Public Research, Technology Licensing, and IP Commercialization; Mapping Interdependencies in the Cell Therapy Field

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Study rationale: Examining role of public funding for science in supporting markets for IP

The state, through control over public funding for science as key in shaping firm innovation, competitiveness:

- Silicon Valley VC's provided US$ 104 Million in seed, startup funding for biotech firms in 2012;
- NIH provided US$ 258 Million in funding for three SF universities, and US$ 41 Million to SF start-up firms through Small Business Innovation Research grant scheme.

Public research fuelling academic entrepreneurship....

Spin-offs from publicly funded academic institutions

… as well as corporate R&D at established firms

- Emergence of ‘open’, networked innovation models in many high-tech industries since late-1980s.
- Growing reliance in corporate R&D on academic input.

Spin-offs from publicly funded academic institutions

The innovation ecosystem 'feeding off' publicly funded academic work

Increasing reliance in firm R&D on public research

Spin-offs from publicly funded academic institutions

UCL

Public funding for science

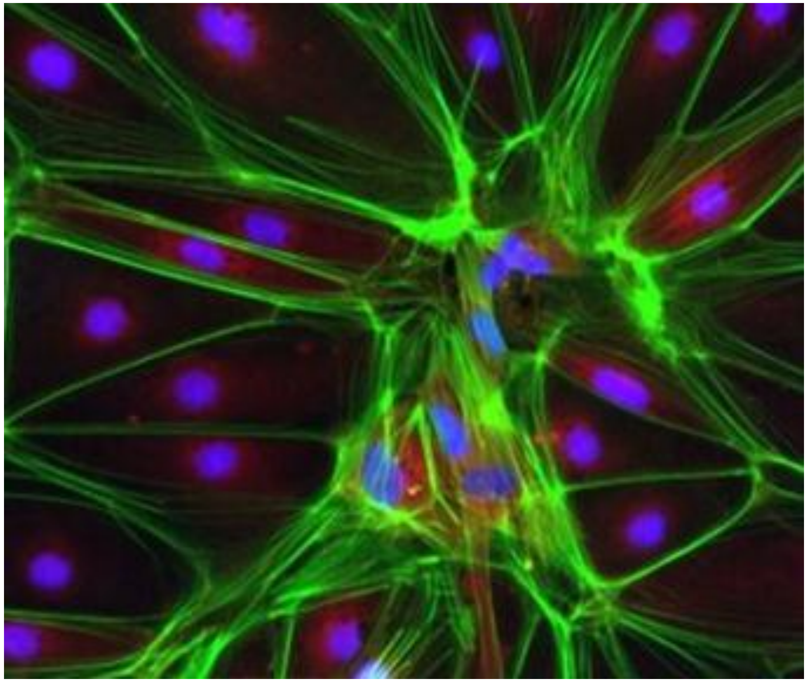
The initiation of novel IP commercialization projects

- Universities as critical suppliers in IP markets (Henderson et al. 1998; Mowery et al. 2004; Adelman and DeAngelis 2007).
- Commercial R&D projects in high-tech industries often find their origin in academic research (e.g. Cohen et al. 2002; Mansfield 1996).
- R&D investment decisions contingent on expected availability of input from scientific communities in downstream R&D.

The success of IP commercialization projects

- Input from scientific community as critical to R&D success in science-intensive sectors (e.g. Cohen et al. 2002; Fleming and Sorensen 2004; Jong and Slavova 2004).
- Willingness of critical partners (e.g. top researchers, licensing partners, VC's, CMO's etc.) to commit to a specific sector contingent on funding environment.

Research setting – The cell therapy sector



- New cell therapy technologies as transformative for healthcare.
- Technology development in cell therapy as ‘science-driven’.
- Stem cell research as key focus of public initiatives; As part of 2013 economic stimulus, Japanese science ministry earmarked ¥21.4 billion (US$ 3.5 billion) for research on stem cells.

US federal moratorium on specific human Embryonic Stem Cell research (hESC) 2001-09 as an episode of state intervention warranting further examination

President George W. Bush imposes a moratorium on federally funded research on new lines of human embryonic stem cells in August 2001.

.. vetoes bill by US Congress to lift the moratorium in July 2006.

CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

California votes for Proposition 71 to spend US$ 1 Billion on stem cell research to ‘offset’ federal moratorium in November 2004.

