0.0%	0
		answered question	67
		skipped question	1



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2. To whom did your patent assignment practices/policies apply prior to Stanford v. Roche? (choose all that apply.)

	Response Percent	Response Count
Faculty	98.1%	52
Non-faculty researchers	90.6%	48
Staff	94.3%	50
Students who use University research resources and facilities	79.2%	42
Visitors	54.7%	29
	Other (please specify) Show replies	8
	answered question	53
	skipped question	15



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Which of the following best describes your general patent assignment policy prior to Stanford v. Roche? (choose one)

	Response Percent	Response Count
Individuals are required to sign an agreement with present conveyance language ("I hereby assign")	20.8%	11
Individuals are required to sign an agreement with future assignment language ("I agree to assign").	47.2%	25
Individuals are required to sign an agreement with "my employer shall own" language.	5.7%	3
No agreement is required but a policy states that the university/research institutiion owns the intellectual property.	24.5%	13
None of the above.	1.9%	1
	Other (please specify) Show replies	8
	answered question	53
	skipped question	15



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 How did your institution implement its patent assignment policy prior to Stanford v. Roche? (Choose all that apply.)

	Response Percent	Response Count
In an agreement signed at time of employment/appointment	55.6%	30
In an employment letter at the time of employment	13.0%	7
In a general faculty/staff employment policy	59.3%	32
When submitting a research proposal or accepting a research award	9.3%	5
Only by presenting assignment for execution when filing a patent application	22.2%	12
When clearing conflicts of interest for consulting arrangements	0.0%	О
	Other (please specify) Show replies	7
	answered question	54
	skipped question	14



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5. Did your policies concerning patent assignment distinguish between federally funded research and non-federally funded research? If yes, please explain.

	Response Percent	Response Count
Yes	5.5%	3
No	94.5%	52
	If Yes, please explain. Show replies	3
	answered question	55
	skipped question	13



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Does your institution review and approve any of the following types of individual agreements with other institutions or industry? (check all that apply)

	Response Percent	Response Count
Confidentiality	83.6%	46
Consulting	38.2%	21
Collaboration	81.8%	45
Material transfer	94.5%	52
Sponsored research outside the university	52.7%	29
Visitor Agreements between your faculty/staff/students and an outside entity	45.5%	25
Visitor Agreements between outside faculty and your institution	69.1%	38
	answered question	55
	skipped question	13



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	Response Percent	Response Count
Yes, after the Supreme Court decision	41.8%	23
Yes, after the lower court (Federal Circuit) decision	30.9%	17
Yes, independent of Stanford v. Roche	12.7%	7
No, but plan to	9.1%	5
No, do not plan to (Skip to 'Other Outcomes')	5.5%	3
	answered question	55
	skipped question	13



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8. To whom does your new patent assignment policy apply? (Choose all that apply.)

	Response Percent	Response Count
Faculty	100.0%	43
Non-faculty researchers	95.3%	41
Staff	93.0%	40
Students who use university research resources and facilities	79.1%	34
Visitors	55.8%	24
	Other (please specify) Show replies	16
	answered question	43
	skipped question	25



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Which of the following best describes your patent assignment policy after Stanford v. Roche? (Choose one)

		Response Percent	Response Count
Individuals are required to sign an agreement with present conveyance language ("I hereby assign")		59.6%	28
Individuals are required to sign an agreement with future assignment language ("I agree to assign")	•	4.3%	2
Individuals are required to sign an agreement with "my employer shall own" language.	-	4.3%	2
No agreement is required but a policy states that the university/research institution owns the intellectual property.		25.5%	12
None of the above.	_	6.4%	3
		Other (please specify) Show replies	12
		answered question	47
		skipped question	21



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10. How is your institution implementing new patent assignment policy to staff? (Choose all that apply.)

	Response Percent	Response Count
In an agreement to be signed by all new and existing employees/appointees	26.7%	12
In an updated employment letter at the time of the next change in employment status	13.3%	6
In an agreement to be signed by new employees only, but not existing employees	26.7%	12
In a general faculty/staff employment policy	57.8%	26
When they submit a new grant proposal or accept award	20.0%	9
When they submit an invention report	44.4%	20
When clearing conflicts of interest for consulting arrangements	4.4%	2
	Other (please specify) Show replies	15
	answered question	45
	skipped question	23



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11. Do your new policies distinguish between federally funded research and non-federally funded research? If yes, please explain.

	Response Percent	Response Count
Yes	6.4%	3
No	93.6%	44
	If Yes, please explain. Show replies	6
	answered question	47
	skipped question	21



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12. In response to Stanford v Roche, is your institution going to begin to review and approve of any of the following types of faculty/staff/student industry agreements that it did not previously review? (check all that apply)

	Response Percent	Response Count
Confidentiality	70.0%	7
Consulting	60.0%	6
Collaboration	40.0%	4
Material transfer	60.0%	6
Visitor agreements – outgoing	60.0%	6
Visitor agreements - incoming	60.0%	6
Sponsored research	60.0%	6
	answered question	10
	skipped question	58



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13. Is your institution implementing any training or compliance programs in the wake of Stanford v. Roche? If yes, please explain.

	Response Percent	Response Count
Yes	22.4%	11
No	77.6%	38
	If Yes, please explain.	12
	answered question	49
	skipped question	19



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14. Have any of your licensees or potential collaborators changed their due diligence practices as to chain of title for old or new inventions? If so, explain.

	Response Percent	Response Count
Yes	18.5%	10
No	81.5%	44
	If yes, please explain. Show replies	8
	answered question	54
	skipped question	14



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15. Have any licensees raised questions about the adequacy of your institution's chain of title, or sought warranties that there are no encumbrances on ownership of the licensed patent rights?

	Response Percent	Response Count
Yes	30.2%	16
No	69.8%	37
	answered question	53
	skipped question	15



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16. Have any licensees asserted of	claims about chain of title?
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	Response Percent	Response Count
Yes	3.7%	2
No	96.3%	52
	answered question	54
	skipped question	14



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17. Are you aware of any federal grant-making agencies raising any questions about the adequacy of your institution's chain of title practices?

		Response Percent	Response Count
Yes		1.9%	1
No		98.1%	53
	an	swered question	54
	8	kipped question	14



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18. If there have been any requests for warranty of title or ownership conflicts, how has your institution approached them? (Check all that apply)

		Response Percent	Response Count
Not applicable		75.0%	36
Reduced license fees.	ı	2.1%	1
Negotiation		25.0%	12
		Other (please describe) Show replies	8
		answered question	48
		skipped question	20



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19. Have you observed any other practical implications of Stanford v. Roche?

	Response Percent	Response Count
Yes	5.7%	3
No	94.3%	50
	answered question	53
	skipped question	15



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Discussion and Questions