Introduction to CVIP

- UML-CVIP Overview
- Technology Transfer Principles
- UML-CVIP Commercialization Process
- UML-CVIP in Context
- UML-CVIP Activities
UML-CVIP Overview

CVIP = Commercial Ventures & Intellectual Property
(Technology Transfer Office)

- Mission
  - Commercialization of UML technologies

- Philosophy
  - Facilitate research efforts
  - Encourage inventiveness
  - Advocate for UML research community

- Approach
  - User-friendly
  - Provide tools, education & advice
  - Responsive to PIs
  - Proactive with business and venture communities
UML-CVIP Team

- **George Kachen, Director**
  - Ph.D., Applied Science, MS, Nuclear Engineering
  - Previous Director UML Nanomanufacturing Business Development
  - 30+ years bus. dev. & tech transfer experience

- **Jill S. Murthi, Associate Director**
  - MBA, Patent Agent, candidate ALM, biology
  - Previous tech transfer experience MGH/Partners
  - 10+ years in biotech bus. dev. & IP mngt. roles

- **Diana L. Locey, Tech Transfer Assistant**
  - Notary public
  - 9 years+ at UML
Technology Transfer

- The movement of knowledge and discoveries to the general public

- Required by the US Bayh-Dole Act (1980)
  - Universities given ownership of inventions generated under Federal grants
  - Universities must protect and commercialize these inventions
Technology Transfer

“Defining ‘technology transfer’ is quite simple; it primarily involves taking discoveries generated in the lab, transferring that knowledge to industry, [and] turning it into commercial products and applications. Technology transfer plays an important role in innovation. Great discoveries are made within academia on a daily basis, and it is vital to both the economy and society that these ideas are developed.”

Nikki Porter, Life Sciences Division, University of Toronto Innovations Foundation, “Technology Transfer: At the Crossroad of Business and Science”, Science online 07May09
Technology Commercialization at UML

- Maximize commercial utility of intellectual property while preserving the mission of the university
  - Revenue generation
  - Broad dissemination of technology for public use
  - Enhance reputation of University
UML-CVIP Commercialization Process

- Inventing
- Patenting
- Marketing
- Licensing
UML Intellectual Property Best Practices

- Disclose to CVIP every invention conceived and/or reduced to practice that arises out of or relates to your research, educational or other institutional activities at UML.
Inventions

What is an invention?
- An invention is the discovery or creation of a new material, a new process, a new use for an existing material, or any improvement thereof.

Categories of inventions
- Devices, methods, processes, materials, chemical or biological compositions of matter.
When to Disclose Inventions

- If you think you may have an invention
  - Disclose it promptly and thoroughly to CVIP
  - Do so *before* you submit a manuscript for publication
  - Do so *before* you address a meeting, conference, seminar or symposium
  - Do so *before* you speak with a company representative or anyone outside UML
Invention Evaluation

- PI’s Role
  - Submit to CVIP completed confidential invention disclosure (CID) form
    - E-form provided on CVIP website
    - Obtain signatures by all inventors
    - Extremely important to be as thorough as possible
    - Don’t forget to keep up your notebooks – signed & dated
    - Inform CVIP of additional development and improvements

NOTE: Submitting an invention disclosure does not provide any protection (yet). Discussions about your technology at this stage should be handled with extreme caution and done only under an obligation of confidentiality.
Invention Evaluation

- **CVIP’s Role**
  - Assign a “case manager”
  - CID “submitted” vs. CID “accepted”

- **Submitted**
  - Ensure CID is complete
  - Confirm Participation Agt. executed
  - Confirm funding sources and verify any existing “claims” (e.g. options)

- **Accepted**
  - Evaluate for novelty, non-obviousness aka “patentability”
    - Novelty prior art search
  - Assess for commercial potential aka “licensability”
  - Prepare summary of CID for presentation at Case Managers Mtg
Invention Evaluation

- CVIP’s Role (cont.)

  - Make Go/No Go decision – communicate to PI

Per the UML IP Policy, a decision will normally be made by CVIP and the PI notified within 90 days from the acceptance of an invention disclosure.
Invention Evaluation

CVIP’s Role (cont.)