President Barack H. Obama reverses federal hESC moratorium by Executive Order in March 2009.

hESC research funding moratorium as an ideal social science ‘experiment setting’

1. Moratorium localized during specific period

Innovation dynamics in cell therapy field in US
before hESC research funding moratorium:

Public funding for research → IP commercialization

vs.

Innovation dynamics in cell therapy field in US
during hESC research funding moratorium:

Public funding for research → IP commercialization

vs.

Innovation dynamics in cell therapy field in US
after hESC research funding moratorium:

Public funding for research → IP commercialization

2. Moratorium as geographically localized, contained to single country

Innovation dynamics in cell therapy field in US ***before*** hESC research funding moratorium:

Public funding for research → IP commercialization

vs.

Innovation dynamics in cell therapy field ***outside*** US ***before*** hESC research funding moratorium:

Public funding for research → IP commercialization

vs.

Innovation dynamics in cell therapy field in US ***during*** hESC research funding moratorium:

Public funding for research → IP commercialization

vs.

Innovation dynamics in cell therapy field ***outside*** US ***during*** hESC research funding moratorium:

Public funding for research → IP commercialization

vs.

Innovation dynamics in cell therapy field in US ***after*** hESC research funding moratorium:

Public funding for research → IP commercialization

vs.

Innovation dynamics in cell therapy field ***outside*** US ***after*** hESC research funding moratorium:

Public funding for research → IP commercialization

hESC research funding moratorium as an ideal social science ‘experiment setting’

Existing studies using this research setting highlight:

- A drop in scientific publications in hESC research following the enactment of the moratorium (Furman et al. 2012; Owen-Smith and McCormick 2006)
- Mobility of academic researchers active in hESC research away from geographic areas affected by the moratorium (Levine 2008; 2012).

Data

- Data on 864 university-industry deals in cell therapy field over period 1986-2010 from Thomson Reuters's Recap IQ Series, Deal Builder.
- Project-level data on 633 cell therapy commercialization projects initiated by firms over period 1986-2011, from Citeline Pharmaprojects database (i.e. development milestones, project characteristics).
- Firm-level data on firms initiating cell therapy commercialization projects (e.g. location, size).
- US and non-US samples are roughly similar (i.e. no. failed projects, distribution projects among small vs. large firms).

Funding restrictions and the launch of novel IP commercialization projects

Proposition 1a:
The enactment of scientific funding restrictions in a scientific field has a negative impact on the propensity of firms to launch new IP commercialization projects that build on research in that field.

Proposition 1b:
The negative impact of the enactment of scientific funding restrictions on the propensity of firms to launch new IP commercialization projects in a field is larger for firms that are geographically located in the country where these restrictions are enacted.

