



EMBC 2016 Symposium

Thursday, August 18th, 2016, 11 am – 12:30 pm – Grand Republic B

Start-Up IP roadmap

Entrepreneurship Symposium: How to Start a Start-Up

Moderators:

Dorin Panescu, PhD, FIEEE

Prof. Dieter Haemmerich, PhD

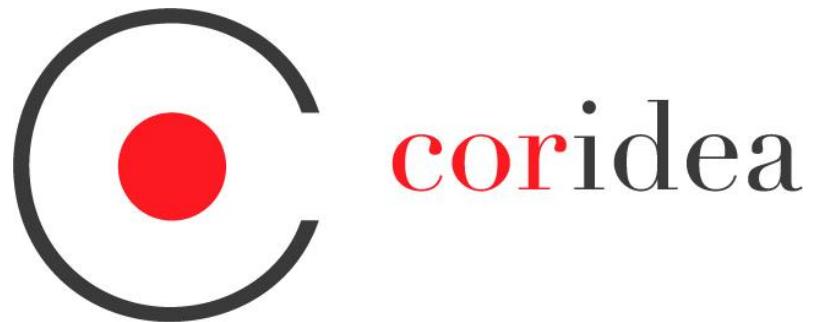
Entrepreneurship Symposium: How to Start a Start-Up

Part I



- **Howard Levin, M.D.**
Title of the presentation: Translating Ideas into Therapies
 - His inventions/co-inventions or patents have helped successfully launch 8 companies, including Ardian – successfully sold to Medtronic.
 - Past positions in these companies including President, Chief Scientific Officer, Chief Medical Officer and VP of R&D.
 - He is an author over 80 issued U.S. patents, an additional 100 published patent applications and 70 medical publications.
- **Theodore Papagiannis, J.D., P.E.**
Title of the presentation: Start-Up IP roadmaps: Patent Protection & Preparation for IP Due Diligence
 - Partner in the Medical Device group at Knobbe Martens and a licensed Professional Engineer in California.
 - Over 10 years in guiding start-ups and investors in patent and trademark portfolio management, licensing, IP risk evaluation, strategic IP.
 - Expertise in variety of areas,: spine, ,orthopedics, cardiovascular, ablation and other tissue ablation, skin care, cleantech technologies.
- **Mark Gelfand, M.S.**
Title of the presentation: How to establish an academia-industry partnership
 - Over 25 years developing medical devices in academic, startup and corporate environments: integrative physiology, systems and IP.
 - With Dr. Levin, cofounded Axon Therapies, Soffio Medical, Cibiem, CHF Solutions, Ardian and Respicardia, serving as CTO.
 - Mr. Gelfand is an author/co-author of 100+ issued U.S. patents in the fields of heart failure, resuscitation, sleep apnea and dialysis.
- **Richard Schmidt, Ph.D.**
Title of the presentation: Start-up Lessons Learned
 - Technical and business leader with extensive experience in engineering and commercializing complex.
 - Focused on medical technologies for cancer treatment.
 - Many publications and patents on nuclear medicine and X-ray equipment topics.

Translating Ideas into Therapies



Howard R. Levin, M.D.

EMBC 2016 Symposium

● Focus of This Presentation



- Who are we and what did we learn (the hard way)
- How do I determine if my idea is a clinically and commercially viable project
- Some real world examples of how we evaluate ideas

Serial Entrepreneurs with Long Track Record of Successful Innovation



- We founded CHF Solutions, Ardian, Respicardia, Cibiem, Soffio Medical and Axon Therapies and provided IP for eValve, PLC Medical
- Functioned as CEO/CMO/CSO/CTO of companies
- We started ***in academics*** and had to ***unlearn*** some of what we knew/ ***adapt to business***



Howard R. Levin, M.D.

- Heart Failure/Transplant Cardiologist from Johns Hopkins/Columbia
- Author on over 50 peer-reviewed scientific publications

Mark Gelfand, M.S.

- Control systems engineer and physiologist, Division of Cardiology, Johns Hopkins
- Author on landmark NEJM paper as well as part of first spin out of company from Johns Hopkins

15

years of joint innovation as Coridea

100+

patents issued

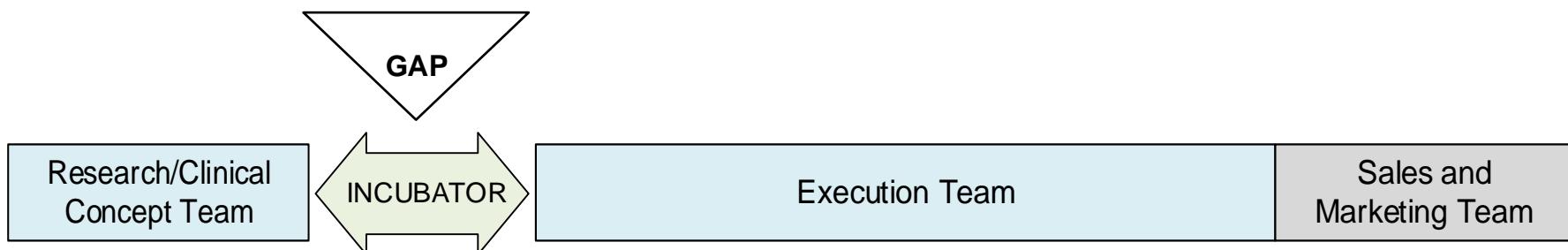
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Companies started, 3 successfully acquired, another has sales in EU and currently one in Series B/one in Series A

● Device Development Process

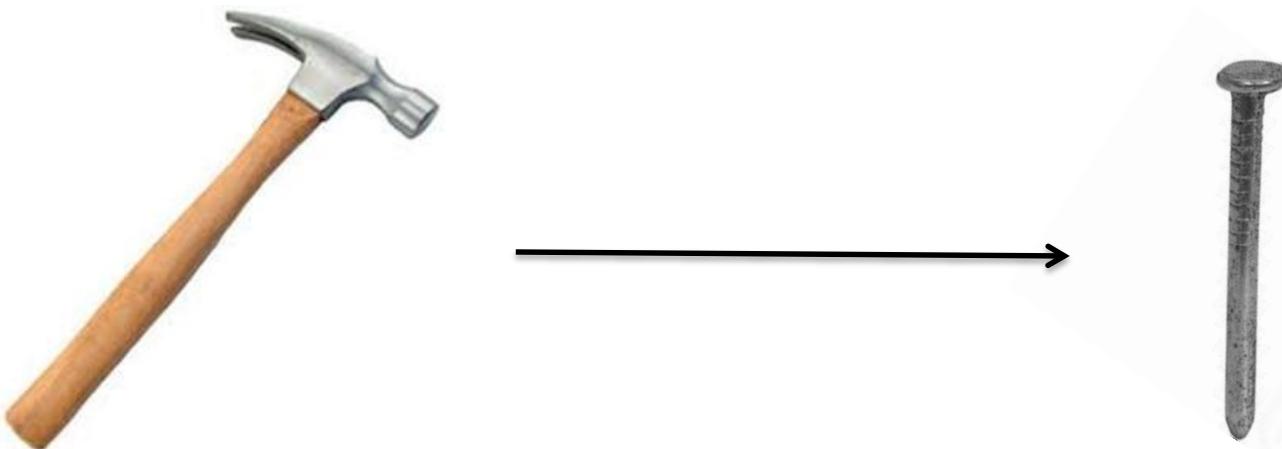


- Academic/clinician comes up with an idea for a device and starts a company. They find they can't practically implement it in humans
- Execution team is hired to make commercial device, do clinical trials, sales, etc.
- Companies commonly fail after this transition because of “gap” that exists in identifying/developing answers and “translating” scientific, clinical, market, etc. issues to execution team – 1° issue for academia
- Lead to the development of incubators that helped to bridge this gap



- From day 1, you and your team need to go outside their comfort zone of science and engineering
- Address/make a plausible plan for the engineering, clinical trials, regulatory, IP, marketing, reimbursement, etc. to “package” and shop your idea
- But what process should I take?

● Standard Device Idea Assessment Process



- You have been working on an idea that has been NIH/other funded for several years → it looks like it “works” well in animals and may have clinical benefit
- While placing stents, a physician notices that if the catheter they used had a specific curve, some of their hardest cases would become faster and easier
- A scientist noticed that if pacemakers implemented a new stimulation algorithm, it would improve cardiac output in the most difficult patients
- Are these “good” ideas? **For Mankind, Yes. Fundable as A Business, Maybe...**
- How does one tell which it is?

● Why Do You Care if it is a Business



- “Good for Mankind” ideas can be widely used if can be performed with already FDA-approved devices using modifications able to be made within the ability of physicians (steam a curve into a catheter, program certain set of pacing parameters)
- If outside of these practical limits, to get the money needed for development and regulatory approval, it must be a “business”
- The people you need to raise money from want to get a financial return on their investment for taking the risk of funding development, clinical trials and regulatory approval
- Thus, the devices you are developing must be able to be sold in large enough numbers to make your investors money – most can’t
- Thus, many clinically important ideas never get developed or widely used as a result of not being fundable as a business

What Should I Initially Focus My Effort on Showing?



- Does my idea justify someone giving me money
- Why should they trust me to spend it wisely
- Obtain the information needed to present a detailed plan including specific deliverables, timeline and budget for your first round of funding

My Take Away Message to You:

- **The vast majority of your ideas can be assessed and eliminated**
- **On paper ONLY**
- **Without ever building anything or setting foot in the lab**
- **By following a structured approach**

Our Evaluation Roadmap: What Do I Need To Know To Decide If I Should Move Ahead



Issue	Description
Unmet Clinical Need and Therapy Goal	What is the specific clinical indication we are going after What overall clinical benefit are we trying to achieve
Initial Device Design	Is there at least one potential device design that can be used to implement our proposed therapy
Proposed Technology/ Technical Risk	Do you have to develop a totally new approach. Can we repurpose some existing technology? Can you limit the “novel” issues (every risk) to < XX% of the project
Clinical and Regulatory Risk	Is there a known trial design or are you the first to work in this area Number of patients required Inclusion/exclusion criteria What measurable and accepted clinical and/or physiological endpoints exist in both the short-term (immediate to 3 months) and long-term (3 months to 2+ years) that will justify moving ahead with the study, continued funding or future acquisition Required duration of follow-up Does an FDA or ISO/IEC guidance exist
IP Risk	What is potential to own therapeutic space and core or enabling technologies Freedom to Practice Is our device novel
Reimbursement	Does it exist, can we piggyback on existing reimbursement

Our Evaluation Roadmap: What Else Do I Need To Know To Decide If I Should Move Ahead

