Using Inter-college Undergraduate Teams to Support Technology Commercialization

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ABSTRACT
Based on a May 2003 National Collegiate Inventors and Innovators Alliance (NCIIA) course grant, undergraduate students from the Colleges of Engineering and Business are enrolled in a pilot course entitled *Market-Pull Technology Commercialization*. The course was developed in conjunction with the Penn State Technology Transfer Office. The goal of the course is to help improve the lower-than-desired return on investment on university research leading to commercialized products/services. The technology commercialization process is complex:

a) the creators of technology rarely have insight into the markets for their inventions, are often not interested in the details of commercialization, can be secretive, and often tend to move on to the next discovery or invention rather than take the intellectual property protection steps of provisional patents.

b) the business and financial communities often do not take the time, or have the resources, to understand the new technologies and perform complex due diligence. This lack of due diligence can contribute to rejection of innovation because companies may discount the new technology as NIH - "not-invented here".

c) the lawyers, to provide effective support of technology transfer and commercialization, need understand the technology, have a vision for where the technology can address market needs, and can craft the license and option agreements to satisfy all the other stakeholders in the process – researcher, business, educational institution.

Effective transferring innovation to a commercial product requires these three different functional communities to interface – **technical researcher/inventor, business and legal**. The 'how-to' literature in this field is largely focused on legal process rather than the human factor issues which are far more important. The subtleties of the transfer must be transacted through

active involvement by the technical staff from both the providing and receiving entities. This is often called an 'agency' model.

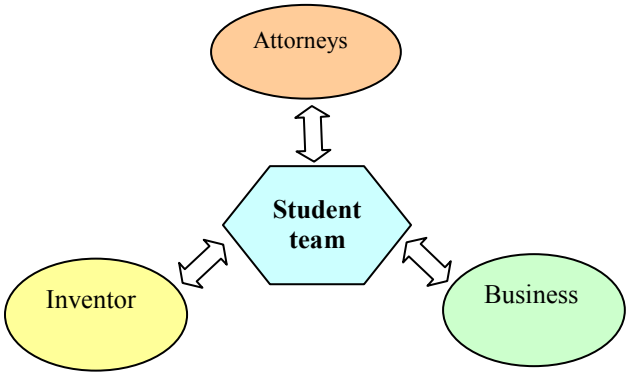

Figure 1: The *BA/ENGR497E course investigate if undergraduate teams can help bridge the gaps between key players in technology commercialization process.*

The courses (Fall 2003 and Spring 2004) are taught in a problem-based learning format, with the engineering and business faculty leading the class as mentors. In Fall 2003, the engineering, business, pre-med/pre-dental students divided into four interdisciplinary teams of 6 to 7 students each to analyze commercialization options for two neonatal care inventions by Dr. Charles Palmer at Penn State's Hershey Medical Center. The objectives for the four student teams in the Fall 2003 pilot course was to: 1) to understand the two inventions and related patents, license and option agreement and 2) to suggest methods to bridge the chasm between these key players in the technology commercialization process 3) be technology commercialization "agents" for the two inventions.

This paper reviews details of course format, results from the Fall 2003 semester's work, and progress to date in the Spring 2004 course. In addition, the plan for assessment is summarized which investigates student growth in entrepreneurial and technology transfer skills and team work.

Introduction

The *Market-Pull Technology Commercialization* course was developed and co-taught by faculty in the College of Engineering and Business, with input from with the Penn State Technology Transfer Office (TTO). The course used the principles of problem-based learning, and meets many of the educational and skill objectives described in the ABET2000 General Engineering Skills (Criterion 3). [1] The course format also aligns well with the stated goals and objectives from the Directorate of Engineering/NSF to [2]:

- have students do technology strategic planning
- engage in learner-centered communication
- develop student's ability to see beyond prevailing paradigms
- develop student's ability to overcome non-existent assumptions

The advantages of this methodology are summarized at Penn State's problem-based learning web site: http://pbl.ist.psu.edu/index.html.

The two inventions addressed in the course were both from Penn State's Hershey Medical Center, and are described briefly below. (More information can be found at the Pediatric Innovation Center web site: http://www.hmc.psu.edu/pedsinnovation/areas/).

- **Neonatal Chest Brace** is covered by two patents and one license agreement to a PA medical device company. Hug n' Snug is an external chest support splint for neonates between 750 and 2500 gram weight, is designed to be an alternative to mechanical ventilator for particular respiratory distress scenarios, and is in the FDA (Food and Drug Administration) device approval process.

