The Use of MTAs to Control Commercialization of Stem Cell Diagnostics and Therapeutics

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The Current State of Stem Cell MTAs

- What is a material transfer agreement (MTA)?
- Distinguish IP license from material license
  - Similar to models for software, old Bell telephone system, test prep books, seed "bag tags", etc.
- Why are stem cells (and other bio materials) licensed, not sold?
- Similar to rationale for licensing tangible property generally
  - Control
  - Avoid some limits on IP such as first sale, patent exhaustion, reverse engineering, perhaps even fair use
  - Can establish rights to return of materials

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The Current State of Stem Cell MTAs

- 2001 Bush Order + WARF/Thomson patents = tightly controlled federally funded stem cell research market
  - Why? WARF patents arguably cover all current approved stem cell lines
  - But, perhaps ironically, government license requirement under Bayh-Dole prevents WARF from tying up federally funded research (35 U.S.C. 202(c)(4); *not* march-in rights)
  - However, because approved stem cell lines were derived without federal funding, owners still retain some leverage over federally funded research

Background of WARF/Thomson Patents

- Public Health Service (PHS) funded U Wisconsin research leading to first Thomson patent (5,843,780); assigned to WARF
    - WARF has been assigned further Thomson patents: 6,200,806 and 7,005,252. Neither states that the U.S. has rights
- WARF licensed the Thomson patents to WiCell Research Institute with rights to sublicense
- WiCell administers both the Thomson patents *and* approved stem cell lines that Thomson derived
- WiCell entered into a Memorandum of Understanding (MOU) with PHS to set terms for the mandatory PHS license to the Thomson patents under Bayh-Dole

The Existing WiCell Controlled Stem Cell Research Licensing Regime

- PHS-Sponsored Research
  - WiCell-PHS MOU and Simple Letter Agreement
  - Third Party MTAs governed by WiCell-PHS MOU
- All other research
  - Standard WiCell Industry Research MTA
  - WiCell Commercialization Licenses/MTAs
- Note: WARF direct exclusive license to Geron for certain diagnostic and therapeutic R&D efforts
- WiCell's Licensing Models
  - Therapeutics
  - Diagnostics
  - Research Products

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Where Does CIRM Funded Research Fit In?

- Can distinguish commercial from non-commercial research, *but in either case WiCell is not obligated to license Thomson patents*
- Although CIRM intends to model, and not conflict with, Bayh-Dole in IP rights allocation, the CIRM system will not be part of, or have the same effect as, the federal Bayh-Dole system (including existing PHS rights to the Thomson patent(s))
- As such, unless stem cell lines can be derived completely independent of Thomson patents *and* current stem cell lines controlled by Thomson patents, WiCell will continue to control terms of stem cell commercialization

Looking Beyond the Thomson Patents

- One benefit of existing approved stem cell lines: no major donor issues so far (but note Cellartis line withdrawal)
- In the rush to get many new donors, will consent issues conflict with downstream commercialization?
- ACT Consent Form
  - Includes explicit waiver of any donor rights in commercial benefits
  - Is this meaningful consent; i.e., does a donation for "science" or "research" motivate potential donors differently than donations to corporations or for-profit enterprises?
- CIRM must establish system to guide and control complete commercialization rights chain
  - Egg donation to research units (consent forms)
  - Translational/applied R&D (MTAs)
  - Manufacture/distribution/sale (Licenses & MTAs)

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