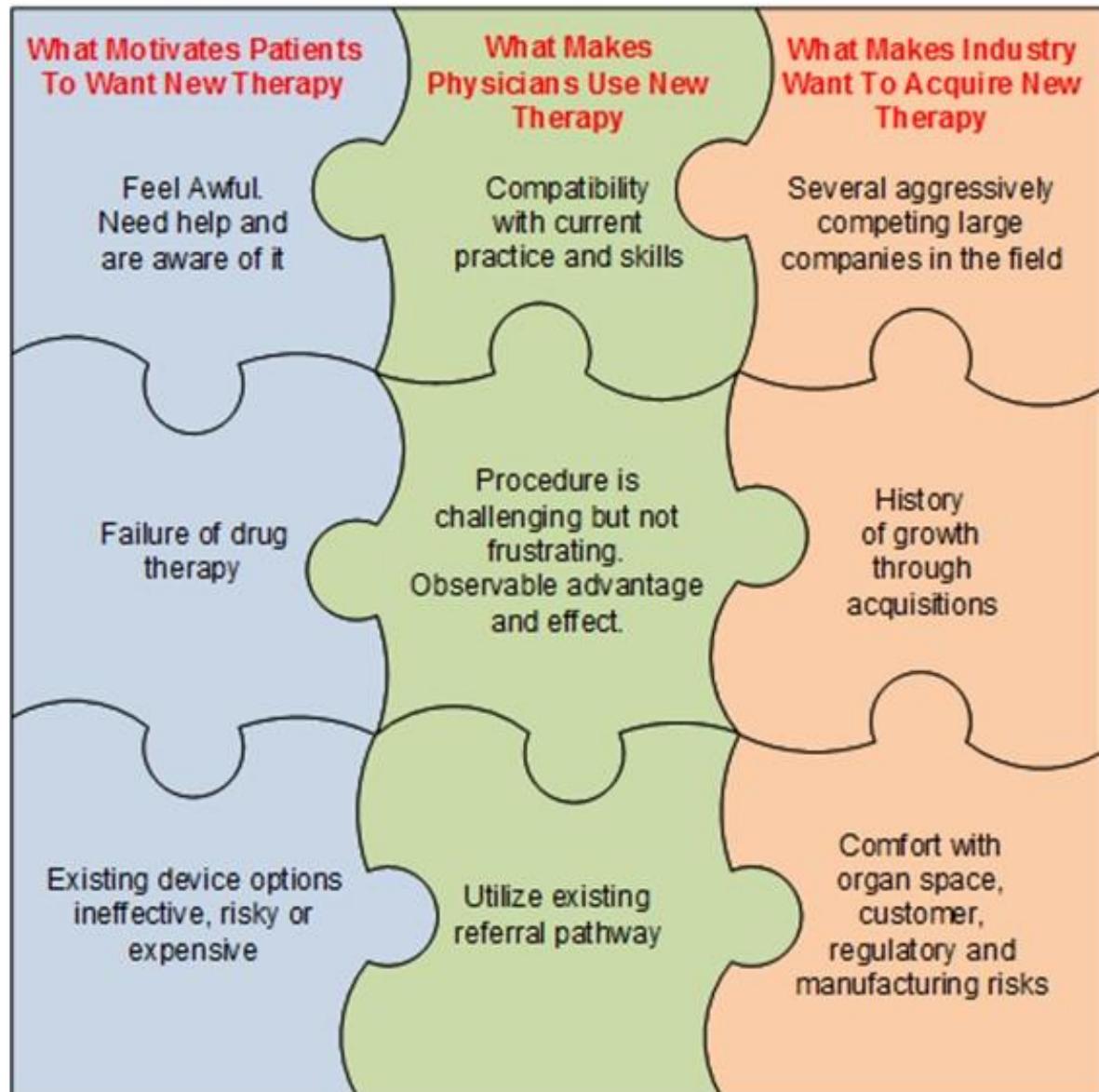


Issue	Description
Time From Idea to Approval	How long before you get acquired or become cash flow positive Is that an acceptable Return On Investment (ROI) for your potential investors
Sales and Marketing Risks	For each of the indication(s), what is the base and maximum market size and what factors are related to that Who are the potential users of the proposed embodiment(s) How does it fit their existing skill set? Who “owns” the patient Is it a normal referral pathway between the user and referrer?
Exit Strategy	Who are the logical acquirers for the proposed therapy
Potential for early investment/exit	What information would be needed by the acquirers to make an early strategic investment or acquisition possible and when would that data be available
Need for sales ramp to exit	Does the proposed therapy need to enter sales to be acquired
Within our core competence	Is the proposed therapy within our existing expertise or are we comfortable extending to that clinical area because of the overlap of physiological expertise
Key Issues to resolve	What are the major issues that need to be resolved prior to starting moving to next phase of preclinical trials, basic embodiment development/testing, etc.?
Potential for early risk reduction	What can be done to quickly reduce risk? What logical milestones exist for company financing?

What Are Some Of The Other, More Marketing-Based Drivers Of Adoption And Acquisition



- What are “stakeholders”
- How do they affect your choice or implementation of an idea



● Our First Experiences



- My first startup was called **Cardio Technologies Inc.** Non-blood contacting LVAD Company. Spent too much time making perfect device. Eventually ran out of money
- Product concept (external heart compression) still only device differentiated from competition but current devices “good enough”
- Mark’s first startup was a Johns Hopkins spinout called **Cardiologic Inc.** developing “Vest CPR”. Great article in NEJM showing improved outcomes . Failed when tested by “real” users
- Restarted by Three Arch as Revivant Inc. Acquired by Zoll. Product AutoPulse® is now standard in CPR

Initial Lessons Learned

- Both approached the development process “too academic”
- Understood nothing about the “business” of developing medical devices
- Best is the enemy of good (enough to prove “it works”) – need to accomplish this in order to raise more money
- Good ideas will commonly survive – you will just not make any money personally



CHF Solutions Inc. 1999 Venture Funded Startup (MPM, SV Life Sciences)

CHF Solutions, Inc. was acquired by Gambro in 2010. We raised Series A and B completed development to 510(k) and transferred company to CEO and became consultants in 2003

- Completed development and approval under \$10 million in three years.
- Excellent clinical results. Device was becoming standard of care for market segment

Lessons Learned

- Commercialization without existing reimbursement is a bad idea, even if physicians and salesmen seem enthusiastic about the product.
- Poor fit with existing medical practice. Cross-cultural device between nephrology & cardiology
- No acquirer with access to cardiology market and franchise in blood purification. Single acquirer dominant in nephrology space that could afford to wait. Expectations of return for 510(k) device shall be realistic.

● Turned Experience Into Major Success



2003 Ardian, Inc. ATV, Versant, Strategic investment (Medtronic)

- To address an unmet clinical need, we synthesized information from unrelated physiological and areas into a proposed therapy
- We completed preclinical and early clinical studies
- Started the company and brought on experienced execution team
- Came back at end to help develop next-gen devices to protect against “fast-followers”
- Received Edison Award, Cleveland Clinic #1 of 10 Top Medical Innovation Award, #1 Most Important New Device Therapy from AHA/ACC/TCT
- Largest pre-revenue medical device acquisition in history (\$800 MM+)

Take Away Points

- Synergy with interests of physicians and acquirers is essential
- Having both physiologic & technical risk requires early risk reduction strategy
- True ownership of a huge new IP field adds a lot of value (Ardian)

● How Can I Practically Do This



- Very hard for a clinician or scientist to do this on their own
- Just not trained/have the experience to do all of the required tasks well
- You can
 - ✓ Partner with someone (engineer/business person) who has already been through it
 - ✓ Find “less-sophisticated” money and do it yourself → eventually face the same issues
 - ✓ License to incubator → take royalties

Note:

- While possible, unless you quit your day job, don't expect big payday
- You put in an idea → they put in \$100 MM and 5-10 years
- Return is proportional to the risk you personally take

● Summary



- You can greatly increase the chance of obtaining funding and eventual commercial success of a project by taking a structured approach early on
- Don't believe your own propaganda – If the project is bad, kill it quickly
- Limitations in resources and IP timing limit ability to develop devices in the academic environment
- However, there are many places in which you can contribute to the successful development and commercialization of a device both within and outside of academics - you need to find what is right for you

Entrepreneurship MiniSymposium: How to Start a Start-Up: Patent Protection & Preparation for IP Due Diligence

Theodore G. Papagiannis, Partner at Knobbe Martens



Patents – General Information

- What is a patent?
 - The right to exclude
 - Does not mean you can practice the invention without infringement risk from others
- Types of patents
 - Utility
 - Provisional U.S.
 - Non-provisional U.S.
 - PCT & OUS
 - Design
 - Claims: device vs. method

IP Due Diligence – General Information

- **Timing:** when is IP due diligence conducted
- **Content:** what does IP due diligence entail
 - Landscape analysis (“freedom-to-operate”)
 - Patentability analysis
 - Ownership
 - Agreements

IP Due Diligence – Tips for Startups & Other Targets

Be prepared!

- Work with IP counsel to be as ready as possible
 - Consider an IP audit if unsure about company's IP position
- Lack of preparation likely to scare the investor or acquirer and to make the process more difficult
 - Could kill or delay the deal (or provide leverage to the other side)
 - Long-lasting impact
- Consider the various aspects of IP diligence and how to improve the company's position with respect to each

IP Due Diligence – Tips (continued)

Landscape (“Freedom To Operate”) – Analysis & Preparation

- Landscape searching
 - Conduct independent searching to identify third-party risk
 - Update searching periodically
 - Update searching promptly when company technology changes
- Monitoring
 - Monitor any pending applications and close patent families
 - Monitor key competitors
- Other options:
 - Consider getting an opinion of counsel for any close references
 - Consider challenging a patent via the IPR process

IP Due Diligence – Tips (continued)

Patentability – Analysis & Preparation

- U.S.: Obtaining U.S. patent protection
 - File provisionals promptly in view of first-to-file
 - Consider taking an aggressive approach (e.g., use Track I program)
 - File voluntary continuing applications
 - Utilize USPTO Pilot Programs

IP Due Diligence – Tips (continued)

Patentability – Analysis & Preparation (cont.)

- **OUS:** Obtaining OUS patent protection
 - Utilize the PCT system
 - File OUS applications strategically and intelligently
 - Utilize programs to enhance OUS patenting process (e.g., PPH)

IP Due Diligence – Tips (continued)

Ownership and Agreements – Analysis & Preparation

- Ownership
 - Obtain prompt signatures from inventors (assignments, declarations, etc.)
 - Evaluate and, if needed, modify IP assignment provisions in employment and consulting agreements
 - Consider implications of prior employment/consulting agreements

IP Due Diligence – Tips (continued)

Ownership and Agreements – Analysis & Preparation (cont.)

- Agreements
 - Review and consider amending existing license agreements, non-disclosure agreements (NDAs) and other agreements
 - Pay close attention to key provisions (e.g., agreement assignability, possible impact of royalties and other payments, etc.)

QUESTIONS?



Orange County

San Diego

San Francisco

Silicon Valley

Los Angeles

Seattle

Washington DC

How to Establish an Academia-Industry Partnership

Mark Gelfand

Coridea

Aug 16, 2016

● Introduction



- Mark Gelfand (mgelfand@coridea.com)
- I'm a biomedical engineer and inventor. I have more than 100 issued patents worldwide. At least 80% of them cover devices that started as a "sketch on the back of a napkin" and ended in clinical practice today.
- I co-founded and served as a CTO of six successful medical device startups. These startups raised > \$100 mil. of venture capital and returned > \$billion to investors. Two more are in early stages now.
- As a CTO I'm ultimately responsible for the technology and IP policy, strategy and IP implementation. This invariably involves academic collaboration in some form.
- Most of the examples I will be giving come from our 20 years of collaboration with Johns Hopkins University but we also work with many other labs in U.S. and Europe.

Coridea is a Technology Incubator



We are serial entrepreneurs and inventors

15 Years of joint innovation as Coridea

100+ Patents issued

6 Companies started together
Several licensing deals

> \$100 million raised

> \$1 billion returned to investors

Howard R. Levin, M.D.

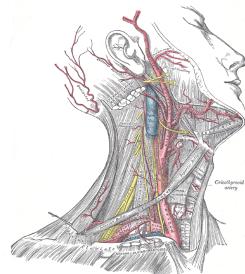
- Heart Failure / Transplant Cardiologist from Johns Hopkins/ Columbia University
- Author on over 50 peer-reviewed scientific publications

Mark Gelfand, M.S.

- Control systems engineer and physiologist, Division of Cardiology, Johns Hopkins, Nellcor (respiratory business)
- CTO of 6 medtech startups, Technology and IP expert, author of 110 U.S. patents



None of These Would Exist Without Academic Collaboration



Cibiem

Founded 2011, in Series B
SVLS and Third Rock Ventures



ARDIAN

Founded 2003, Acquired by Medtronic
for \$800mm in 2010



evalve

Seminal patent, Acquired by Abbott for
\$410 million in 2010



chf solutions®

Founded 1999, Acquired by Gambro for
\$77 million in 2010



Respicardia®
Respiratory Rhythm Management™

Founded 2006, Investment and
distribution by LivaNova. Commercial
in E.U. PMA trial completed

Soffio
MEDICAL

axon
therapies

Series A Companies Funded in 2013-
2015



CardioLogic

Founded 1992, Acquired by ZOLL
Medical in 2004

RenalGuard®



PMA trial underway, product on sale in
Europe

● Idea's Journey to Become a Product



- Idea makes a long journey to become a product
- In the process it will change. **Unlike a new drug medical device will never look like the first concept and it will never stop evolving.**
- Even with perfect funding and execution it will take 5 to 10 years depending on its complexity. Many people and institutions will contribute to the maturation process: university, startup and industry R&D.
- There will be role for academia in different stages between conception and acceptance into clinical practice
- Fundamentally important to this discussion is that while seminal patent may originate from academia, it will be the intense R&D process during Series A funding that will create the majority of IP portfolio. Universities don't always appreciate this.
- It is in fact though that during the design phase of the project that 100% of the international IP will likely be created. Technologies today cannot rely on US patents only. They will not be funded.