Figure 2 – Neonatal Chest Brace

- **NORI** (Nasal-Oral Respiratory Interface) is covered in one Penn State patent, and has an option agreement to the same PA medical device company as the Chest Brace. NORI is a flexible U-Shaped device to support endotracheal tubes and other oral tubes with minimal or no adhesive tape which may tear epidural skin layers. In addition, the NORI can prevent palate and gum grooving for infants with long-term use oral tubes.

Figure 3 – NORI, placed on neonate-sized doll

Students were recruited from across Penn State by cross-listing the course as both a business course (BA497E) and engineering course (ENGR497E). With an enrollment of 25, students were placed on an invention team (matching their preference):

Team 1 – NORI (6 students: 2 engineering, 2 business, 1 liberal arts, 1 science)
Team 2 – NORI (6 students: 2 engineering, 3 business, 1 science)
Team 3 - Chest Brace (6 students: 4 engineering, 2 business)
Team 4 – Chest Brace (7 students: 4 engineering, 3 business)

The goal of the course is to help improve the return on investment on university research leading to commercialized products/services. At the start of the course, answers to the following questions were expected from each of the four teams:

- What recommendations would they make to faculty at PSU to improve the technology transfer (TT) process?
- What could the TTO do to improve the TT process and to increase the value of PSU's research output?
- How could licensees of PSU's technology improve their interaction with PSU for mutual benefit?
- What engineering design changes could be beneficial to commercialization?

Across the 15 week semester, guest speakers included a senior representative from the FDA Device Division, product managers from the PA company with agreements for the Neonatal Chest Brace and NORI, Penn State's TTO, and an entrepreneur who had licensed biomedical technology from another Big 10 university. These presentations, along with lessons on the critical IP documents (patents, license agreement and option agreements), web-based secondary market research and primary market need analysis formed the in-class content coverage. In addition, because the inventions/products are based within Penn State, students were required to sign the Penn State *RAG-13: Special Intellectual Property Agreement Form for Students - For Use When Assigning Intellectual Property to The Pennsylvania State University*. The guidelines, rules and form can be viewed at http://guru.psu.edu/policies/RAG13.html.

The student teams also undertook both primary and secondary market research, the former at leading neo-natal care units in major hospitals where they spoke with leading physicians and practicing nurses. They researched competitive products, pricing, etc., examined the patent structures, the licensing formats, and the history of interaction with the licensor from both technical and legal perspectives.

Course Details, Results and Suggested Improvements

In the first seven weeks of the Fall 2003 course, all the students learned the basics of IP management, the history of the two inventions, met the inventor and representative of the licensing company, and did secondary market research on the Total Available Market (TAM) for neonatal breathing devices in the US and internationally. At week 6, the students began working in their product team – either focused on the Chest Brace or NORI. Each team gave a work in progress update in week 8, as well as a final presentation in week 14, summarizing results of the team's market analysis, redesign concepts, and suggestions on ways to minimize TT delays.

Below is the Fall 2003 course schedule for the *Market-Pull Technology Commercialization Course:*

Week 1: Course kick-off; introduction of two inventions (Chest Brace, NORI)
Week 2: Secondary Market research - start
Week 3: Review of three patents (2 Chest brace, 1 NORI);
Week 4: Travel to Hershey Medical Center; visit neonatal intensive care unit
Week 5: Review, analysis and discussions on Chest Brace license and NORI option agreements
Week 6: PA Life Sciences Greenhouse presentation; role and investment in NORI; students select NORI or Chest Brace project to focus on
Week 7: Senior representative – PA medical products company; presentation/Q&A

Week 8: Mid-term team presentations initial findings on product need/viability
Week 9: Develop primary market data tools (surveys/questionnaires)
Week 10: Senior representative – Food and Drug Administration; presentation on device approvals; Q&A
Week 11: Penn State Technology Transfer Office presentations; examples of successful and non-successful IP sharing and tech commercialization
Week 12: Team Progress Presentations
Week 13: Biotech entrepreneur speaker and team progress checks.
Week 14: In-class Final presentations

There was a wealth of insight that came out of the four teams, including some observations which impact the structure of the Spring 2004 course, point to improvements in faculty involvement in the commercialization process, and suggest improvements in the TTO/licensee relationship. The most important insights were:

1. The Down-sides of the Technology Push Model for Technology Commercialization. Penn State, in common with most if not all universities, has a "technology push" model for TT. In the technology-push model, frequently the first time the TTO learns of promising results from research for new materials, devices or processes, the inventor is asking for help in securing a provisional patent. At this point, significant research and prototyping has been competed. In these technology-push cases, two results are often seen:

