Hurdles in Managing University R&D Projects

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Agenda

1. Mission
2. Evaluation of Ideas
3. Who are the Customers?
4. Development Process
5. Intellectual Property
6. Questions/Answers

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Alice –

“Would you tell me, please, which way I ought to go?.........
I don’t much care where.”

The Cheshire Cat –

“Then it doesn’t matter which way you go.”

- From Lewis Carroll’s
“Alice’s Adventures in Wonderland”
Example of Cornell Engineering College Mission

• Provide students with broad and exceptional education to become creative leaders and mentors in an increasingly complex world.

• Lead responsively the discovery of new knowledge and transforming technologies.

• Create a better future for all people.

• Research Areas:
  – Biomedical Engineering
  – Nanomaterials
  – Energy, environment, and sustained development.

-paraphrased from Cornell University College of Engineering, 2005
Why stay within Mission?

1. Reputation of the institution.
2. Funding.
3. Facilities. (e.g. is a vivarium consistent with university policy?)
4. Tenure.
5. Collaboration with faculty/staff.
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So, is our mission to advance science or create royalties?
Is profit evil?
Advance Science

Make Profit

We can do both simultaneously!
Typical Royalty Split

1/3 University
1/3 Inventor
1/3 Department  ➔  more research
Evaluation of Ideas

1. Internal Tech Transfer Office.
   • Contract negotiations.
   • Provisional patents.
   • Need sponsor for 12-month non-provisional.

2. Sponsor.

3. NYSTAR sponsored program at SU.
   - Empire State Development Corp sponsored programs at Niagara, Stony Brook, and RIT patterned after SU.

4. External Board – seek sounding board.
Johns Hopkins Medical Alliance

- $500 million annual research.
- Very small royalty stream.
- Review board:
  - Device manufacturers & Pharmas
  - Venture Capital
  - Academia
- Advice
  - Competitive technologies
  - Market
  - How to commercialize – VC money, strategic partner, license, IPO.
  - Probability of success
Who are the Customers?

1. Students – don’t forget why we are here.
2. Sponsor – government, company.
3. University – publish or perish.
Development Process
1. Don’t miss anything.
2. Understand how long it will take.
Development Process

- Project Authorization
- Design
- Clinicals
- Regulatory
- Retrospective

Is there really an unmet need?
Grave Alarm
Development Process

- Project Authorization
- Design
- Clinicals
- Regulatory
- Retrospective

Effort vs. Time

Is the idea really novel?
What can be learned from literature and patent search?
Development Process

- Need
- Research
- Feasibility (loop)
- Project Authorization
- Design
- Clinicals
- Regulatory
- Retrospective
- On Market

Time

Effort
How do you know if you are on plan?

1. Gantt chart

<table>
<thead>
<tr>
<th>Task</th>
<th>Responsibility</th>
<th>1Q09</th>
<th>2Q09</th>
<th>3Q09</th>
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</table>
How do you know if you are on plan?

1. Gantt chart
2. Weekly team meetings
   • Everyone involved
   • No finger pointing
What happens when you get off plan?

1. Don’t compromise:
   - Safety
   - Quality - reputation

2. Trade off:
   - Budget - people and dollars
   - Schedule - market introduction date
   - Scope - less features
Development Process

- Need
- Research
- Feasibility
- Design
- Clinicals
- Regulatory
- Project Authorization
- Retrospective
- On Market

Effort vs. Time graph

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Cut your losses. Move on to next project.
Development Process

1. What could we do better?
2. Process, not people.

Not always necessary.
Don’t:

1. Underestimate the cost to get to market:
   - Design for manufacture
   - Agency approvals
   - Setting up production line

2. Underestimate the value of established distribution:
   - Cost to operate
   - Name brand recognition
   - Product pull through

3. Overestimate the worth of your patent
   - Workarounds unless broad, pioneering patent
   - Kodak has 200 patents before new product is launched
Intellectual Property
1. Single source at university for IP policies and practices.

Tech Transfer (or Office of Sponsored Research) should provide direction for researchers and let them do what they do best, research.
Intellectual Property

1. Single source at university for IP policies and practices.
2. Mandatory written agreement by staff to comply with IP policies, including NDA.
Intellectual Property
1. Single source at university for IP policies and practices.
2. Mandatory written agreement by staff to comply with IP policies, including NDA.
3. University ownership of IP.
   - They can license it – exclusive, non-exclusive in field.
   - IRS Revenue Procedure 2007-47 bars university from granting a license to sponsor before IP is developed.
   - But, university can grant 1st Right of Refusal at competitive terms in a field.
Intellectual Property
1. Single source at university for IP policies and practices.
2. Mandatory written agreement by staff to comply with IP policies, including NDA.
3. University ownership of IP.
4. Mandatory lab notebook policy. (Lisa Dolak e-)

- Syracuse University New Technology Law Center, 2005
Inventorship

• Foreign countries are all “first to file”.
• USA is the only country that is “first to invent”.

So, keep a lab notebook.
Braun US 6,898,457
Filed: 9/16/1998

Welch Allyn US 6,631,287
Filed: 4/3/2001
Lab notebook: 6/9/1997

e.g. Braun foreign patents because first to file,
Welch Allyn US patent because first to invent (swear behind).
Don’t wait too long to file:

Welch Allyn filed Video Endoscope 2 months before Olympus
How should research records be kept?

- Traditional bound notebook with sequentially numbered pages.
- Record in ink. May be in colors for clarity.
- **State the need, teach solution, and explain what you feel is novel.**
- Date each entry.
- Use pages sequentially. Use line out and date spaces.
- Cross out, don’t erase, mistakes or date changes.
- Cross reference by notebook and page number related works, including other notebook entries, physical samples, computer printouts stored outside the notebook.
- Securely affix inserts (data printouts, photographs, napkins) with signature and date across one side and either the top or bottom.
- **Sign and date entries, changes, and corrections at the end of each work day. All inventors must sign each page.**
- **Have entries, changes, and corrections witnessed and dated by at least two non-inventors, but who understand the work.**
4. Field distance is adjustable for adults vs. children. Use shortest distance and FOV.
1. Use in both ear 4 month old or age.
2. SENSOR
   *1 = single IR sensor
   *2 = scanning 2-D sensor
   *3 = 2-D IR array

3. Use known temp source to calibrate prior to testing in ear.
   Place calibrator source at the virtual aperture.
When are inventor & witness signatures needed?
1. Needed for anything that could become IP.
2. Not needed for raw data.
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(Again, let Tech Transfer Office handle this in a timely manner.)
Intellectual Property
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4. Mandatory lab notebook policy.
5. Inventors must disclose IP to university.
6. Policy for distribution of royalties.
Publications – teach your novel idea

• Foreign patents are invalidated by publication prior to filing.
• USA patents get 12-month grace period.
• Poster, paper, thesis, ……..
• Be sure to give Tech Transfer department and Sponsor 30 to 60 days notice before publishing time to file patents.
Timing is Everything

1. University semesters don’t match with industry.
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Start & stop anytime?
Timing is Everything

1. University semesters don’t match with industry.
2. Extending research/clinical hinders industry’s market introduction and jeopardizes future relationships.

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1. University semesters don’t match with industry.
2. Extending research/clinical hinders industry’s market introduction and jeopardizes future relationships.
3. Diligence – termination or loss of exclusivity
   – University show best effort v. positive outcome.
   – Strategic partner must market product/service
     • on market date
     • minimum sales
   – Government sponsor has march-in rights.
Effective University Research

• Benefits the public
• Provides scholarships
• Funds further research
• Educates students
Questions

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