● Quick Recap: Trends in Healthcare & Industry



- Purchasing decisions moved from doctors to health care executives. Improvements of technology that add cost are not popular.
- Strategics became very large, risk adverse but at the same time are seeking new therapies for untreated diseases that can advance shareholder value. Cost effective management of chronic diseases like heart failure or diabetes came to the front of clinical needs.
- VCs migrated away from early stage funding because of long time to ROI and high rate of late stage failures in randomized trials. These real world tests eroded trust in new physiologic approaches and early stage academic preclinical & clinical results.
- Regulatory and reimbursement climate became more stringent and more unified internationally. “Europe First” strategies are not so easy anymore.
- Strategics require products for international markets with international IP. This has huge implications for academic collaboration. They expect large IP portfolios that protect the area, not a lone patent protecting one device.

● Quick Recap: Trends in Startups & Academia



Startup

- Building infrastructure in a startup became a less popular use of capital. Capital efficiency increased and investors prefer lean virtual teams executing using external resources.
- Value of early human data is at it's peak. Investors expect participation from strategics and potential acquirers after FIH data.
- Strategics and angels are much more active in early stages
- Non dilutive early funding from SBIRs has never been this important and as hard to get

Academia

- NIH money is tight and the importance of funding from industry is increasing, especially for younger, less established labs
- Patenting became more expensive. Technology Transfer is wrestling with the cost of maintaining portfolios but receiving little return on investment

● Role of Academia as an Inventor



- It is indisputable that best ideas come “from bed to bench”. Conceived by a practicing physician they usually start with: “wouldn't it be nice if [...] ?” “Wouldnt it be nice to replace a valve without stopping the heart?”
- Startups today find amazingly evolved networks of contract R&D organizations. They tell physician inventors: “*bring us your idea and we will turn it into a medical device*”. (If you have funding.)
- In most cases it is not true. To treat the first patient today in any country medical device needs to meet rigid requirements. Engineers expect design inputs that are set and wouldn't change during the design cycle.
- What they should be telling inventors is: “*bring us your prototype tested in animals and a set of specifications and we will turn it into a medical device*”. (If you have lots and lots of funding.)
- Few academic institutions are equipped to bring their idea to that level. Thus there is need for translation research and organizations like Foundry, Coridea or MD Start.

● The Unfortunate “Academia as a Lone Ranger” Model



This is real. It happened to us and we continue to see this pattern.

- Seminal invention is conceived in academia by a physician scientist
- They enabled it with the best drawing that they could and tossed it over the fence to the university’s technology transfer. They are busy people.
- Technology licensing, operating within strict budget of few thousand dollars, filed “a patent” that is likely to be published as a PCT 18 months later without much change. Meanwhile the inventor likely published his results thinking that the invention is secured.
- When, in due time, their patent is examined, the inventor finds that patent claims are not supported by engineering drawings and they will at best receive very limited coverage. University informs him that international patenting is outside of their budget.
- Industry alerted by the publication and excited by published results may decide to create their own IP portfolio using their considerable prototyping and engineering resources. This does not help the relationship.

● The Alternative Model: "Fear of Academia"



- Industry veterans with prior startup or corporate R&D experience conceived an invention. It is not a mere improvement. It may become a new therapy.
- They know all the constraints of manufacturing and regulatory environments. They can build prototypes and study prior art. They can create a valuable patent portfolio that will stand the test in EU and China.

But

- They don't understand physiologic mechanisms or lack intellectual freedom to investigate alternative indications. They lack access to the lab and a multidisciplinary team of physiologists, anatomists and surgeons. **Commercial labs test products to rigid protocols; they don't facilitate experimentation.**
- They lack scientific credibility that is needed to convince investors that their invention has clinical and scientific merit

And

- They are afraid to collaborate with the Academia early in the invention process. They fear that the academia will drag them into complex intellectual property arrangements that will impede their ability to make deals.

● Both Sides Play From Their Strengths



Startup

- Has budget and engineering resources to create patents that will create value for the future acquirer
- Can receive commercial funding and non-dilutive funding from SBIRs
Importantly just having an SBIR is not enough. NIH will not pay for patenting or pursue international FIH trials that are essential for commercialization.
- Obtains license of option from the Academia and engages international team of attorneys to create and prosecute IP.

Academia

- Lab can help founders seed the project and obtain early data by investing money and by contributing data, work and materials
- Dedicated investigator accelerates bench to animal to FIH pathway.
- Investigator and Institution lend credibility to the project and facilitates funding from Strategics, VCs and SBIR

● Benefits Outweigh Risks



Startup

- Although startup has to accept potential burden of royalties on the acquisition price, it also gets a negotiating partner with a lot of clout and legal muscle
- Creates the environment that allows them to control patent filing and prosecution to maximize value and **defer potentially damaging early publications**
- Improves chances of funding and has strong support for SBIR when it comes to scientific merit and innovation

Academia

- Through option and licensing recovers patenting cost and participates in a much better “leveraged” IP portfolio
- Receives funding for the lab by becoming a subcontractor to the startup
- Indirectly gets access to SBIR funding that they cannot otherwise get through the partner with “commercialization” credibility

● Inventorship and ownership of IP



- If Company already developed the product and just wants Academia to test it, things are relatively simple. We will not discuss those.
- Invention may be conceived in academia and improved by startup or Invention may be conceived by startup and improved in academia.
- In both cases first and foremost: **realistic expectations need to be set between the academic scientist in charge of the lab and the company.** This is best done before any formal agreements are negotiated or joint patents are filed.
- If a mutual invention occurred in the absence of agreements, don't despair. Both sides have strong motivation to reach an agreement. Nobody will fund or license “split IP”.
- In many cases, especially in EU, we see universities that are disinterested in ownership of IP and give rights in exchange for funding
- In other cases, such as our collaboration program with Johns Hopkins, university is keen to participate as a partner with a commercial entity

● All-important Publication & Priority Dates



- In the relationship patenting and timing are all-important. Published patent becomes prior art to Companies' future patents. It also informs competitors.
- **Cold facts:** patent is published 18 months after earliest priority date. Getting funding (including SBIR) may also take years. After that the development cycle is typically 12 – 18 months. Publication of an “academic” seminal patent before the actual R&D is done can hurt the Company.
- Benefit of provisional patents is indisputable. They are inexpensive and accepted worldwide but need to meet quality standards in the countries of future filing. They are confidential and if abandoned will never become prior art or known to anybody.

Bottom line:

- It is crucial to develop the IP strategy with the Academia that is based on **trust, realistic expectations and Company needs**. Methods of therapy can be patented in the U.S. but not in E.U. and Asia. Inventors have a right to request suppressed publication by not filing a PCT but rarely use this right.

● What makes you an inventor?



It is important to capture inventions as they occur and identify inventors of each filed claim. Coridea uses trained patent engineers that work with the external counsel to maintain clear record of inventorship. An inventor may believe that they have a right to assign to the company but may also have conflicting obligations. They also may not be an inventor.

What makes you an inventor?

- Contribution to conception and reduction to practice of the claim
- Merely assisting in reduction to practice (such as giving information or resources) is not an invention. This is the area where academics get easily confused. They often approach authorship of invention as an academic paper.
- Common reasons for patent invalidation: claiming invention by somebody else, not including a contributor
- **Bottom line:** Inventorship is defined in legal terms and is better left to your legal team. Work with them closely, don't rely on the University Tech Transfer to do diligence.

Start-Up Lessons Learned

“Good judgement comes from experience; Experience comes from bad judgement”

Richard C. Schmidt, MS

CEO, Medical Engineering Innovations, Inc.

Madison, Wisconsin

www.mei-america.com

Richard Schmidt Bio



- **Worked with five startups:**

- *MEI (RF Surgical Tool Development)*
- *RefleXion Medical (Radiotherapy)*
- *RecoStat (Consulting)*
- *CPAC (Proton Therapy)*
- *TomoTherapy (Radiotherapy)*

- **Degrees:**

- *Physics*
- *Mechanical Engineering*

- **Experience:**

- *Research and Development*
- *Building and managing multi-disciplinary engineering teams*
- *Fund-raising, investor relations*
- *Corporate governance and infrastructure*
- *Market Research*

- **Other Training:**

- *Finance*
- *Project Management*
- *Time Management*
- *Lean Six-Sigma*

- **Co-author on papers published in:**

- *Nuclear Physics*
- *Accelerator Physics*
- *Medical Physics*

- **Patents:**

- *X-ray detectors*
- *X-ray targets*

Overview

- #1 Rule when starting a business
 - Things to know before you start a business
 - Corporate Operations:
 - General
 - Time management
 - Hiring
 - Funding:
 - General
 - Pitching
 - Stress Management



#1 Rule



Your product **MUST** solve a problem
with a **viable** market need

AND

the *addressable market* must be
more than \$100 million

Before you start a business...



- Understand yourself:
 - Motivations, Goals, Comfort Zone...
- “People don’t buy what you do, they buy why you are doing it”
 - [Simon Sinek TED Talk](#)
- There will be a cost...
- It’s harder than you think:
 - Maintain your focus
 - Can you be: positive, objective, flexible, tolerant, creative, patient, driven...?