GO DECISION – Rationale

- Invention is novel & non-obvious
  - Prior art search conducted
- Invention is enabled and/or additional development is planned
  - Review of existing data
  - Discussion with PI
- Invention is commercially viable
  - Market size & growth potential assessed
    - Public & proprietary databases consulted
  - A sponsor or potential licensee has committed to reimbursing patent costs (e.g. an “option” exists)
  - CVIP determines it is likely to attract a licensee(s)
Invention Evaluation

- CVIP’s Role (cont.)
  - THE “COVER SHEET” PROVISIONAL

NOTE: In the event that a public disclosure is imminent, a “cover sheet” provisional patent application may be filed as a precaution. This is NOT a GO decision. The same analysis of an invention disclosure must still be completed to advance the invention.
Public Disclosure

- File patent application before making a public disclosure

- An invention may be unpatentable if public disclosure is made prior to filing a patent application
  - Exception: 1 year grace period in U.S. only

- A public disclosure can be, for e.g.:
  - A poster presentation at a scientific meeting,
  - The publication (including on-line) of an abstract or article, or
  - A conversation with a company representative without a confidentiality agreement in place

- A verbal or written public disclosure *anywhere in the world* may be treated as prior art by the patent office
Invention Evaluation

- CVIP’s Role (cont.)
  - NO GO – Rationale
    - Invention deemed not patentable
      - Not novel & sufficiently non-obvious
    - Invention not enabled & no plans exist to do so
      - Standards differ for various “arts”, e.g. chemistry (lots) vs. medical devices (little)
      - Enablement/proof-of-concept a factor for both the patentability & commercializability analyses
      - May temporarily put invention ON HOLD pending further development / proof-of-concept
    - Invention is determined to have limited commercial potential
Invention Evaluation

90 day evaluation period begins

Inv Disc Accepted by CVIP

Inv Disc submitted by PI

Inv Disc Complete?

YES

CM informs PI
- Reasons explained,
- alternatives given

NO

CM sends back to PI

Evaluation of invention begins

File patent application?

YES

NO

-Patentability assessment
-Commercial assessment
Patenting

- **CVIP’s Role**
  - Work with outside patent counsel to draft application directed to the invention
  - Manage ongoing prosecution of intellectual property
    - Patent office responses
    - Marketing / licensing status
    - Continued perceived commercial value
- **PI’s Role**
  - Work with CVIP & outside counsel as requested by CVIP to advance prosecution
Patent Fundamentals

- A patent is a legal instrument
  - Can be treated like any other asset
    - i.e., assigned, licensed or sold to another
- Time-limited monopoly
  - Term is 20 years from non-provisional application filing date
    (for applications filed on or after June 8, 1995)
- Confers a right to exclude others, not a right to practice (FTO)
- Claims determine “meets and bounds” of the invention
- U.S. = first to invent vs. ROW* = first to file
  - Notebooks!

*ROW = Rest of World
Patent Fundamentals

- An inventor has an idea (concept) and pursues its development by showing that the idea will work (reduction-to-practice)

- To be patentable, an inventor’s idea must meet all of the following criteria:
  - Patentable Subject Matter (USC 35 §100)
    - Inventions are patentable – discoveries are not
    - “anything under the sun made by man” – Diamond v. Chakrabarty 1980
  - Utility (USC 35 §101)
    - Approved statutory class & useful for some stated purpose
  - Novelty (USC 35 §102) – prior art
    - New, original & true
  - Non-obviousness (USC 35 §103) – also prior art
    - Significantly different from combinations of existing prior art
  - Written description, enablement, best mode (USC 35 §112)
    - Clearly described, reproducible, fully disclosed, supported by data and/or examples, inventor “in possession”
Inventorship vs. Authorship

- Inventorship is different than authorship
  - An author of a scientific paper is not necessarily an inventor of a patent – very different rules apply

- Inventorship is determined by the relevant U.S. or international patent law
  - An objective process
  - Determined by analysis of each and every claim
  - Must be correct or jeopardizes patent validity

- To be an inventor one must contribute to the conception of the invention
  - Conceptual contribution to a single claim constitutes inventorship
Ownership vs. Inventorship

- Ownership is different than inventorship

- Per the Participation Agreement, inventions generated in the course of your academic employment are assignable to the university

- Duty to assign flows from inventorship

- CVIP is responsible for confirming the inventorship and ultimate ownership of inventions
It can take anywhere from 3-5 years (sometimes longer) to get a patent to issuance in the U.S.

