Intellectual Property in Research Agreements

CTL CENTER FOR TECHNOLOGY LICENSING AT CORNELL UNIVERSITY

Types of IP

- Data and reports
- Tangible materials
- Inventions – patentable; patents can be used to exclude others
- "Background" vs foreground
  - "Conceived and reduced to practice during the Research"

Key questions

- Who owns it?
- Who has the right to use it, and how?
- Who benefits financially?
- Keep these separate! Too often people fixate on who owns it. Manage rights to use and financial benefit via licenses.

Types of license grants

- Option to license vs license
- Exclusive vs nonexclusive
- Field
  - Research use vs “commercial use”
    - Surface difference seems easy – use in selling products or not
    - How to classify data included in a regulatory submission or grant application? Both are part of the business for companies and for universities.
  - Therapeutics, diagnostics, etc
  - Disease
- Consideration – paid-up, or with revenue sharing, or fees and royalties?

Why do we care?

- Company
  - Exist to make money for investors and help people
  - Wants “deliverables” - research results it can use
  - Wants freedom to operate - to be unencumbered by IP from others
  - Wants to protect and expand its own IP to compete and to exclude competitors

- Funders
  - Want to make an impact it can measure (even the NIH!)
    - Reporting of immediate results, credit in publications
    - Reporting of longer term results - patenting and licensing and commercialization
  - Ensure other researchers can use research results (e.g. reagent sharing)
  - Some want a share of any income so they can become evergreen

- Cornell
  - Do great science - need money and materials
  - Make an impact – need commercial partner, generally.
  - Basic fairness/recognition (be listed as inventor on a patent)
  - Comply with federal laws and regulations (tax-free bonds, Bayh-Dole, HIPAA)
  - Comply with Cornell policy
  - Preserve potential for long term benefit

Principles

- Faculty must be informed of what the agreement says, and consent to it
- No unfunded obligations (e.g. no requirement that we file patent applications)
- No rights to background IP
- Cornell owns inventions made by Cornell faculty and staff (this is Cornell policy; can be waived)
- No commercial NERFs (financial terms must be “market rate”)

Who handles?

- Negotiations
  - OSRA / BioPharma Alliances / Joint Clinical Trials Office
  - CTL handles outgoing MTAs. CTL advises other offices; may actively participate at times
  - Faculty will be consulted for thorny terms; will be asked to sign/acknowledge the agreement
- During the research
  - Faculty
    - Comply with terms (e.g. not mixing money, not doing off-scope work with company drug)
    - Generate reports
    - Essential that faculty communicate with OSRA/BPA/CTL

Tangible materials

- Tissue samples, organoids, PdX
  - Incredibly valuable to companies today
  - Need to be mindful of IRB/consents and our mission
  - Must get something of value (can include data from processing) and cover costs
- Other biological material (plasmids, mice, etc)
  - Progeny, derivatives
  - Modifications
- Chemical matter

Tangible materials incoming

- Few strings, generally
  - Can't use in people
  - Can't send to others
  - UBMTA
- If incoming material is a drug candidate
  - If company-driven clinical trial, SRA, or MTA
    - Company will demand, and we generally give, all IP rights
  - If investigator-initiated:
    - If your idea is a truly new use for an existing drug, please disclose the idea to CTL before you approach the company
    - IP is negotiated based on whether we have anything

Tangible materials outgoing

- Key issue is whether we have the right to send, or not
  - Getting material from X and sending to Y is generally not OK
  - Serious liability if X and Y are two different companies!
  - Litigation in CAR-T field between Juno and Novartis arose over use of material sent from St Jude to Penn; Penn "incorporated cDNA from St. Jude into a vector" it licensed to Novartis. St Jude had licensed their material to Juno. Novartis ended up paying St Jude $13M.
- Rights granted – generally nonexclusive, research only, nonclinical

Data and reports

- Outgoing data
  - Results of experiments conducted here
  - Patient data?
    - Incredibly valuable to companies today
    - Need to be mindful of IRB/consents and our mission
    - Must get something of value (company data from processing it?)
- Incoming data
  - Incoming data (e.g. company applies novel sample prep or sequencing, or other company results)
  - We want right to publish, use in grant applications and patent applications
- Reports
  - May describe an invention! If so, disclose to CTL prior to submitting report.
- Rights granted – generally nonexclusive, research only.
  - But also perhaps for regulatory submissions, grant applications, patent applications, etc.

Inventions

- Company perspective and university perspective
  - Company is one entity, thinks of its IP as one package
  - University is sprawling; we think about IP on a per-inventor or per-lab basis.
- Background vs foreground
  - Background (no rights granted – companies often ask for license to all Cornell background IP)
  - Foreground:
    - During collaboration – nonexclusive right to use for research
    - After:
      - Nonexclusive right to use for research
      - Option to license for developing products/services