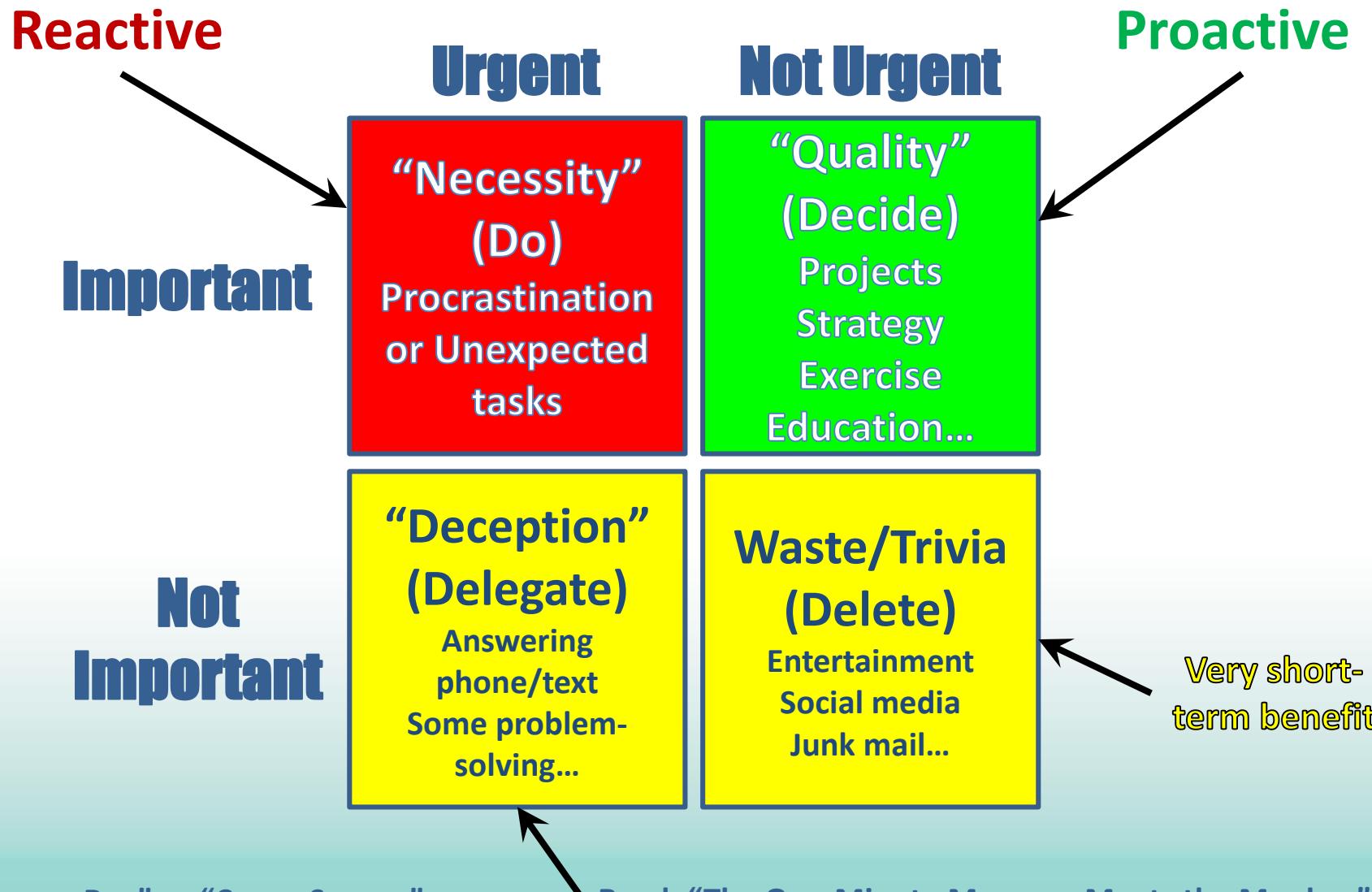
Corporate Operations: General



- Where is the value in your company?
 - How do you protect that value?
- Keep accurate corporate records
 - Do it with the utmost integrity
 - Understand the terminology:
 - [Investopedia Term-of-the-Day](#)
- It's important to know what you know...
 - NEVER be afraid to ask for help
 - ALWAYS be interested in learning something new

- No one can really multi-task...
 - Schedule time to work on individual tasks
- Have multiple irons in the fire all the time
- Make lists... 
- Last thing you do before you go home at night
 - Know what is on your schedule tomorrow
 - Prepare
 - Percolate

Corp. Ops: Time Management



- “*Hire for Attitude, Train for Skills*”
- Who should you hire?
 - People who *make up for your gaps*
 - People who are *smarter than you*
 - *You are building a talented, diverse team...*
- Hire great people and *get out of their way*
- What is your #1 job as a functional manager?
 - *Removing obstacles*

Funding: General



- Raise *twice as much* money as you think you will need
- Raise money *before* you need it
- Capital Efficiency:
 - Doing a lot with a little money may mean that your core team has *other sources of income*
 - Develop relationships with *synergistic benefits*

Funding: Rules



- Securities Act of 1933, Regulation D, Rules 504, 505, 506:
 - Exemption from *registration*
 - Prohibit *general solicitation*
 - Some exceptions if investors are “*accredited*”
 - JOBS Act of 2012, Section 201(a) – changes to Securities Act Rule 144A
 - *Crowdfunding*
 - *Regulation A+*

Funding: Investors

➤ So where do you find money?

- Family, Friends and Founders
- Angel Groups
- Venture Capital Funds



- Grant agencies (*non-dilutive!*)
- Investor and *Start-up Conferences* (!)
- Web Searches
- Networks:
 - Your own
 - Board members
 - Investors

Funding: Crowdfunding



- Generally not appropriate for medical devices:
 - Interstate: extensive financial disclosures (\$)
 - W/I state: is there enough interest? (\$)
- Crowdfunding:
 - Small amounts means LOTS of investors...
 - Someone has to manage this effort

Funding: Pitching



- You will Pitch many times
 - Most Pitches will not result in funding...
- Create Pitches of three lengths:
 - 1 Breath: When you meet someone for the first time
 - 30 seconds: The “Elevator Pitch”
 - 15 minutes/15 slides: Meeting presentation

Funding: 1 Breath Example



Who are we?

What do we do?

MEI is developing procedure-specific, RF

surgical tools to treat cancer patients.

We believe that we can double the five-year survival rates for PLC patients

Why should you care?

Funding: Elevator Pitch Example-1



- ("1 Breath" pitch): MEI is developing procedure-specific, RF surgical tools to treat cancer patients...

Why are we doing this?

- Our initial product for liver resection was conceived by a liver surgeon who was dissatisfied with the lack of good tools that could be used to perform this procedure

Strengthen problem statement

- W/o a liver resection <1% of liver cancer patients survive for 5 years
- With the best treatment available, only about 1/3 of the patients survive for 5 years

How our product solves the problem

- Since blood loss is the key factor affecting patient survival, we have focused on minimizing blood loss and optimizing the tool for this procedure

Funding: Elevator Pitch Example-2



Prototype exists and validates the concept!

- Our SwiftBlade™ product has dramatically reduced blood loss in surgical studies

Where are we on the timeline?

- We are ready to start survival surgeries and are raising

- \$1.2 million to get us to revenue in the next 12 months

What will it take to start making money?

Funding: 15 Minutes/15 Slides



Topics covered in the Elevator Pitch:

1. Who are you?
2. What do you do?
3. Why are you doing it?
4. What is the market need?
5. Strengthen the problem statement
6. Tell how your product solves this problem
7. What progress have you made?
8. What is your timeline?
9. How does the company make money?

In addition to what is covered in the Elevator Pitch:

1. How big is the *addressable market*?
2. Who are your *competitors*?
3. Why are you better than them?
4. Who is on your *team*?
5. What is your *IP/Regulatory status*?
6. What do your *customers* think of your product?
7. How much *money* is needed?
8. How/When do *investors exit*?

Reference material to have available:

1. 3-5 year Cash Flow
2. Acquisition comparisons
3. Marketing plan
4. Funding History
5. Cap. Table

Stress Management



- If you think it is stressful working for someone else...
- Figure out what you can't change and move on...
- Don't let things fester – deal with them promptly
- If you make a mistake – admit it and move on
- Schedule “down-time” for yourself
 - At the end of the day, put it all “on the shelf” so you can recharge and deal with it fresh tomorrow

Why do we do it?



- We want to get things done
- On a mission...
- What you want does not exist...
- This is how you are wired
- *It can be the most rewarding experience you ever have!*

If You Decide To Do It...



Best Wishes

For Your

Success!

Other questions?

Contact me if you need:

- *Quick advice*
- *Mentoring*
- *Company advisors*
- *Board members*



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- <http://www.mei-america.com>
- <https://www.linkedin.com/in/richard-schmidt-ms-78931618>



EMBC 2016 Symposium

Thursday, August 18th, 2016, 3:30 pm – 5 pm – Atlantic B

Start-Up IP roadmap

Entrepreneurship Symposium: How to Start a Start-Up

Moderators:

Dorin Panescu, PhD, FIEEE

Prof. Dieter Haemmerich, PhD

Entrepreneurship Symposium: How to Start a Start-Up

Part II

- **Reese Terry, M.S.**

Title of the presentation: How to start your own start-up

- Founder of Cyberonics, Inc. First company to get FDA PMA approval for epilepsy and chronic depression implantable stimulators.
- Helped found focused on never congestive heart failure treatment technologies.
- Epilepsy Foundation of America World Changer Award in 2012, 2012 IEEE EMBS Professional Career Award, Society of Brain Mapping and Therapeutics 2013 Pioneer in Technology Award.

- **Nitish Thakor, Ph.D.**

Title of the presentation: Technology Transfer

- Pioneered many technologies from brain monitoring to prosthetic arms and neuroprostheses.
- Over 290 journal papers.
- Co-founder of 3 companies.

- **Michael R. Christensen, J.D.**

Title of the presentation: Entering the Patent World Strategically and Economically

- Partner in the Medical Device group at Knobbe Martens.
- IP expertise technologies in MRI-compatible infusion pumps, treatment of stroke, diabetes, atrial fibrillation and back pain.
- Experience with patent due diligence for VCs and in developing strategies for expediting patent prosecution both US and OUS.

- **Dieter Haemmerich, Ph.D.**

Title of the presentation: Successful SBIR/STTR Funding

- Outstanding SBIR grant experience.
- Past chair of the Therapeutic Systems and Technologies Technical Committee (2010 – 2015).
- Over 90 journal papers and 8 issued US patents.



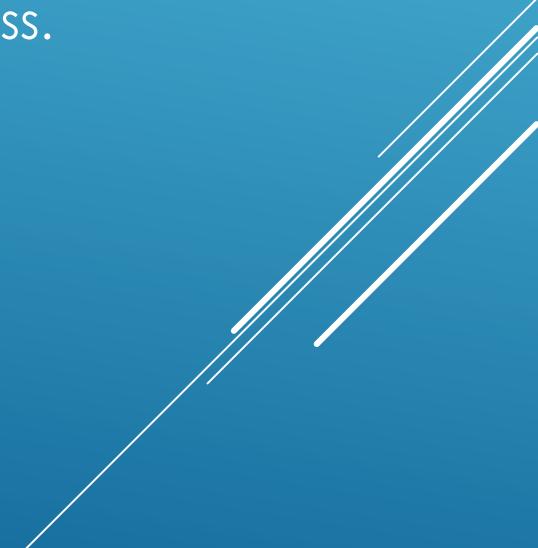
HOW TO STARTUP YOUR OWN STARTUP

Reese S Terry Jr
Founder, Cyberonics Inc.
IEEE Life Fellow

EMBC 16 MiniSymposium
August 18, 2016

- ▶ Biomedical Engineers develop solutions to problems
- ▶ Identify an unmet medical need and design a device or procedure that will benefit patients
- ▶ Develop good understanding of the underlying basic science and good relationship with physicians or other inventors in the specific area.
- ▶ The goal is to get it to patients, not start a company.
- ▶ The product must make a profit in order to get to the patients
- ▶ The manufacturing cost must be a small fraction of the potential selling cost, with a goal of 30% or less.

THE BIOMEDICAL ENGINEER'S MISSION



- ▶ Almost ALL medical device advancements have been made by individuals or small companies
- ▶ Sell the idea internally to your company
- ▶ Obtain a patent and license it to an external company
- ▶ Start a company around the product if market is large enough

PATH TO THE PATIENT



- ▶ Experience with two small high growth companies – Cordis and Intermedics
- ▶ Exposed to a wide range of predominately implantable medical products
- ▶ Successfully started Cyberonics, which grew to >\$300 million annual revenue and merged to form LivaNova at >\$1.2 Billion and 4,500 employees valuation, Experience with wide range of implantable medical products
- ▶ Coached others in start up efforts in various fields and board member of other early stage medical companies

MY BACKGROUND



- ▶ Talk to physicians and others about the product idea
- ▶ Try to get an idea about the market size and competitive factors
- ▶ Determine who will be the primary customer and who will pay for the product
- ▶ Will this be a product line or will it be a platform to support a company
- ▶ Identify potential medical practice barriers to entry
- ▶ Be self critical in developing the plan

DEVELOP A BUSINESS PLAN



- ▶ Investors will focus on your patent strengths and strategies
- ▶ Research the existing patients in the field using internet or help from patent firms
- ▶ File provisional patents
- ▶ Goal is to obtain broad patents if possible, but there may be many existing patents, patent applications, and publications that will limit scope of coverage.
- ▶ Research and identify potential “freedom to operate” patents

PATENTS



- ▶ Investors will want to know the time, cost and risk to get product into clinical studies: First human studies – the first milestone
- ▶ In house design, use consultants, or contract out the design
- ▶ Use off the shelf components and devices or custom design
- ▶ Work with an experienced regulatory consult in developing the plans
- ▶ Follow FDA, ISO and Notified Body Directives for Product Development Procedures
- ▶ Develop Verification and Validation Testing Plan
- ▶ Determine the number and requirements for the bench tests, animal tests and biocompatibility tests

PRODUCT DEVELOPMENT PLAN



- ▶ Clinical evaluation is typically a Pilot Study (second milestone) followed by a Pivotal Study (third milestone)
- ▶ Organize a clinical advisory board to plan the study; include regulatory consultants and statisticians
- ▶ Conduct studies in US, Europe or elsewhere? Time, cost and reliability concerns.
- ▶ Carefully the primary outcome measure – hopefully a reliable physiological measurement
- ▶ Determine the study size to achieve a statistically significant efficacy outcome. Look at other studies in the area to evaluate placebo responses and other study factors.
- ▶ Submit proposed plans to FDA for their suggestions.