It can take anywhere from 5-7 years (sometimes longer) to get a patent to issuance in ROW.
Patenting Instruments & Costs

- **U.S. Provisional Application**
  - Robustly prepared application = $5-10K
  - Serves as “place holder” at patent office; not examined

- **US Non-provisional Appl. and/or International Appl. (PCT)**
  - Begins prosecution process at patent office
  - Add’l cost from $0 - $5K; factors effecting cost include:
    - How robust underlying provisional appl. was
    - Whether there is new data to incorporate or additional embodiments
    - Whether prior art has been uncovered
Patenting Instruments & Costs

- National Stage Filing (of PCT)
  - REALLY expensive = $25K - $100K+
  
  - Total cost depends on which countries are “elected” for nationalization
    
    - E.g. Australia (AU) = $3K; Canada (CA) = $3K; Europe (EP) = $10K; Japan (JP) = $8K

  - CVIP typically cannot justify support of international patent coverage in the absence of a committed licensee/optionee

**NOTE:** A PATENT APPLICATION IS NOT AN ENFORCEABLE ISSUED PATENT.
Marketing

- CVIP’s Role – business agent
  - Market assessment
    - Characterize the technology: incremental, disruptive, platform, product
    - Characterize the market: size, segment, niche, penetration
    - Characterize the competition: current players, competitive forces, margins
  - Valuation of IP based on these & additional factors
  - Non-confidential marketing summary

- PI’s Role – technical advisor
  - Identify potential licensees
  - Interface with companies to address technical concerns upon request of CVIP
Invention Evaluation

- CVIP’s Role (cont.)

**NOTE:** Any pre-existing contractual obligations must be complied with prior to conducting any marketing activities.

- SRA → Option
- MTA → Restrictions
Marketing Timeline

- Invention Evaluation (90 days)

I. Decision Point 1

Year 0 to Year 1

- Provisional patent filing
  - Continued development & POC of invention

- Marketing summary (non-confidential), “NCS” → CDA

- Marketing campaign
  - Identification and qualification of potential interested parties
  - Implement necessary contracts: MTA, SRA, option, license
  - Follow up and proceed to next steps
Marketing Timeline

II. Decision Point 2

Year 1 to Year 2.5

- Conversion to non-provisional patent application (1 year)

- Publication of patent application → No CDA req’d (w/caveat) (18 months)

- Continued marketing (w/NCS & patent publication)
Marketing Timeline

III. Decision Point 3

- National stage filing deadline
  - Big money – CVIP typically will not proceed without a committed licensee/optionee (who reimburses all patent costs)
  - Failure to nationalized results in permanent loss of potential patent rights in foreign jurisdictions
  - May continue with U.S. application only in some instances

Thus, to be effective marketing efforts need to occur in the first two years after first patent filing.
Licensing

- CVIP’s role
  - Initiation &/or continuation of dialogue (CDA)
  - Term Sheet development -- Deal negotiation
    - Key terms: exclusivity, know-how, field, territory, economics
  - Drafting IP (& know-how) license agreement
    - Fine-tuning, legal review
  - Execution
    - Signature by Bill Rosenberg, Exec. Director, CVIP, UMass
    - Delivery of know-how (if appropriate) and receipt of signing fee, R&D plan

- PI’s role
  - Technical advice/clarification as needed by CVIP
    - Interface with company scientific champion
Licensing Process

- Typically takes 6-9 months to negotiate a license agreement

- Agreements must adhere to all UML, UMass, State & Federal regulations, incl. Bayh-Dole
  - UML IP Policy, freedom to publish
  - UMass indemnification requirements
  - Reserved rights
  - State & Federal export control regulations
UML Distribution Policy

