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The WPI Venture Forum is a program of the Collaborative for Entrepreneurship & Innovation at Worcester Polytechnic Institute

Boosting Business from Blackboard to Boardroom

18th Annual Business Plan Contest November 8

by

GEORGE ARMSTRONG
DAVID THIBODEAU

co-moderators



BOB BAKER



KEVIN O'SULLIVAN



NICK PAPPAS

America's economy is fueled by innovation. Entrepreneurs need all the help they can get to bring their ideas from the blackboard into the board room. Each year the WPI Venture Forum's Business Plan Contest contributes to that cause by inviting technology-based entrepreneurs to take their ideas a step closer to commercialization. The winner will be selected in an exciting finalist face-off on November 8. At stake is an entrepreneur's treasure of cash and in-kind services.

After submitting an initial entry in early October, Business Plan Contest entrants shaped and presented their business ideas through a fun and inspiring judging process. Through the first round, they have been supported and coached along the way by experts that know how to earn funding in the real world. Judging the finalists this year will be three seasoned executives with a stellar track record of advising technology start ups — Bob Baker of SBANE, Kevin O'Sullivan

of MBI and Nick Pappas of MTDC.

President of the Smaller Business Association of New England (SBANE) since 2003, Bob Baker has more than 20 years' experience as business advocate and advisor to small business on tax and capital formation issues that influence their investment behavior. He has sponsored legislative initiatives in economic development and tax policy on Beacon Hill that resulted in the creation and funding of several new Massachusetts development finance agencies. Former VP of Commonwealth Corporation and senior lender for the Economic Stabilization Trust, Baker has also held positions in banking and economic development.

Kevin O'Sullivan is the President and CEO of Massachusetts Biomedical Initiatives (MBI), a

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100 INSTITUTE ROAD, WORCESTER, MA 01609

Gina M. Betti, Administrative Director

508.831.5075 | ventureforum@wpi.edu

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A LETTER FROM A CHAIR

Why Bother with a Business Plan Contest?



David Thibodeau '78

Every year WPI Venture Forum members donate an extraordinary amount of their time, professional services, and most of all, hard-earned cash to support the annual Business Plan Contest. Those of us involved find it to be the most worthy of endeavors. But in my role as coordinator, I have been asked numerous times this year, why do you people bother to do this?

Economists have long tried to develop sophisticated mathematical models that accurately relate the size of a firm to its potential for future revenue growth and job creation. As it turns out, the best metric isn't the size of a company at all, but rather its age. Multiple studies have borne out this reality: just about all job growth in the United States comes from brand-new start ups. They create millions of new jobs every year, while established companies are basically a zero-sum employment game. Enterprises do the bulk of their hiring when they are young, and tend to slow down as they grow old.

This suggests an easy answer to the recent rhetoric among our politicians — we should be encouraging people to start as many new companies as possible, rather than incentivizing existing enterprises. But the answer

isn't really that simple. One also has to consider which businesses generate the most opportunities. That new restaurant on the corner, small retail outlet, or garage is the most common type of start up. These may hire a handful of employees but they are never going to grow to a significant size. They are not out to capitalize on a new

idea or create new markets. Instead, most are just trying to provide an existing service to an existing customer base.

Fortunately, the answer to this pressing national question can be found right here. The surest way to grow the economy is to encourage innovative technology-based startups. Those of us involved with the WPI Venture Forum Business Plan Contest are proud to help identify and support these enterprises that are so critical to growth. Who knows? The winner on November 8th could become the next Genzyme or EMC!

I look forward to seeing you at WPI soon.

Sincerely,

David Thibodeau '78

WPI Venture Forum Business Plan Contest
Coordinator

Principal and Shareholder, Hamilton Brook
Smith Reynolds

Leahy-Smith America Invents Act Becomes Law

Back in September, President Obama signed into law a bill that had been long debated by Congress. The new law, known as the “Leahy-Smith America Invents Act” (the Act), is the most significant amendment to United States patent law since 1952.