CLINICAL EVALUATION PLAN



- ▶ Get help developing and marketing and sales plan
- ▶ Does it compliment other products or will it be a “missionary” sale and need a dedicated sales force
- ▶ License, independent sales representatives, distributor, or direct sales organization
- ▶ Estimate sales ramp over the first few years and cost of the sales and marketing for a business plan

MARKETING PLANS



- ▶ Determine funds and investment horizon required to meet critical milestones
- ▶ When and how will investors be able to cash out?
- ▶ Typical funding sources: bootstrap, friends and family, grants, angel investors, venture capital investors
- ▶ This stage requires almost full time effort
- ▶ You may need a partner to “sell” the plan to investors
- ▶ The potential rewards for the patients, inventors, and founders make it all worthwhile effort and a necessary step forward
- ▶ However:
 - ▶ You must be prepared to invest months or years and still be unsuccessful in raising the necessary funding
 - ▶ Even if funding is successful, the clinical study may fail or time and cost become prohibitive
 - ▶ The effort may not work out financially or professionally for the inventors and founders

FUNDING THE PLAN

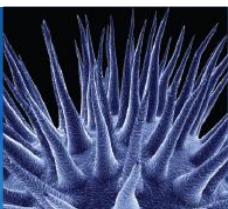


- Some of you here today will develop the next big medical product!

GOOD LUCK

Entrepreneurship MiniSymposium: **Entering the Patent World Strategically and Economically**

Michael R. Christensen, Partner at Knobbe Martens



Outline

- **What Rights Does a Patent Give You?
(Why File?)**
- **When Should I File for a Patent?**
- **What Should I File?**
- **Where Should I File for a Patent?**

WHAT RIGHTS DOES A PATENT GIVE YOU?

What Rights Does A Patent Give You?

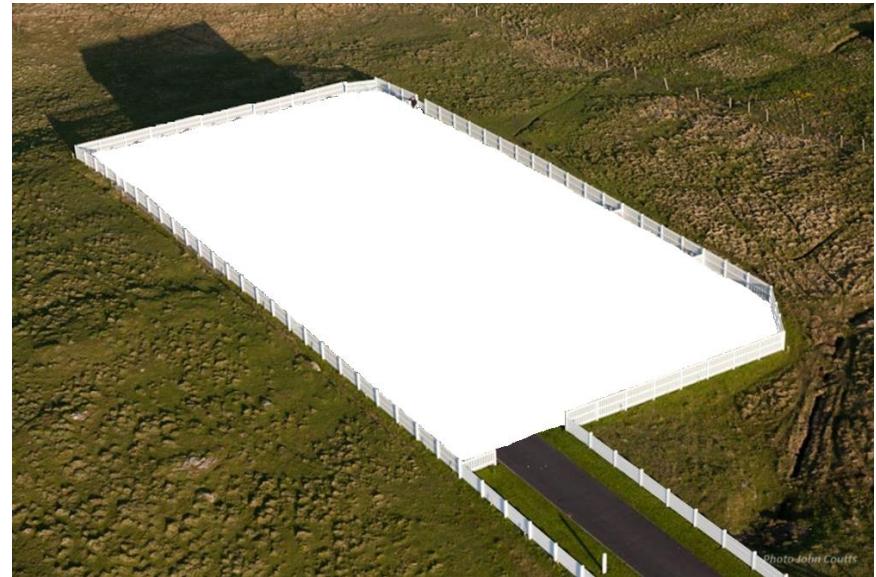
- Which of these is correct?
 - a) “They can’t sue us because we have strong patents.”
 - b) “We can sue them for infringing our patents.”
 - c) Both a) and b)

What Rights Does A Patent Give You?

- Which of these is correct?
 - a) “They can’t sue us because we have strong patents.”
 - b) “We can sue them for infringing our patents.”**
 - c) Both a) and b)

What Rights Does A Patent Give You?

- Gives the patent owner the right to **exclude others** from making, using and selling (20 years)
- Does NOT provide right to practice invention yourself



Why Obtain Patents?

- **Protect against competitors entering your market**



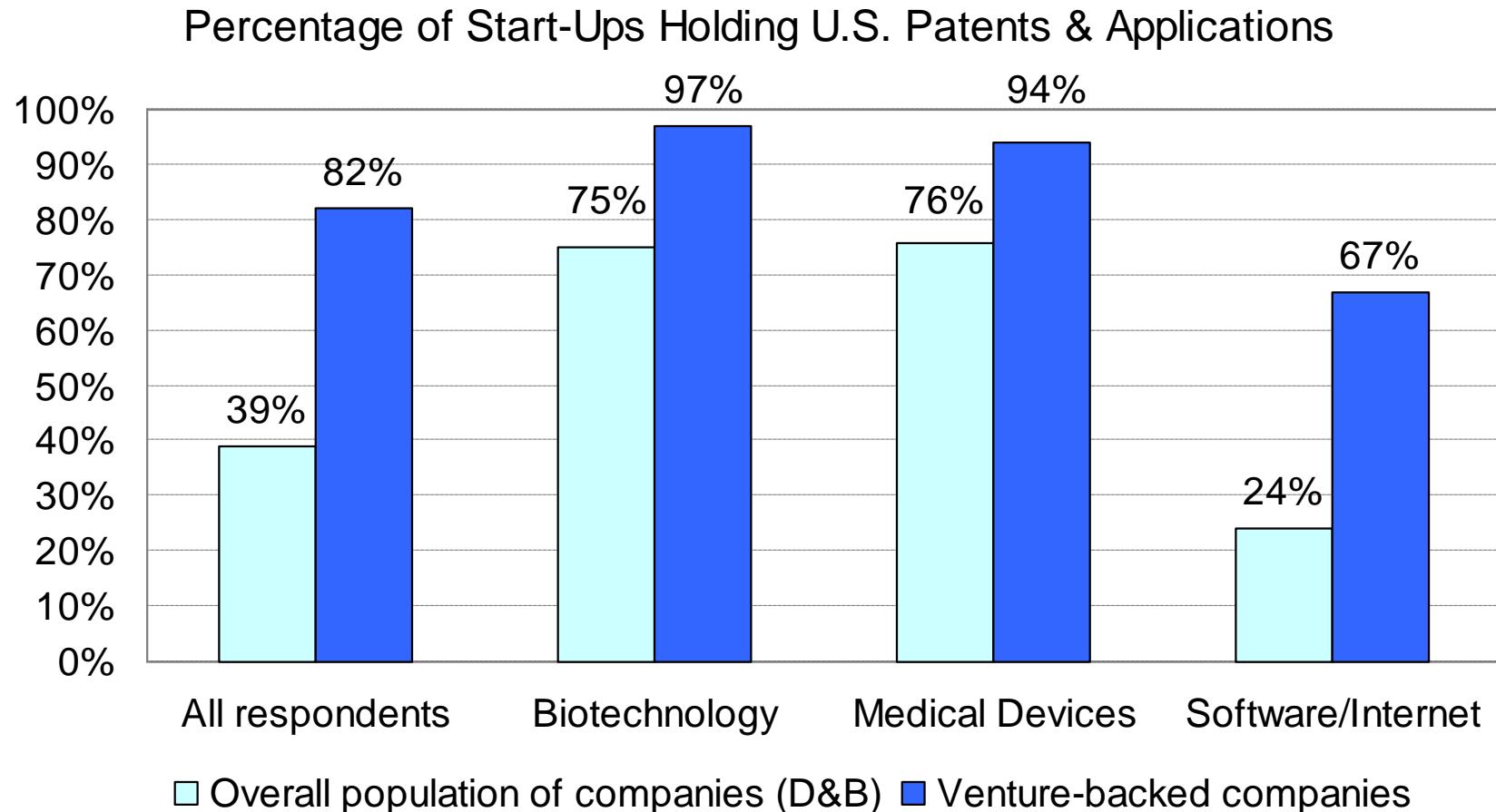
- **Defensive purposes**



- **Raise capital**
- **Derive licensing revenue**



Is IP Required for a Start-Up?



Berkeley Patent Survey (2008)

Some Top Medical Device Patent Awards

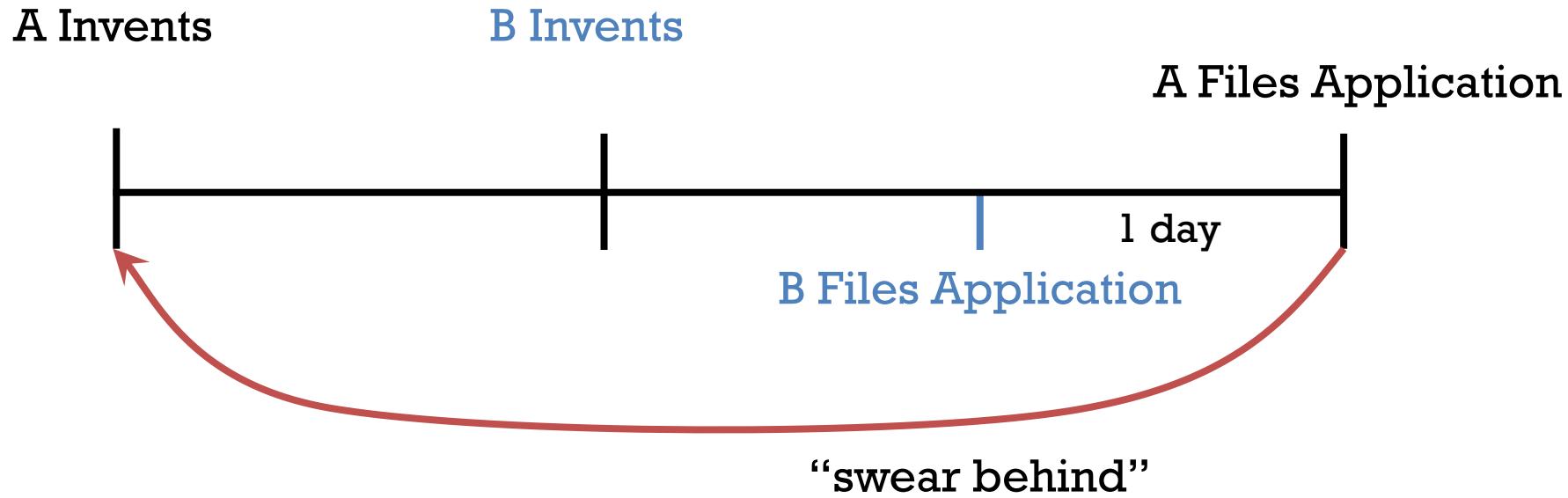
\$1.35 billion	Michelson v. Medtronic	2005	Spinal Fusion
\$750 million	Medinol v. Boston Scientific	2005	Stents
\$501 million	Saffran v. Boston Scientific	2008	Stents
\$467 million	Masimo v. Philips	2014	Pulse Oximeters
\$425 million	Johnson & Johnson v. Guidant	2003	Stents
\$392 million	Edwards v. Medtronic	2014	Heart Valves
\$330 million	Masimo v. Tyco	2006	Pulse Oximeters
\$300 million	Medtronic v. Siemens	1992	Pacemakers
\$270 million	Johnson & Johnson v. Medtronic	2003	Stents

WHEN SHOULD I FILE?

When Should I File?