- significant effort has been invested by faculty and the TTO on developing the inventions that may have only a very small market. In fact, there could be a range of better products already in the market place, and the new invention fulfills no buyer value. This case happened for one of the inventions in the course, OR

- the product does have a viable market, but primary market survey data shows some design improvements could enhance the market size. This case happened for the two student teams focusing on the chest brace. One team suggested a redesign of the size-adjustment mechanism, allowing for single-handed adjustment. The second team, after undertaking interviews with neonatal physicians, redesigned the product to address questions on skin-coverage area that could degrade device performance and comfort. Both student teams' redesign may add valuable intellectual property to PSU intellectual property assets. The NORI inventor and the chest brace licensing company both supplied electronic CAD (Computer-Aided Design) files to the student teams, so updated design files could be supplied back to Penn State and the licensing company.

2. Design/Development Record Keeping. Lack of design records by the inventor can result in significant delays in technology commercialization. For example, one of the inventions studied could have been closer to market introduction in the US already thereby earning revenue for the University, if a) the design control rules now required by the FDA had been followed and b) Penn State had understood the product claims that the product could carry. The lack of design records and an over-optimistic patient benefit claim was made to the FDA which moved the product from a Class I to a Class II device. This change delayed FDA approval and added major cost in the development program for the licensee. If PSU and the inventor had delivered the design control package to the licensee, it would have added significant value to the IP. All

faculty should understand the design control protocol, and methods should be found to encourage or incentivize faculty to follow the design control steps as part of their research documentation.

3. Work with "young" inventions. The two inventions researched by the four student teams in Fall 2003 had several advantages: medical devices to support health and well-being of neonates, simple and elegant solutions to two user needs, and IP protections in place. However, both the Chest Brace and NORI inventions have matured to the point where they have been prototyped and improved over a multi-year period, with functional prototypes in clinical trials. The other end of the invention age spectrum can also present problems for the students. If the invention is so new that no provisional patent has been filed, the researcher must be very careful in disclosing the IP too early, including working with Penn State undergraduates who by Penn State policy have 100% ownership of their IP. Working on such "newborn" inventions would involve complex disclosure agreements, and restrictions on how much technical information the students could discuss with companies. In summary, the inventions used in the Market-Pull Technology Commercialization course should be "young" inventions, in which IP protection is in place, but design changes can be made based on market needs and suggestions from potential users.

Based on the end-of-semester team presentations, the students recommended the following specific actions:

1. Training in TT for the faculty and researchers. The TTO should create online courses on TT, patent issues, FDA pre-submission requirements including design control process. Completion of these courses should be a requirement prior to the TTO accepting an invention for disclosure and processing. There is a model already at PSU for this type of on-line education for faculty, namely materials and on-line quiz for all faculty and staff working with human participants in research. (See the Office for Research Protections web site at http://www.research.psu.edu/orp/ . The online quiz described at http://www.research.psu.edu/orp/hum/train/intro.html must be taken and scored above a 90% for the faculty to be qualified to participate in any biological or social research on humans that is used in published papers or reports.)

Another recommendation was the creation of an Annual TTO Conference for all PSU researchers/inventors, with sessions to

- demonstrate/discuss some TTO commercialization success stories
- train attendees on working with FDA, the design control procedures, etc.
- provide networking opportunities for research/invention collaborations
- educate attendee on IP protection steps - - Non-disclosure agreements, etc.

2. Licensing and Option Agreement recommendations. To improve communication among the three stakeholders in the technology commercialization process (Figure 1), students suggested three actions:

a) TTO should strongly encourage the researcher/inventor to look at market needs early in the research/invention cycle… before the researcher comes to the TTO with a request for provisional patent support. If the researcher does not personally want to do this, then the TTO should find a way to provide this analysis support: will result in higher value IP.

b) Each license or option agreement should require that the university and researcher are provided results of any market analysis summary related to the invention done by the licensee. This would help everyone "know what the licensee knows" and could help in making decisions on research/product refinements.
c) If TTO already has agreement(s) with a corporation and additional licensing or option agreements are being set up, use this opportunity to:
- make improvements/revisions to the first agreement(s), if needed
- write the new agreement with knowledge of the success or problems earlier agreements

3. Market Analysis by Student Teams. The *Market-Pull Technology Commercialization* course should put teams of students on very early stage inventions, where they can look at the market opportunities earlier in the invention's development. The teams can then provide feedback to the faculty and the TTO long before the created IP has no value in the commercial market place. The premise is that by providing potential customer/licensee input at this stage, there is a much greater chance that the IP created would have a higher value, and would be much easier to transact. In summary, a mechanism to put market- pull into our technology commercialization model is vital. The use of student resource for this provides a wonderful educational opportunity as well as value to the university and its researchers. (A few of the students were so fired up by this idea, they were contemplating looking for a market opportunity themselves and then seeking the technology to fill the market need from Penn State or at other Universities. These students have internalized the market-pull commercialization approach to become entrepreneurs and create value for all the stakeholders).