Among the most significant changes is adoption of a “first-inventor-to-file” system, replacing our historical “first-person-to-invent” system. As a consequence of this provision, effective March 2013, traditional interference proceedings which determine priority between inventors will be phased out and replaced by a new “derivation proceeding.” A new “Patent Trial and Appeal Board” will determine whether an applicant who first filed an application derived the claimed invention from another applicant claiming the same invention in a later-filed application.

Other significant changes broaden the scope of prior art that is available to challenge patentability. Also effective in March 2013, foreign published applications or issued patents to which granted United States patents claim priority will become prior art effective as of their filing dates — for purposes of both novelty and obviousness. Similarly, certain activities that defeat patentability when conducted in the United States, such as prior use and placement of products “on sale,” will now defeat patentability when conducted in foreign countries.

Patentability can also be defeated where, before the filing date of the patent application, the claimed invention is “otherwise available to the public.” The Act also expands “prior user rights,” previously limited to business method patents, to commercial use of any subject matter in the United States.

Third parties will also be able to introduce obstacles to patent applicants in new ways, both during prosecution and after the patent issues. For example, patents and printed publications which qualify as prior art, as well as certain statements by a patent owner before a Federal Court or the Patent Office, may be entered by the public during patent prosecution. There will also be significant changes to reexamination of issued patents. A “supplemental examination” will enable a patent owner to address issues that might relate to allegations of inequitable conduct. If a threshold of a “substantial new question of patentability is met,” an *ex parte* reexamination will be ordered. The Patent Office is eliminating *inter partes* reexamination, and will now offer two new proceedings that can be instituted by third parties, called “post-grant review” and “*inter partes* review.”

Post-grant review will be available within nine months after issuance of a patent for consideration of any ground of invalidity, such as lack of enablement, lack of novelty and obviousness of the claimed invention. *Inter partes* review, by way of contrast, will be available starting nine months after patent issuance or reissuance, and will be limited to consideration of novelty or non-obviousness relative to patents and printed publications.

The threshold for each type of review is also different. Post-grant review will require the information presented to demonstrate that it is “more likely than not that at least one of the claims challenged” will be unpatentable or “raises a novel or unsettled legal question that is important to other patents or patent applications.” *Inter partes* review, on the other hand, will require “a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged...”

by

SCOTT PIERCE

Hamilton Brook Smith Reynolds



Several newly-introduced provisions affect litigation. For example, the requirement that a patent application disclose what the applicant considers to be the “best mode” of practicing the invention has been eliminated as a basis for invalidating a patent. Also, willful infringement cannot be established by showing that an alleged infringer failed to obtain the advice of counsel. The Act also restricts joinder of defendants in an infringement action.

The Act is complicated and leaves many questions to be resolved by the courts, but there is one message that stands clear: FILE FIRST!

Scott Pierce, a principal of intellectual property law firm Hamilton Brook Smith Reynolds, practices in the areas of biotechnology, chemistry, chemical engineering, medical devices, and pharmaceuticals, and is also an Adjunct Professor at Suffolk University Law School teaching biotechnology patent law. Scott can be reached at scott.pierce (at) hbsr.com or 978-341-0036. ✓

A LOOK AT THE OCTOBER 2011 MEETING

Life Science Innovation More

by

MICHAEL LAFLECHE



Case presenter Patrick O'Donnell (left) responds to comments from panelists Kevin Bitterman, Rob Brown and L

Is innovation anything more than a buzzword in life sciences? Participants in the October 11th meeting of the WPI Venture Forum sought to answer that question. Co-moderated by Mike Travis, Principal of Travis & Company and Janine Susan, Esq. of Burns & Levinson's Life Sciences Group, this month's meeting featured several experts who answered that question with a resounding "Yes."

Kevin Bitterman, Principal at Polaris Venture Partners, addressed how innovation is most definitely occurring in the life sciences industry. Polaris Venture Partners works with many companies in this sector, and the firm has discovered several cutting-edge methods for success. Venture money is not the open spigot it once was. In fact, Bitterman speculated that this could be a permanent market correction.

He categorized industry developments into "The Good," "The Bad," and "The Ugly." Many of the "Bad" and "Ugly" relate to the level of regulation imposed on medical device and pharmaceutical ventures that are starting up. In fact, in a survey conducted by the National Venture Capital Association (NVCA), the number-one obstacle to growth in this industry was overregulation, particularly by the FDA.