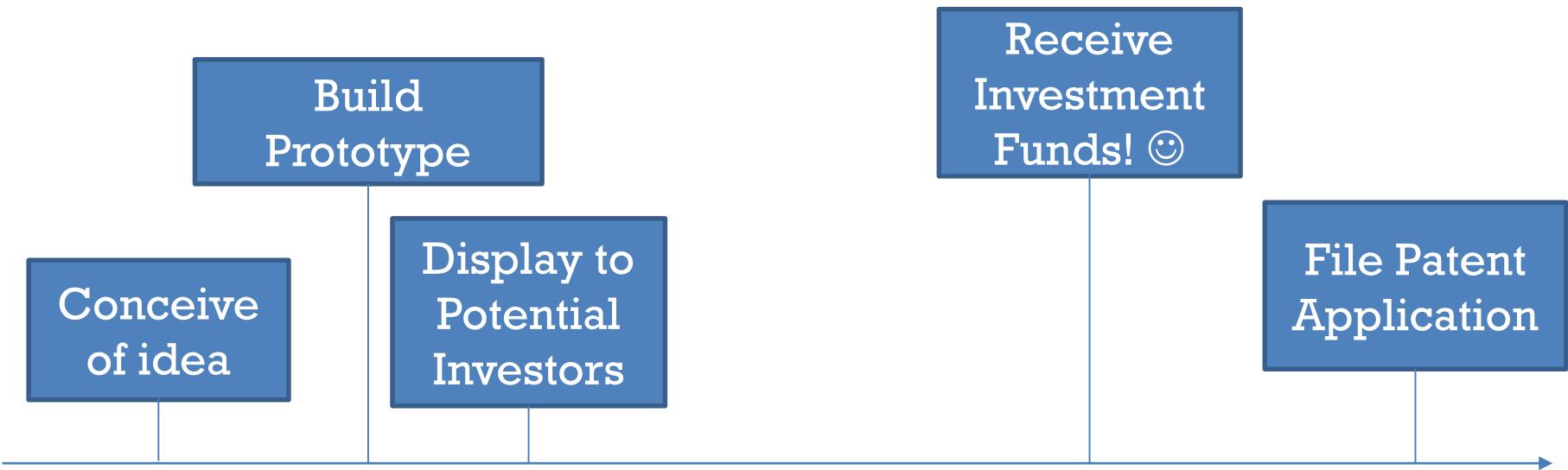
- **Early and Often!**
 - “First to File” gets priority
 - As soon as you can describe a valuable invention
 - No prototype required
- Disclosure before filing can be **fatal** to your rights... especially foreign rights
- Must foreign file within 1 year of US filing

When Should I File?

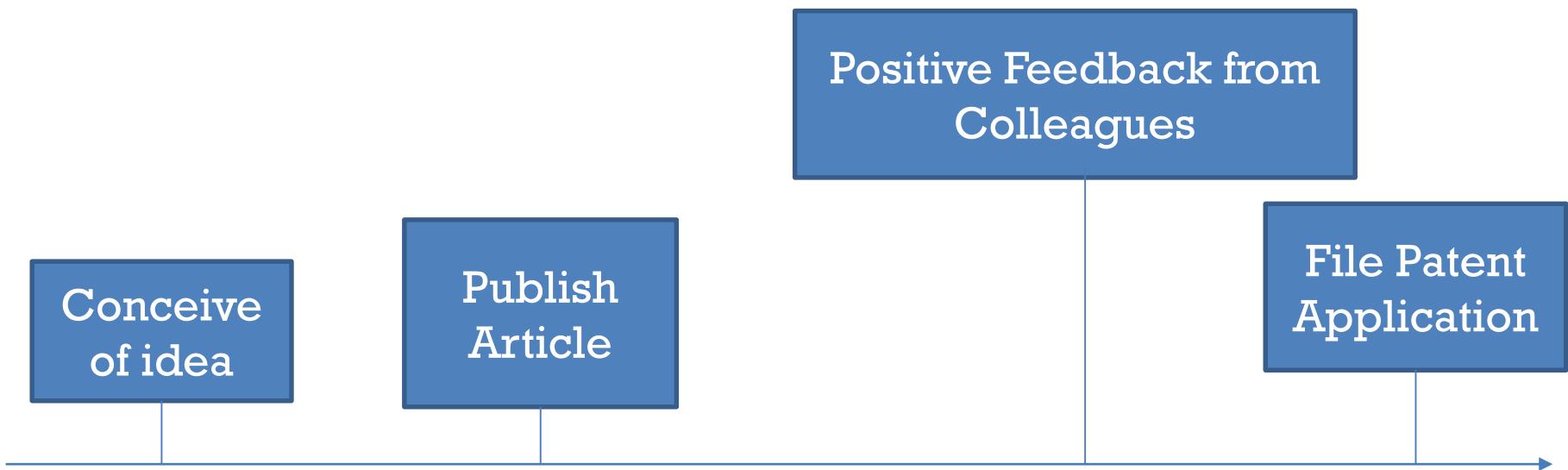


- Pre-AIA – A could swear behind and A gets patent
- Post-AIA – A cannot swear behind and B gets patent

Example Scenario 1:



Example Scenario 2:



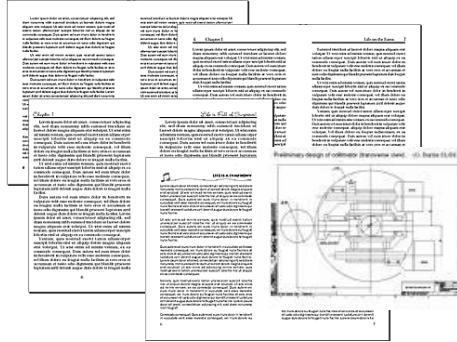
WHAT SHOULD I FILE?

Provisional vs. Non-provisional

PROVISIONAL	REGULAR (NON-PROVISIONAL)
• Not published	• Published unless request for non-publication is filed with application
• Expires after 12 months	• Remain pending until reviewed by the PTO
• Cannot become a patent	• Can become a patent
• No formatting guidelines	• Strict formatting
• Claims not required	• Claims required
• Costs from \$500-\$10K	• Costs from \$10K-\$25K

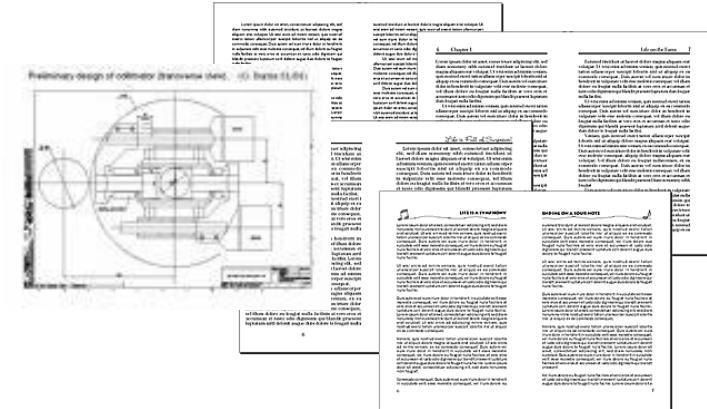
Provisional Strategy

- File provisional application
- Within 12 months, File regular nonprovisional application ***including claims***



Must support claims to benefit from provisional filing date

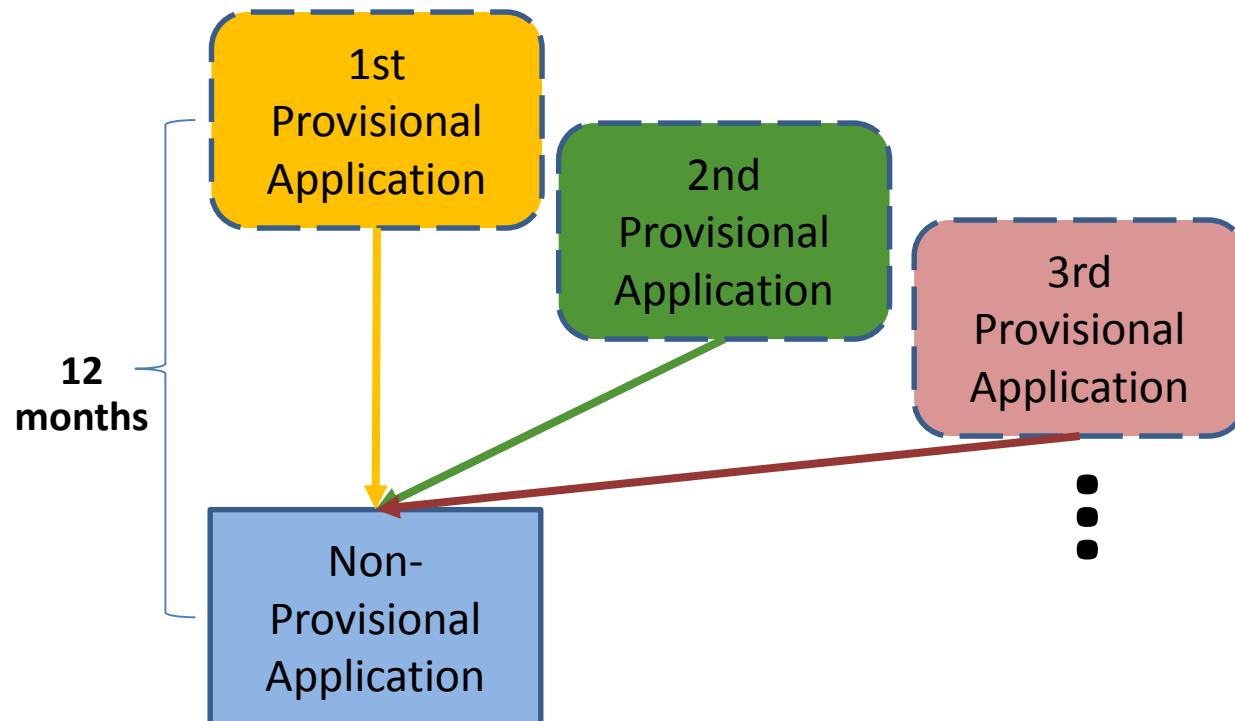
If so . . .



Filing date will revert back to provisional filing date

Provisional Strategy

- In view of new “first to file” rule, can file multiple provisional applications within the 12 month anniversary period
- Roll-up provisional applications into one large non-provisional application

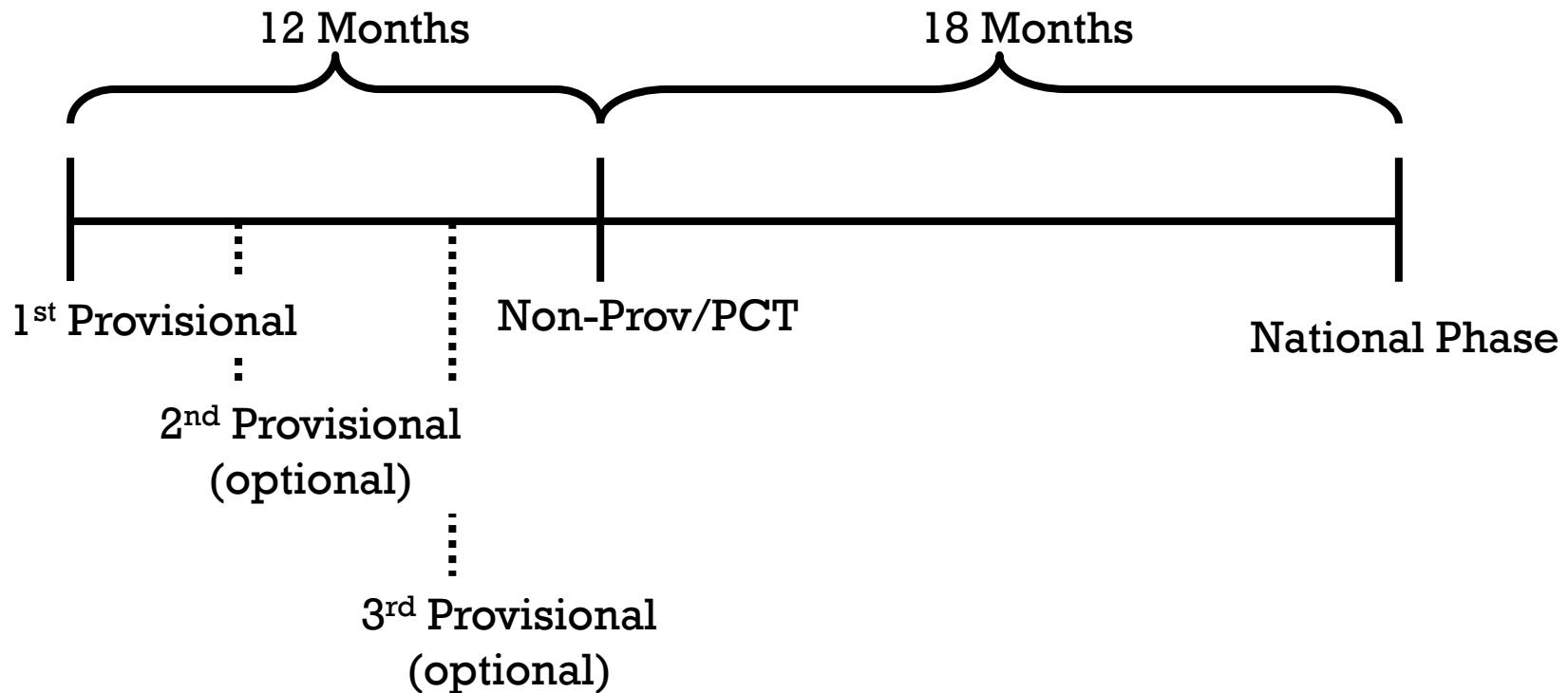


PCT (International) Patent Application

- Secures option to pursue patent protection in all PCT member countries (over 140), including U.S.
- Prepare and file single application, with claims
- Delay national phase prosecution for up to 30 months from earliest priority
- Obtain non-binding preliminary examination
- Cost: About \$4K - \$5K more than Regular Non-Provisional US Application

