Technology Transfer @ UC San Diego

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October 10, 2013

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Technology Transfer Office

TTO Goals – the Mission

- Facilitate the transfer of useful technologies for public benefit
- Foster local, regional and national economic development
- Reinvest in the research infrastructure
- Recognize and reward innovative employees with monetary incentives tied to successful commercialization

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TTO – Team and History

- Local since 1994
- 26 FTE's
  - 12 licensing
  - 5 patent
  - 4 finance
  - 3 disclosure
  - 2 support
  - 4 Rotating students and interns

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Legal Backdrop for TTO

- Bayh-Dole Act
  - Universities may retain ownership of IP if they maintain an active TTO program
    - Patent, market, reward inventors, reinvest in research, broad public benefit
- The Tax Act
  - fair market value for private use of public assets
- Political Reform Act
  - Prevent personal gain from public activities

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TTO Functions - Disclosures

- Intake appox. 450 new disclosures annually for new inventions, materials and copyrights
  - Create legal record within UC's tracking system
  - Assign to one of 12 licensing officers with SME
  - Report innovation to stakeholders
    - Federal, State & non-profit
    - private sponsors with licensing rights
  - Coordinate a strategy with possible joint-owners

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TTO Function - Triage

- Assess disclosures for licensing potential
  - Patentable?
    - Novel, Non-obvious, Useful
      - Prior pubs a key concern
  - Clear path / title?
    - Do we own this, or does it rely on previous work at another employer – freedom to operate?
  - Marketable?
    - Does this address a large enough market?
    - Is infringement detectable?

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TTO Function - Patents

- We manage the patenting of all UCSD inventions
  - Active docket of close to 2,000 applications and 1,200 issued patents worldwide
  - Sole campus authority to hire outside counsel

- Contract with outside IP lawyers for bulk of the work
  - Manage their invoices and the re-invoicing of licensees
  - Recover average of 75% of patent costs via licensing

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TTO Functions – MTA's

- Coordinate all "out-bound" material transfers
  - Assess the chain of custody for material's origin to ensure we have the right to re-transmit
  - Is the material original to UCSD or a derivative of someone else's material?
    - Materials may be subject to third party rights
    - Materials may originate under various treaties

- *Key Point: keep good records of all incoming material and purchase orders for goods and services
  - may dictate later options for the PI's research outcomes

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TTO Functions - Licensing

- Act as match-maker between techs and companies / VC's / entrepreneurs
  - Market, market, market!
    - Web site, social media, newsletters, events, P2P
- Negotiate and sustain licensing relationships
  - Assist licensees with investment / intros
- Maintain 5-20 year partnership
  - Amendments
  - PR

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TTO Function – da Money!

- We manage the distribution of TTO activity income to stakeholders
- $26M - $31M per year in total revenue
  - Patents:
    - 35% to inventor(s) as personal income paid each December
    - 9% to the inventor lab
    - 6% to the Department
    - 50% to the Chancellor's fund
  - Copyrights:
    - 33% to the Author(s)
    - 33% to the Department
    - 33% to the Chancellor's fund
    - Alternate 85/15 split for Lab/Chancellor

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Questions from the Group

Q: How do technologies get licensed?

- A: Several ways.
  - 70% of deals originate via PI's network
    - Own start-up
    - Research sponsor
    - Industry colleague
    - Conference attendee
    - Consulting client
    - Grad student on their way out

Usually on the disclosure form

  - Remainder sourced through cold-calling and TTO's network

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Q: What is the process and cost of a license?

- A: Typically we'll work with the licensee to learn their business model and constraints, then develop a license that matches their intended roll-out of the IP.
  - This leads to sensible fees and diligence targets
- All licenses include recovery of the UC's patent costs, but not research investment
- All licenses should reflect the value of the IP to the total effort required to reach the market
- Fees and timing are sector specific

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Sample terms of a license:

- Lead compound for a new drug (3-18 mos.)
  - Objective: see the UCSD compound validated through Phase 1, 2 and 3 clinical trials, culminating with FDA approval
  - Timeline: 10+ years before expected product sales
  - Meaningful diligence targets
  - Up-front fees: Often equity if a start-up, or $10'sK
  - Milestones on successes:
    - Phase completions ~ $100'sK
    - FDA approval ~$1M+
  - Royalties on sales, a few percentage points or less

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Sample terms of a license:

- Non-exclusive end user of Software (days to weeks)
  - Objective: facilitate the use of UCSD developed tools at commercially attractive price
  - Timeline: months before first commercial use/ sale
  - Fees: total consideration pegged at fraction of cost to re-write from scratch
    - Apply a man-month saved approach = $10K/mo.
  - Royalties: only if exclusive, then to offset our lost opportunity to license others

Q: Can a PI license their own IP?

- A: Yes
  - Preference is for small and local businesses, so PI start-ups are encouraged
    - As long as sponsor obligations are met first, there is no restriction on licensing your own work, regardless of funding source
  - Certain activities will need to be reported on PI's Form 700 and annual departmental reports, which may trigger COI oversight

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Q: What is a joint license?