Based on the Fall 2003 course, the following changes are being made for the Spring 2004 course

- Three "young" inventions will be used in the class. These inventions are still malleable, have (as a minimum) a provisional patent applied for, technical publications, and the researchers are open to student teams doing market and design investigations. In addition, the TTO welcomes help on product feasibility analysis.
- Slightly smaller class size (20 students)
- Students begin primary market research much earlier in the semester. In Fall 2003, some of the most important data was collected during the primary market research in weeks 11-14. In Spring 2004, primary market research will begin in the first half of the semester.
- Deliverables from each invention will be customized to assist inventor in optimizing the research or invention, and to assist PSU TTO in making solid market-need decisions on further patent expenditures leading to licensing or creating a new spin-out company.
- Although the technology commercialization work is open-ended problem solving, the students requested more structure to the course itself, with a more definitive grading structure.

Full assessment of the students in the Fall 2003 course did not occur due to delays in obtaining Human Subjects approvals for the social research. A full assessment program is being prepared for the Spring 2004 course and is summarized below:

Hypothesis:
Undergraduate, interdisciplinary teams can actively support technology commercialization of Penn State inventions, with this activity benefiting the students having improved entrepreneurial skills in leadership, self-efficacy, creativity, communication and team work.

Methodology:
This hypothesis will be tested using several assessment approaches.

1) Pre- and post course survey. Half the survey measures specific knowledge gains in technology commercialization process/terminology, and the other half is a self-assessment of improvements in creativity, idea generation and presentation skills and teamwork.
2) On-line quantitative assessment using the E-SHIP Minor tool [3], which measures leadership, self-efficacy, creativity communication and team work skills.
3) Focus groups, such as those presented in the NCIIA 2004 paper: *Evaluation of Entrepreneurial Endeavors in the classroom: The student perspective* (Rzasa, Wise and Kisenwether)

Conclusion

The Fall 2003 pilot course for Penn State's *Market Pull Technology Commercialization* demonstrated that students could function well on inter-college teams in a problem-based learning environment. The four student teams delivered solid suggestions to both the TTO and to the inventor on how to improve the return on investment on university research leading to commercialized products/services. Referring back to the questions posed earlier:

1. Recommendations to faculty at PSU to improve the technology transfer (TT) process: *be as methodical as possible in design/development record keeping. A well-documented history of the invention's evolution increases the IP value and can reduce FDA approval times for inventions related to drugs, medical devices.*
2. Ways the TTO could improve the TT process and increase the value of PSU's research output: *institute an on-line TT training course which all faculty must complete and pass the quiz before getting IP management support from the TTO. Offer an Annual TTO Conference to show success stories, educate researchers on best practices for TT and commercialization, and support TT collaborations.*
3. How licensees of PSU's technology can improve their interaction with PSU for mutual benefit: *update the TTO on progress in meeting license or option milestones with open communications. Establish and maintain a common knowledge base between all stakeholders: licenser, licensee and inventor.*
4. Engineering design changes which could be beneficial to commercialization: *two design modifications where developed in CAD to improve ease-of-use and accurate adjustment of the Chest Brace size. For the NORI, a three-point attachment approach was proposed as well a redesign to distribute the hydrogel pads across the neonate's face for increased stability.*

The *Market-Pull Technology Commercialization* course will be offered for the second time in Spring 2004, in which the following changes will be made to improve the course: use of "young" inventions, an earlier start and more in-depth use of primary market research, and student travel to visit companies who want to be part of the market-pull activities. Finally, if funding is available, a multimedia case-based CD-ROM for the *Market-Pull Technology Commercialization* course could be developed to help scale the course to beyond the 1 faculty/20 student model. This CD-ROM could be available to other colleges and universities for broader research into using intercollege undergraduate student teams for market-pull technology commercialization.

Acknowledgements

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Biographies

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