Timeline for Filing

- Typical Filing Strategy

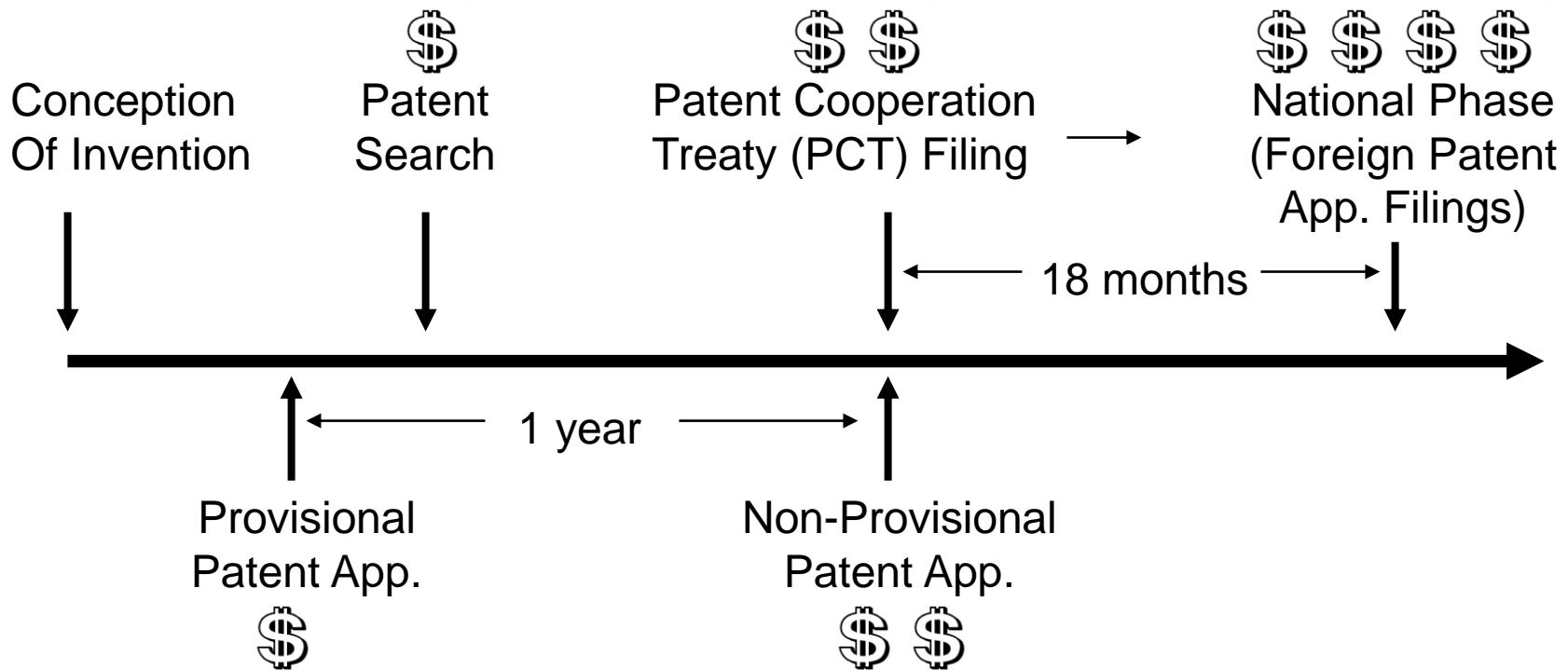


WHERE SHOULD I FILE?

Considerations

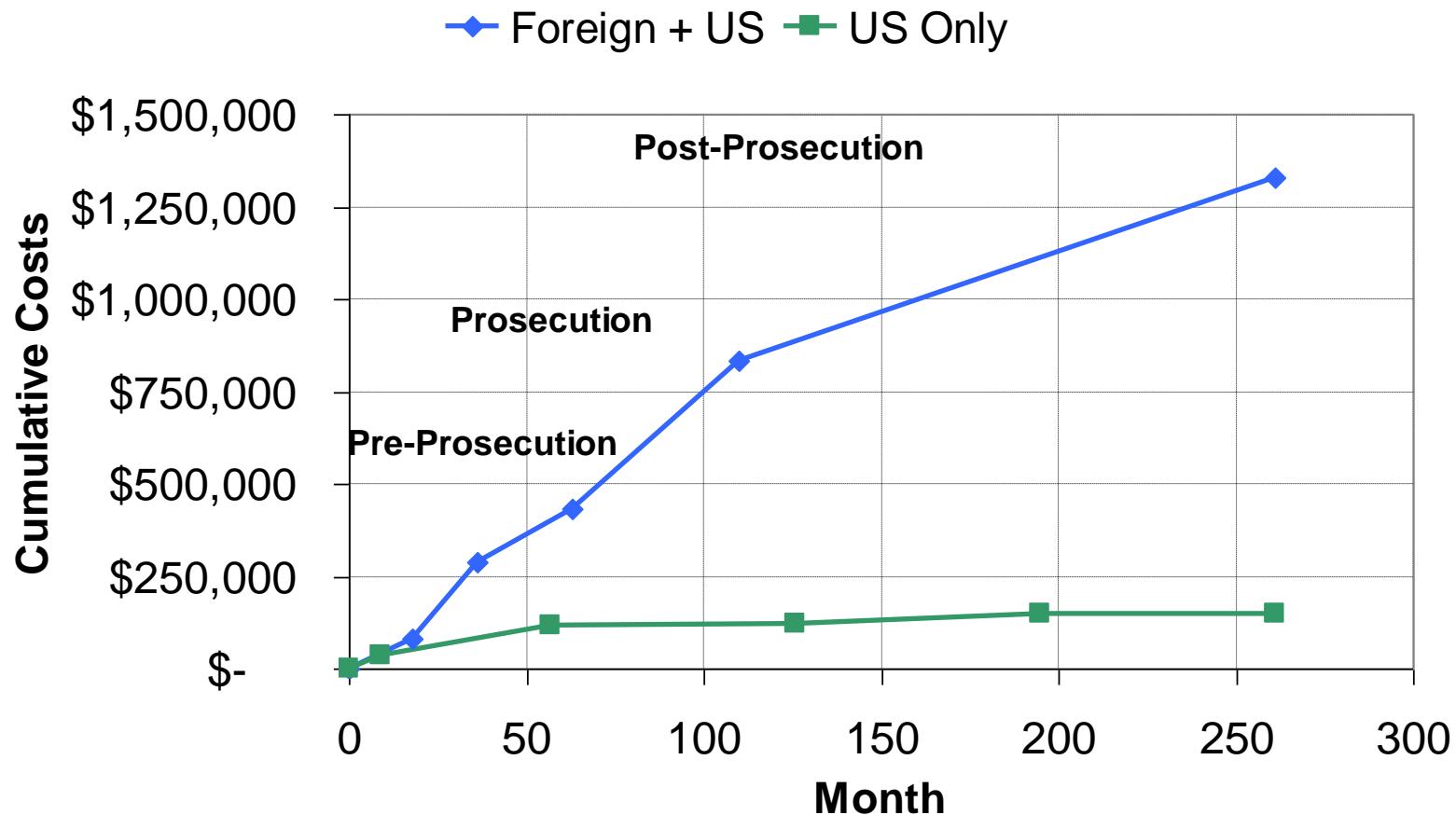
- Are you satisfied with patent protection only in the US?
 - Can you tolerate a foreign competitor supplying unprotected markets outside the US?
- Where are your sales, customers, manufacturing, etc.?
- Where will acquirers want you to have protection?
- Is your novelty in method of treatment or in the device?
 - Most OUS countries do not allow method of treatment claims
- More countries = significantly more costs

Foreign Filing Timeline and Expenses



U.S. vs. International Patent Protection

Cumulative Costs: U.S. alone vs. U.S., EU (DE/FR/UK/IT) and JP combined; assumes 8 U.S. apps in 2 years; PCT filing all apps



IP
FOR A
**NEW
AGE®**

QUESTIONS?



Orange County

San Diego

San Francisco

Silicon Valley

Los Angeles

Seattle

Washington DC

Disclaimers

- This presentation and our discussion constitute an educational and informational presentation of general IP law and should not be construed as individualized legal advice or representation.
- The presentation of these materials does not establish an attorney-client relationship. Representation can be initiated only upon completion of our standard new client/new matter process, including completion of a conflicts check, execution of an engagement agreement and payment of any applicable retainer.
- Any discussions are based solely upon nonconfidential information you may provide. It is our understanding that you will not provide us with any confidential information and will not do so until representation is initiated.

Technology Transfer

University-Industry Experience

Nitish Thakor

Director, SINAPSE
National University of Singapore
www.sinapseinstitute.org

Professor, Biomed. Eng.
Johns Hopkins University
www.jhu.edu/nthakor

Technology Transfer

University-Industry

Personal Experiences

- Co-founder of 3 currently active companies
- More than dozen patents
- More than \$30M in funding from Federal, Foundations, local venture/investors
- Products, and revenue generating
 - Prosthetics
 - Retinal imager for diabetes
 - Medical image sharing

- Infinite Biomedical Technologies
 - Prosthetics
- Vigilant Medical
 - Retinal Imager
- Vasoptic Medical
 - Image Share

All spun out of Johns Hopkins,
former students

Venture 1 – Prosthetics



Personal Experiences

- Growing clinical need
- Emerging Ecosystem of funding
- Grant funding available
- Modest competition
- Low threshold for IP, regulatory barriers



infinite
biomedical technologies

JOHNS HOPKINS
UNIVERSITY

improving patients lives through the
development of innovative medical devices



WORLD'S LARGEST RFID EVENT

Venture 2

Retinal Imaging for Diabetes



VASOPTIC MEDICAL INC.
ADVANCING HEALTHCARE THROUGH INNOVATIVE DIAGNOSTICS

Personal Experiences

- Very high clinical and society need in a growing disease burden
- Global market for low cost; IP potential
- Grant funding became available (Coulter, NIH...)
- Modest competition
- IP secured