However, it was not all bad news, he continued. In times like this, there are more focused and innovative ways to propose new ideas. He offered several bright spots:

- Incubators promoted and managed by venture capital firms, such as Polaris' Dogpatch Labs, are available for entrepreneurs to develop products.
- IPOs outside the US market offer another source of securing capital. For example, GI Dynamics, a local company, went public on the Australian Stock Exchange in August and raised \$85 million.
- Smaller- and medium-sized startups are exiting more often through mergers and acquisitions.
- Entrepreneurs are showing greater discipline in product development. The ability to be very efficient with lower levels of capital has produced more viable companies.

Bitterman summarized that the life science industry has been one of the most successful places for venture capital partners to place their bets. There is just not as much venture money out there, so the companies that are successfully attracting investors have really strong ideas and are extremely focused. Channeling the spirit of Charles Darwin, Bitterman postulated that the strongest ideas and companies will survive.

Case Presenter:

Histogenics Corp.

Patrick O'Donnell, CEO of Histogenics, a Waltham-based regenerative medicine company, revealed his innovative way of growing through mergers and acquisitions, specifically, the acquisition of a cell therapy company, ProChon BioTech, Ltd., based in Israel. Histogenics develops and manufactures products that improve the body's ability to regenerate healthy cartilage, improve joint function and prevent degenerative disease.

What used to work in the past for business in the life science industry won't work now, O'Donnell said. So Histogenics' approach has been to build a distinctive investment opportunity to entice investors. Prior to the merger in the beginning of 2011, both Histogenics and ProChon were similar in several ways — both had attracted some \$30 million in funding from investors, both had been in business 10 to 12 years, and both were fairly late stage. And, both companies were also having a hard time raising the next round of capital.

Than a Buzzword



Ed Ross.

The solution was to merge two companies with a complementary asset mix and seize a market leadership position. The merger also expanded the pool of potential suitors to acquire this newly merged company. The new Histogenics hired an independent consultant to conduct a back-end analysis for the company and find out: who the potential acquirers might be, the potential exit value of the company, and why they would be considered an acquisition target. This intelligence has been used to ensure the company aligns its capital structure with the current investment environment.

One innovative achievement for Histogenics has been to mitigate the risk of their current NeoCart® cartilage regeneration implants' Phase II clinical study. This was accomplished via the FDA approval path of a Special Protocol Assessment (SPA) that was granted to the company for the Phase III study. An SPA is a declaration from the FDA that a completed Phase III trial's design, clinical endpoints, and statistical analyses are acceptable for FDA review without the risk of potentially requesting additional patient enrollment once the study has been completed. This is based on



Keynote speaker Kevin Bitterman

the Phase II study protocol and its results that were deemed acceptable.

Now with two flagship products, Histogenics has developed technology and products to reverse or prevent cartilage damage, regenerating healthy hyaline cartilage tissue. NeoCart®, autologous engineered neocartilage grown outside the body using the patient's own cells, has been developed for repair of full thickness cartilage lesions. The VeriCart™ cartilage repair matrix is being developed to stimulate cartilage regeneration in a simple, one-step procedure. The goal for both products: allowing patients to have lifelong active lifestyles.

A lively discussion ensued with several industry experts commenting on O'Donnell's presentation and company. Returning to the stage was Bitterman, who was joined by Rob Brown, Founder and Principal at Incite Medica, LLC, a medical device and commercial strategy consulting practice. Rounding out the panel was Ed Ross, President and Managing Director of Excelerate Ventures LLC, a strategy and

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Boosting Business from Blackboard to Boardroom

CONTINUED FROM PAGE 1

private economic development organization that promotes the growth and expansion of the biotechnology, medical device and bioinformatics industries. He previously served as Vice President and Director of Marketing in a combined public/private partnership position with the Worcester Regional Chamber of Commerce and the City of Worcester. From 1986 to 1994, he was a member of the Massachusetts House of Representatives where he chaired the Committee on Redistricting, was Vice Chair of Ethics, and sat on the Ways and Means Committee. He also served on the Worcester Business Development Corporation and was part of the development team which created the highly successful Massachusetts Biotechnology Research Park.