- A: A joint license is often requested by a sponsor that wishes to own UCSD generated IP even if they did not aid in the actual invention.
  - The UC follows an ownership by inventorship policy so if the third party is not an inventor by patent law, they would not be allowed joint ownership of a UC patent
    - Common request of foreign companies
  - True joint inventions are jointly owned and UCSD would try to license it's ½ to the other owner
    - Hard to license separately

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Q: Does policy differ for PI's vs. everyone else?

- A: No.
  - While PI's do get consulting time, the UC's Patent Agreement is signed by everyone and it applies to everyone equally (rare exceptions).
    - Policies on consulting and outside activities are subordinate to the Patent Policy
  - Any inventor, no matter how low on the pole, is treated equally for patent rights, income rights and the right to license their work back
  - Departmental restrictions on outside activities may vary, so ask your Dean or Chair

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Q: When is an MTA required?

- A: A MTA is required anytime tangible materials are leaving the campus to a non-UC recipient.
  - This is important to ensure we comply with export laws as well as third party IP rights and limitations on our use of the material
  - Does not apply to copyrights, which are subject to the UC Copyright Policy and modified BSD open source license
  - ORA is working to streamline MTA's to lessen the burden. Liability and embarrassment are the key factors for compliance.

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Q: Do technologies go out the back door?

- A: Yes, but…
  - Policing non-compliance provides low ROI
    - Campus reluctant to punish faculty who breach patent policy
- Usually self correcting
  - Serious investors and buyers know that professors have IP obligations
    - Will ask for paper trail relating to IP
    - Paper trail leads back through TTO
      - Get our license without risking our patent $

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Industry's TTO Equivalent

- All research based companies pay attention to their IP
  - Possibly via general counsel's office
  - More and more through dedicated IP management personnel
    - Many companies have dedicated in/out licensing teams
      - Scout new third party innovations to bring-in
      - Market own IP for use by others
      - Coordinate between business development and legal
    - Qualcomm derives 1/3 of its income on IP out-licensing
    - Big pharma sources most new therapeutics via in-licensing
- Depending on industry type/ business size, uses of IP vary
  - Strategic vs. defensive

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IP in the Life Sciences

- Patent rights the cornerstone of products
  - Underpin 8-10 years of development
    - $800M in development per approved drug
    - Years of trials to get through FDA approval
    - Must defend investment with broad patent rights
    - Must evolve patent rights to extend protection
      - Extended release formulas typically come near end of original coverage
        - Sacrifice “dailies” to generics
  - One patent may cover entire product, worth $B’s

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IP Rights in High-Tech

- Contrary to Pharma, high tech products usually address a want vs. a need (iPad vs. arthritis)
- Time to market and branding key
  - Entire life cycle of a product may occur before first patent issues
  - Better solutions may exist, but not first to market
  - FDA equalizes Pharma brands, tech brand value significant
    - iPhone, Google, Facebook, etc.
- Tech products subject to many patents
  - (100,000 on Intel cpu) vs. one for Erbitux

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IP in the Bio-Eng Space

- Somewhat of a middle ground between hi-tech and pharma
  - Often require FDA approval at lower PMA or 510(k) threshold
  - FDA process may be 6 mos. – 2 years total
  - Products also may be tools used by Pharma
    - Reagents, assays, micro-arrays, software tools
  - Business models similar to hi-tech
    - Fast to market, looking for barriers to competition, first mover status

Rules of Thumb in IP

- IP key in Pharma and VC backed start-ups
  - Defend investment, hold-off the “me-toos”
  - May be the first asset company builds from
- Hi-tech (especially large co.) often only care about freedom-to-operate
  - Rely on speed to market, channel strength, brand and internal IP
  - Standards bodies and litigation settlements put many co. patents into cross license arrangements

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Consequences

- Almost inverse attitudes towards university IP
  - Pharma has formal in-licensing groups, very affable
  - Hi-tech avoids licensing when possible
    - Will leverage PI's against TTO's
    - Will leverage PI's against OCGA
    - Will undercut our overhead via gifts
    - will push PI's not to patent, publish instead
  - Most hi-tech licensees tend to be smaller cos. Who value UC's assitance

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But we haven't given up…

- Always looking for new ways to interact
  - New programs include
    - Express License for Therapeutics – effective 7/1/12
    - Express License for General Campus – effective 1/1/13
      - Gives option to take a license on known terms without negotations
    - More systematic approach to IP release
      - Both federal and non-federal funded research
        - Not currently applicable to special sponsors, PI's (HHMI, VA, etc.)

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More changes

- Advocating more “knowledge transfer”
  - Seeking out and including tangible examples to aid in licensee’s adoption of UC work
    - Fab’d chips / software / drawings / cell lines
    - Used to languish in lab drawer or into the trash
    - Lower barrier to adoption, more likely to license and realize products of their own
    - No added cost for a lot more value

- *Key Point: Consider keeping inventory of key tangible lab by-products

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Take Away

- Keeping good records is key to protecting future opportunities and mitigating liability
- Attitudes towards IP vary widely by industry
- There is a wealth of experience at TTO and OCGA to assist you, so don't be shy to call

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Questions?

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