- **UML Intellectual Property Policy**
  
  (DOC. T96-040 Passed by the BoT 6/5/96, pp. 106.40)

  Distribution of **Non-Equity** Revenue Derived from Commercialization:

  - Fifteen percent (15%) to the CVIP (President’s Ofc) to fund patents, CVIP operations, and research grants
  - **Thirty percent (30%) to the inventor or creator**
    - Shared if multiple inventors/creators
  - Fifteen percent (15%) to the department or program of the inventor or creator
    - Shared if multiple departments/programs
  - Forty percent (40%) to the campus of the inventor or creator
    - Shared if multiple campuses
UML Distribution Policy

- UML Intellectual Property Policy
  (DOC. T96-040 Passed by the BoT 6/5/96, pp. 106.40)

  Distribution of Equity Revenue Derived from Commercialization:

  - Fifteen percent (15%) held for the account of the CVIP (President’s Ofc) until liquidation
  - Forty-five percent (45%) to the department or program of the inventor or creator
    - Shared if multiple departments/programs
  - Forty percent (40%) to the campus of the inventor or creator
    - Shared if multiple campuses
UMass in Context

- UMass system is 12th overall in terms of licensing revenue among U.S. tech transfer operations
## UML-CVIP Historical Performance

### Inventions & Patents

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CVIP Initiatives

- Faculty Outreach & Support
  - Information & Training Events
    - CVIP & outside patent counsel
  - Contracts: CDAs, MTAs, SRAs
    - CVIP with support from OGC & ORA
  - Advice & Guidance
    - In coordination with VPR, OGC & President’s Office
  - Advocacy & Problem Solving
CVIP Initiatives

- Marketing Efforts
  - Non-confidential summaries & patent publications
  - Direct marketing
  - Website & related links
  - Outreach to companies & venture groups
  - Utilization of students & consultants
  - Presence at events (e.g. MVVF)
CVIP Initiatives

- Annual CVIP Technology Development Awards
  - $25K award for development of new technology for commercialization
  - Assistance to applicants on proposal and presentation
  - Post-award assistance to translate additional research efforts into commercial opportunity
    - Specialized advisory committee
CVIP Initiatives

CVIP Technology Development Awards – FY2009

Last year, 3 of 7 awards granted across UMass system were made to UML faculty.

R. Nagarajan

V. Wang

Z. Gu
CVIP Initiatives

- CVIP Technology Development Awards – FY2010

**Granting Schedule**
- January 15, 2010  Applications Due
- January 29, 2010  Notification of Finalists
- February 25, 2010  Finalist Presentations
- March 5, 2010  Announcement of Awards

*We strongly urge you to consider applying for this award. CVIP will assist you with your proposal and presentation at your request.*
CVIP “Background” Activities

- Transactional work: CDAs, MTAs
- Proactively develop relationships with business & venture community
- Raise profile of UML as perpetual reservoir of inventive activity
- Oversee patent prosecution through outside counsel
- Compliance by companies of existing agreements
- Advise faculty on diverse matters
CVIP Resources

- Advisors
  - UMass
    - OGC (Office of General Counsel)
    - VPRO (Vice Provost Research Office)
  - Internal Advisory Board
    - Faculty – assembled by Provost
    - Advise on all matters
    - Serve as ambassadors for CVIP
  - External Advisory Board
    - VCs, senior business executives
    - Currently being assembled
CVIP P Resources

- **Workload Management**
  - UMass – OGC (Office of General Counsel)
    - Contract Review
  - Outside patent counsel
    - Management of patent filing and prosecution
  - Consultants
    - Portfolio review & management
  - Oversee patent prosecution through outside counsel
  - Compliance by companies of existing agreements
  - Advise faculty on diverse matters
Contact UML-CVIP

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  - Ofc: (978) 934-3235    Email: kerrylee_andken@uml.edu

CVIP is located at:

- Wannalancit Mill Bldg., 600 Suffolk Street, 2nd Floor
- Website: http://www.uml.edu/cvip/default.html
  - Forms, policies, helpful links, this presentation!
  - Major renovation underway