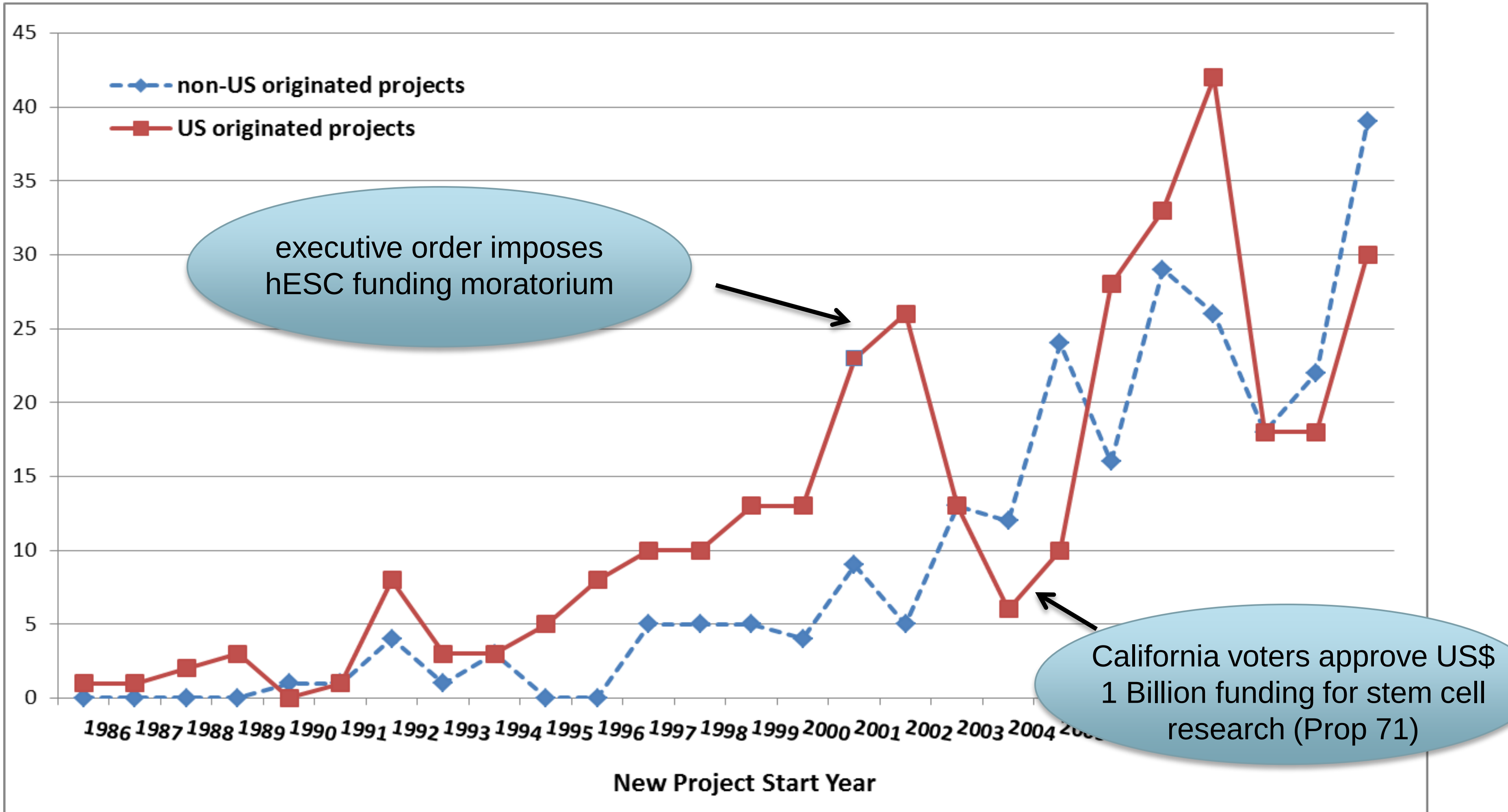
The flow of IP from universities to industry in cell therapy field

	No. cell therapy deals (N = 864)	% cell therapy deals that are with US universities
1986-97	128	34%
1998-00	63	15.8%
2001-03	107	10.3%
2004-07	254	16.1%
2008-11	312	15%

Source: Data collected and compiled from Reap IQ Series

During years after enactment of federal hESC moratorium, the role of US universities diminishes in IP markets in cell therapy field.

Cell therapy commercialization projects entering clinical trials by firm location



Funding restrictions and the success of IP commercialization projects

Proposition 2a:
IP commercialization projects that are initiated when scientific funding restrictions are in place are less likely to be successful.

Proposition 2b:
IP commercialization projects that are initiated in a country where scientific funding is restricted are less likely to be successful.

Project failure rates pre- and post- enactment of hESC research moratorium

	Model 1	Model 2
Post 2001	-572 (.437)	
US projects	.543* (.291)	0.123 (.309)
2001 - 2003		.191 (.704)
2004 - 2008		-1.63 * (.699)
2009 - 2011		-4.52 *** (.762)
fixed effects	Yes	Yes
Observations	453	453

* denotes p<.05, ** denotes p<.0.1, *** denotes p<.001

Impact on project failure rates by cell therapy projects initiated by US firms

	Model 1	Model 2	Model 3 (with controls)	Model 4 (with controls)
Post 2001	0.655 (.554)			
2001 - 2003		1.351* (.636)	1.199+ (.632)	1.382+ (.752)
2004 - 2008		-0.424 (0.419)	-0.443 (.469)	-0.534 (.604)
2009 - 2011		-2.129*** (.480)	-2.339*** (.533)	-2.805*** (.675)
fixed effects	Yes	No	No	Yes
Observations	235	251	237	235