Nick Pappas has been working with early-stage technology companies for more than ten years, advising management teams and boards of directors on market expansion, capital raising and merger and acquisition strategies. Pappas joined Massachusetts Technology Development Corporation (MTDC) in 2009 and is responsible for identifying investment opportunities and working closely with MTDC portfolio companies. He currently manages MTDC's investments in Clarity, Courion, Ntirety, Polatis, TerraTherm and Texterity. Prior to joining MTDC, he was a senior technology investment banker with Oppenheimer & Co., SVB Alliant, and Canaccord Adams (formerly Adams Harkness) both in Silicon Valley and in Boston. ✓

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Long River Ventures

A Look at the October 2011 Meeting

CONTINUED FROM PAGE 5



Professor Soussan Djamasbi's *eBusiness Strategy and Application* students attended.

commercialization consultancy and angel investment cooperative focusing on disruptive medical innovation.

Several key themes emerged from their discussion. The panel applauded O'Donnell for completing a merger of two clinical late

stage companies. O'Donnell reminded the audience that in platform companies with multiple potential products in the pipeline, venture capital firms tend not to place much value on futures. Having a good idea is not good enough. Company milestones must be

market achievements, such as regulatory approval or product launches, and not activity achievements such as completion of pre-clinical studies or manufacturing and production accomplishments. In the future, the panelists agreed, the market will only reward true innovations that have demonstrated superiority over current technologies and bring savings to the healthcare system, but not "me-too" or commodity products.

Michael LaFleche is the Regional Technical Manager with Computer-Aided Product [CAPINC]. For more than 10 years, Michael has been helping New England manufacturing companies develop better products in less time for less cost with 3D CAD and simulation solutions, and can be reached at 203.494.5999 or [mlafleche\(at\)capinc.com](mailto:mlafleche(at)capinc.com). ✓

BPC Winner OsComp Growing Stronger

by
ALLISON CHISOLM

In the year since OsComp Systems won the 2010 WPI Venture Business Plan Contest, the gas compression technology company has worked to close a new round of funding, increased revenue at least five-fold, and has five full-time employees, reported co-founder and CEO Pedro Santos. They have a new office in Houston, while maintaining their current technology lab in south Boston, and expect to grow to 12 employees by year-end.

They have also redirected their business focus, from applying their high-efficiency compression technology to pure natural gas wells to wells with a mixture of oil and natural gas. “We offer a stronger value proposition now,” said Santos in a recent phone interview.

“We are doing great,” he continued. “We have multiple clients, and are fully booked for field trials.” The company has filed a utility patent for the bulk of their intellectual property protection and continues to develop its technology.

The Business Plan Contest’s \$18,500 cash prize has helped them bootstrap further, Santos said, noting “it paid for our upfront IP costs to start that protection process.” The in-kind services provided by Gesmer Updegrove for trademark advice and Hamilton Brook Smith Reynolds for licensing and technology issues were invaluable. In addition, one of the judges, Eric Schultz of HubCast, was helpful in connecting OsComp with a potential partner, Santos reported.

The company is also sponsoring a year-long Major Qualifying Project (MQP) with five WPI mechanical engineering students. Due to the confidential nature of their work (the students have all signed non-disclosure agreements), however, Santos couldn’t describe it beyond “pretty complex.”

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grow our WPI Venture Forum community and to organize blockbuster networking events.

The Marketing Committee helps to spread the word and encourage attendance at our events and programs. We also contribute to the creation of the WPI Venture Forum’s marketing materials, social media presence, web site and collateral.

Sound interesting? We’d love to hear from you—even if you only have an hour or two to share. Please contact Steve Munevar or Lisa Hamaker (at smunevar (at) munevarassociates.com or lisa (at) kaliday.com), or just say hello at one of our events.



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MEETING: 6:00 – 8:30 P.M.*

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November 8

Annual Business Plan Contest

December 13

Impact of Cloud Computing

January 10

Marketing Your Business

February 14

Financing War Stories

March 13

Sports Industry Entrepreneurship

April 10

Manufacturing's Evolving Landscape

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Managing Today's Workforce

June 12

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