

Dollars For Genes: Revenue Generation by the California Institute for Regenerative Medicine

Richard Gilbert

University of California at Berkeley

Conference on California's Stem Cell Initiative

March 2-4, 2006

Questions

- What is the likelihood that research funded by the CIRM will generate significant income?
- How should licenses be structured to maximize California's share of income from technologies developed by the CIRM?

Don't Expect Licenses From the
CIRM to Be a Cash Cow

AUTM Licensing Survey: FY 2004

	U.S. Hospitals and Research Institutes	All U.S. University Research
Sponsored Research Expenditures (\$000's)	\$4,082,415	\$37,162,153
Net License Income* (\$000's)	\$314,452	\$924,842
Net License Income as Percent of Research Expenditures	7.7%	2.5%
Years to Break Even	13.0	40.2

* adjusted for license income paid to others and legal fees, but excluding program operating costs

AUTM Licensing Survey: FY 2003

	U.S. Hospitals and Research Institutes	All U.S. University Research
Sponsored Research Expenditures (\$000's)	\$3,698,783	\$34,826,920
Net License Income* (\$000's)	\$291,623	\$866,814
Net License Income as Percent of Research Expenditures	7.9%	2.5%
Years to Break Even	12.7	40.2

* adjusted for license income paid to others and legal fees, but excluding program operating costs

UC San Francisco: FY 2004*

Sponsored research (\$000's)	\$722,806
Net licensing income** (\$000's)	\$18,203
Net License Income as Percent of Research Expenditures	2.5%

* Source: UCSF Office of Sponsored Research and UC Technology Transfer Program Annual Report FY 2004

** income from royalties, fees, and reimbursements, less legal, system-wide and campus expenses

If licensing revenue is the measure of the CIRM, Californians would be better off investing in municipal bonds

Why Is Licensing Income So Low?

- Average rate of return on corporate investment is 10-15% per year
- Average social rate of return on R&D is 20-40% per year
- Yet university licensing royalties are only 2.5–8% of R&D expenditures

Why Is Licensing Income So Low?

- University research typically requires substantial follow-on investment
 - ◆ Developers may have superior bargaining positions
 - ◆ Analogy to farmer and agribusiness
- Uncertainty + agency problems
 - ◆ Both fixed fee and running royalty licenses have serious agency problems
 - ◆ Fixed fees are risky for the licensee and discourage investment and knowledge transfer by the licensor
 - ◆ Running royalties discourage follow-on innovation by the licensee and can discourage technology adoption

Not All IP Eligible for Patent Protection Is Even Licensable

- Too early stage – more research needed before a company will be interested
- Poor patent claims – too narrow to provide a competitive advantage or unenforceable because it is difficult or impossible to identify infringers
- Insufficient market or poor market dynamics
- Product not sufficiently differentiated from competing technologies
- Problems with manufacturing

Source: UCSF Office of Technology Management

License Structures

- Exclusive v. Non-exclusive license
- Fixed fees v. Royalties
 - ◆ Common argument is that an exclusive license with a fixed fee and a running royalty equal to marginal cost (essentially zero for intellectual property) maximizes the licensor's profit

Exclusive License With Fixed Fee and Royalty at Marginal Cost



But Exclusive - Fixed Fee Licenses Are Not Profit-maximizing in Most Circumstances

- When downstream demands differ, non-exclusive licenses with mix of fixed fees and running royalties can extract more profit
- If license value is uncertain, a running royalty:
 - ◆ Provides better risk sharing
 - ◆ Provides incentives for the licensor to improve the licensed technology to share in additional royalties
 - ◆ Most new technologies require considerable additional investments to become commercially useful

Exclusive - Fixed Fee Licenses Are Not Profit-maximizing in Most Circumstances

- An exclusive license incurs the risk that the sole licensee is lazy or a poor match for the licensed technology or has inefficient incentives to commercialize the technology
 - ◆ The risk of under-investment is particularly severe when the licensee has a related business that would be adversely affected by a new technology

Exclusive - Fixed Fee Licenses Are Not Profit-maximizing in Most Circumstances

- An exclusive license creates a sole-source technology supplier, with all the hazards that go along with vesting responsibility for the development and use of a new technology in a single provider
- At a minimum, an exclusive license requires that the licensor exercise due diligence to assure that the technology will be developed expeditiously and that the licensor and licensee will share equitably in any new developments that emerge from the technology

Characteristics of University Licenses

- In a survey of university licenses granted from 1991-1995, only 22% had greater than one bidder
 - ◆ De facto exclusive
- Nearly all licenses include both upfront fees and royalty payments, but the latter account for most of the revenues
- 45% of university licenses were exclusive in FY 2004
 - ◆ Similar for licenses from U.S. Hospitals and research institutions

Sources: AUTM Survey 2004 and Jensen and Thursby (2001)

Running Royalties Account for Most of Licensing Revenues

Share of licensing revenues

	Running Royalties	Cashed-in Equity	Other
U.S. Universities	79%	2%	19%
U.S. Hospitals and Research Institutions	80%	2%	18%

AUTM Licensing Survey: FY 2004

Nonetheless, Equity Sharing Is an Attractive Alternative

- Equity sharing is a relatively recent, but increasingly common feature of university licensing
- Equity sharing can increase the available “pie” from licensing new technologies

Equity Sharing Is an Attractive Alternative

- Equity sharing can:
 - ◆ Reduce pricing distortions from running royalties
 - ◆ Better align investment incentives and reduce agency problems
 - ◆ Encourage critical knowledge flow among researchers and developers
 - ◆ Lower litigation risks

Equity Sharing Is an Attractive Alternative

- Equity sharing can:
 - ◆ Realize value upfront through IPO or acquisition
 - ◆ Provide some diversification benefits
 - ◆ Lower transactions costs of technology transfer by facilitating initial and subsequent negotiations
 - ◆ Simplify negotiation of grantback provisions

But Equity Sharing Incurs Additional Risks

- Equity returns have very high variance
- Equity returns may be distant or non-existent
 - ◆ Pressure on CIRM to show revenues could bias the institute against equity deals
- Need to match ideas with business expertise
- Licensor may be lured into investing in the downstream venture under conditions of uncertainty and moral hazard
(B.U. Effect)

Equity Sharing Incurs Additional Risks

- Licensor may be at risk for product defects
- Equity is the ultimate exclusive license
 - ◆ Hard to terminate the license for non-performance
 - ◆ Hard to shop for better partners to commercialize the technology

Some General Conclusions

- The Institute will not realize significant licensing revenues for many years
 - ◆ Ramp-up time for new technologies
 - ◆ Need for follow-on investments
 - ◆ Regulatory delays
 - ◆ Litigation delays

Some General Conclusions

- Licensing revenues are likely to be small
 - ◆ Licensing revenues typically 2-5% of total revenues, rarely exceed 15%
 - ◆ Even licenses for blockbuster technologies are not going to realize a high share of downstream profits
 - ◆ E.g. Florida State U. And Taxol
 - \$60 million in licensing revenues on 2002 sales of \$1.2 billion

Some General Conclusions

- CIRM should consider partnering with licensees and equity sharing to appropriate greater research value