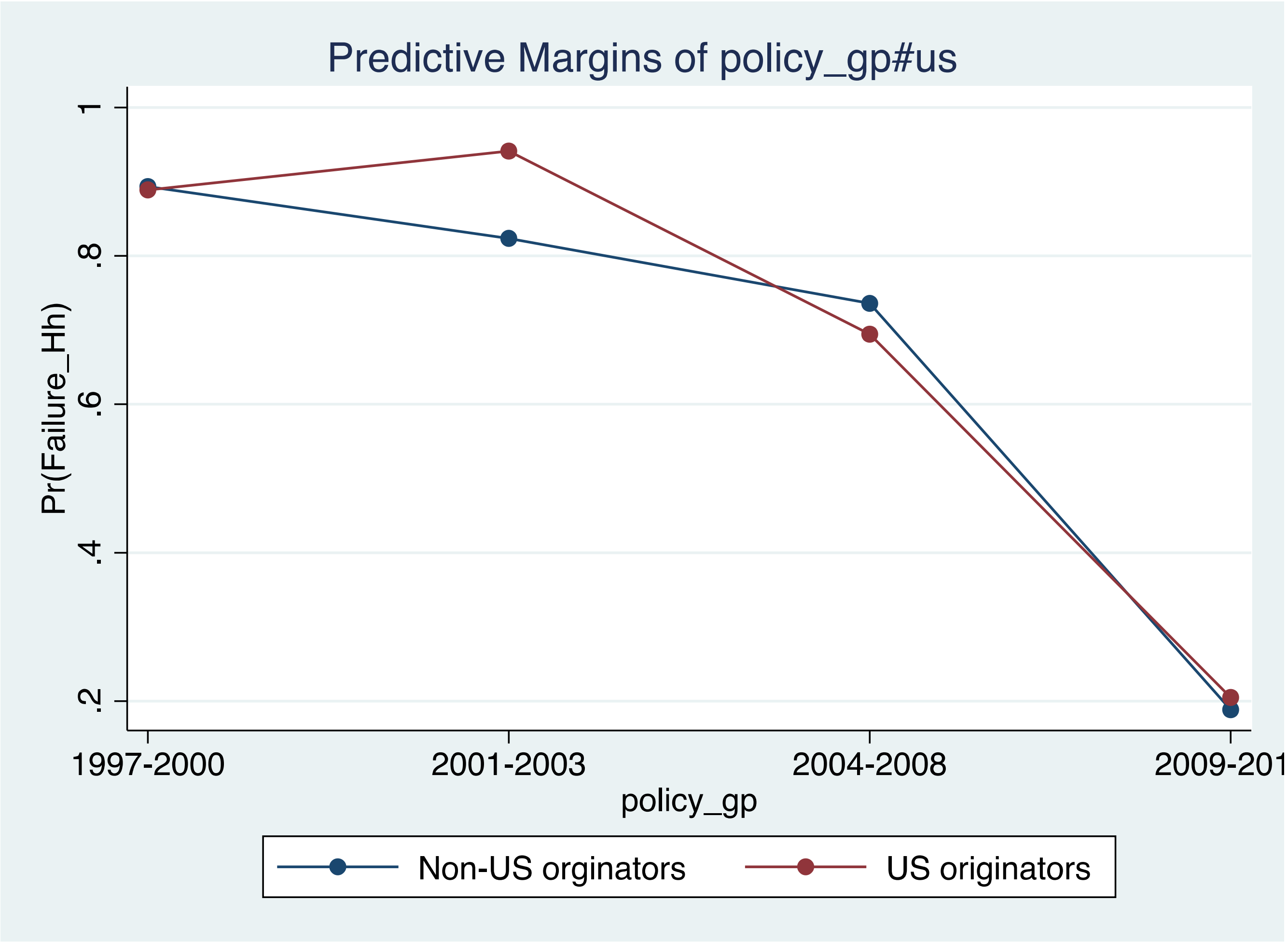
+ denotes p<.1, * denotes p<.05, ** denotes p<.0.1, *** denotes p<.001

Impact on project failure rates by cell therapy projects initiated by US firms and non-US firms

Logit Model	Model 1 (DV = project terminated)	
	coefficient	Std-err
US projects	0.207	(.222)
Before 2001	4.261***	(.697)
2001 - 2003	3.729***	(.289)
2004 - 2008	3.064***	(.378)
Before 2001 * US	0.390	(.623)
2001 – 2003 * US	1.429***	(.334)
2004 – 2008 * US	-0.349	(.323)
Observations/ Pseudo R^2	453 / 0.304	

+ denotes p<.1, * denotes p<.05, ** denotes p<.0.1, *** denotes p<.001
Project and firm level variables are controlled as well as fixed effects.

Predicted failure rates by project cohort for projects initiated by US firms and non-US firms



Concluding remarks

- The funding lever constitutes a powerful lever the state can use in shaping contributions by academic institutions in IP markets and in supporting corporate R&D performance.
- Political decisions about scientific funding policies have spill-over effects; Study highlights unintended consequences of funding cuts.
- Opportunities for the state to use science funding policies as a lever to encourage industrial innovation in areas that are of societal importance.