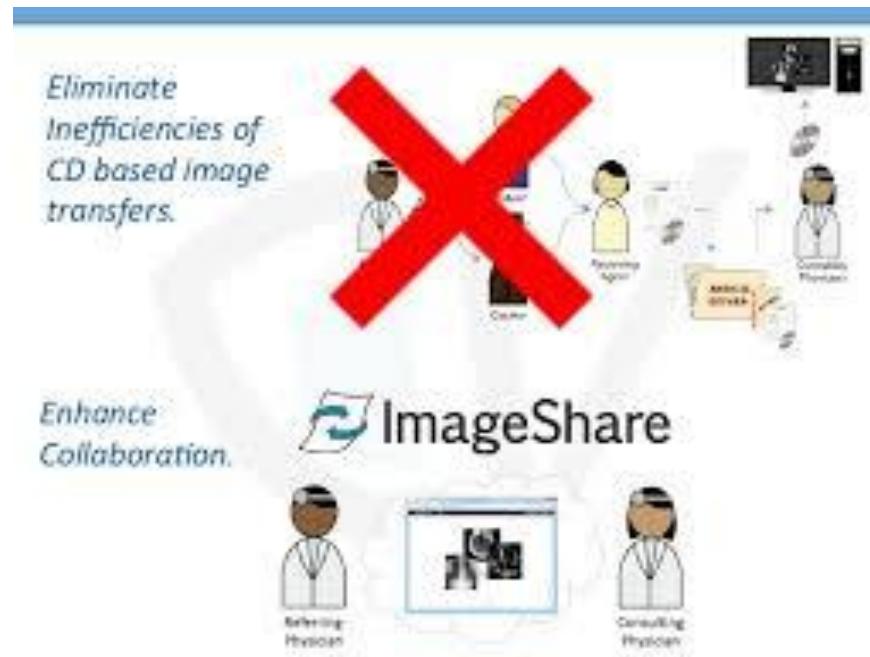


Veture 3 - Image Sharing



Personal Experiences

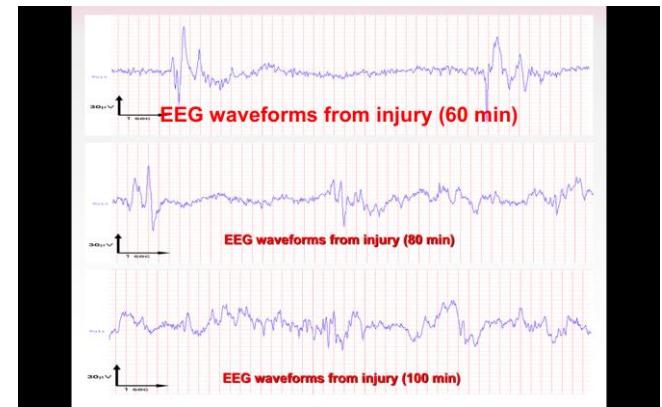
- Serving a niche market
- Quick revenue generating
- Revenue sustained operation
- Business savvy, management
- Modest technology/IP burden
- Niche play in the market



A Success/Failure Story?

SUCCESS – GRANTS!

- r01 on neurological consequences of global asphyxia
- r43 (sbir phase i) to build an EEG machine
- r44 (sbir phase ii) for clinical study to demonstrate clinical utility of spectral and temporal analysis of the EEG
- r44 continuation (sbir phase IIb) for regulatory approval. budget included funding for telemedicine infrastructure to get right physician to right patient at right time.



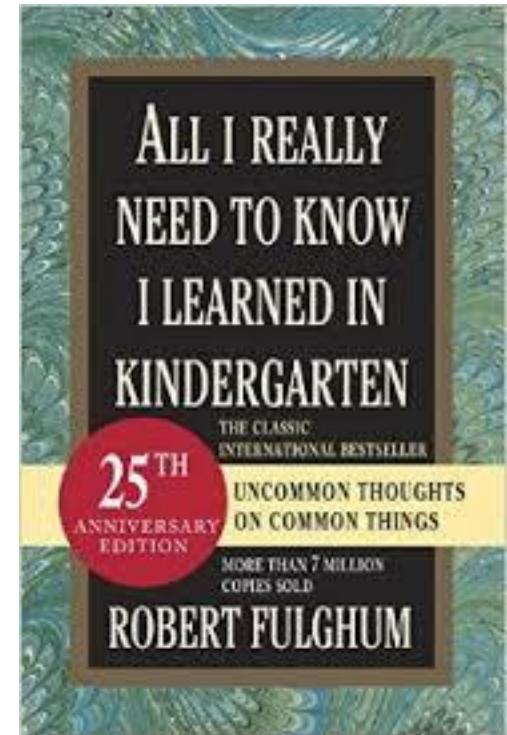
FAILURE – NO MARKET!

- Neurologists did NOT want the data. Medico-legal issue. if nothing is monitored/recorded, nothing to criticize.
- repurposed the telemedicine infrastructure, including audio/video conferencing, EEG display... and MRI image sharing...neuro-ICU at quaternary care medical center

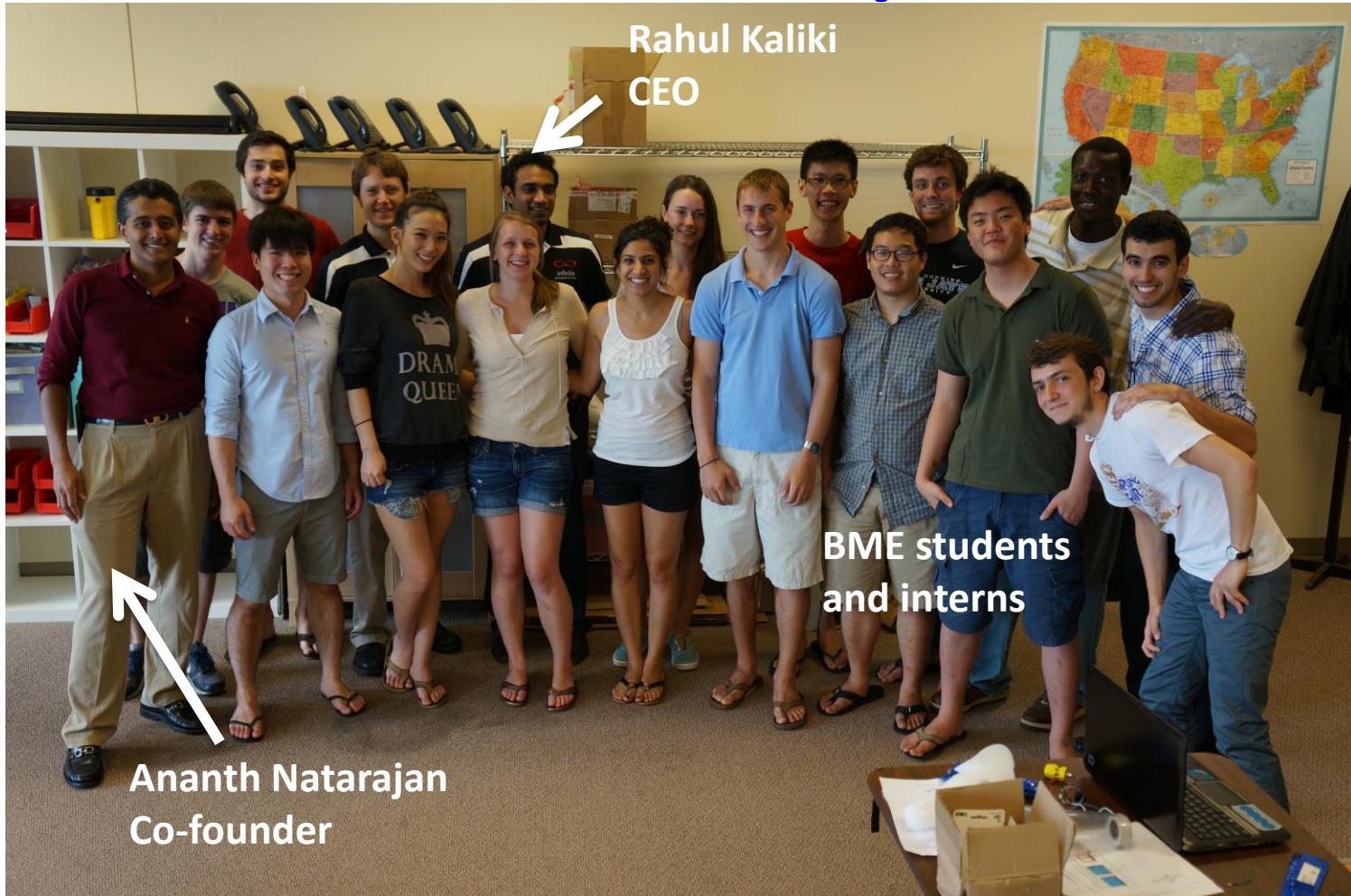


What Did I Learn?

- Notice the emerging trend and frontiers (e.g. DARPA Revolutionary Prosthesis; advances in prosthetic hands/legs)
- Believe in a technology, identify niche, and develop technical solutions
- Grant funding (e.g. SBIR) allows co-existence of R & D and academics to translation
- Motivated students – current/past/network - are the key (institutional support very secondary)
- Great satisfaction from solving the problem, serving the need, balancing research+technology+revenue (higher R&D/lower profit growth)
- Develop a path from grants to real product revenue, or a delicate balance of the two
- Plan for long term (people, product, funding, changing trends)
- Maintain team and its motivation



Most Important The Human Capital



University-Industry Partnership

Courtesy: Infinite Biomedical Technologies

JHU Students, Interns

Technology Transfer

Basic Ingredients

Personal Experiences

- Entrepreneurial spirit – desire to translate/commercialize
- Entrepreneurial students/associates
- Supportive department and Tech Transfer Office
- Ecosystem at the University (colleagues, forums, mentors/experience)

- Translatable technology
- Clinical/user need
- Innovation
- IP, freedom to operate, resources to file IP
- Funding to develop, test
- Team to execute

Technology Transfer

Major Challenges

Personal Experiences

Initial

- Research ->Prototype -> product
- Niche technology/University's IP/translation commitment
- Interested entrepreneurs (students), mentors
- Dependence on grants for development

Sustaining

- Low commercial potential (lack of large market)
- Finding interested clinical partners
- Finding business executives and mentors
- Funds for extensive IP protection, product development, variations
- Reliance on (addiction?) grants
- Shift from research to development to productization

Technology Transfer

Recommendations

Personal Experiences

Initial

- See/capture opportunities
- Seek translational grants (e.g. Coulter, SBIR)
- Remain encouraging/open to interested entrepreneurs (students), collaborators
- Persist at your research institution (IP, licensing) and believe
 - i.e. avoid discouragement (academic second guessing, tech transfer office)

Sustaining

- Go from R -> D -> hand over to P
- Go from students to professionals, from PhDs to engineers
- Network with clinicians
- Network to get executives on board
- Decision
 - Keep control, stay small R&D or
 - Transition from grants to Angel/VC/Industry Partner
- Develop long term satisfying human relationships
- Develop a long term survival/sustenance roadmap

What Did I Learn?

- Notice the emerging trend and frontiers (e.g. DARPA Revolutionary Prosthesis; advances in prosthetic hands/legs)
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What Did I Do Well? What Should I have Done Better?

Did Well

- Recruited, engaged good, motivated students
- Found the right technology at the right time
- Knew/cultivated the right funding sources and success with it
- Balanced Research-Development + Academics&Industry

Could Have Done Better

- Sought out bigger clinical needs, markets
- Worked with professionals
- Develop stronger clinical, regulatory partnerships
- Less R and more P, less focus on grants and more on revenue

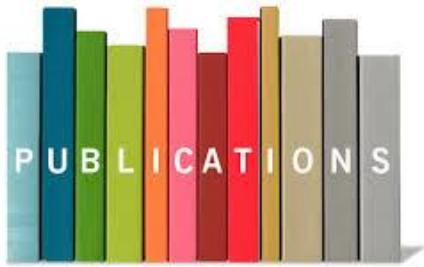
Central Dilemma

More Product/Revenue/IP or More Research/Grants/papers

Can you have your Cake and Eat it too?*Central Dilemma*



Are You in it for Fame or Money



More Product/Revenue/IP or More Publications and Grants



Work with Students or Professionals

Focus on Research vs Products



*Academia – Incubator – Industry
From Lab to Startup to Company*



Successful SBIR/STTR Funding

Dieter Haemmerich, PhD

Professor

Dept. Pediatrics
Medical Univ. of South Carolina
Charleston, SC, USA

Co-founder, Medical Engineering Innovations, Inc. (Madison, WI)

SBIR/STTR Program overview

- **Goal:** Commercialization of New Technologies
- Small Business: <500 Employees
- Mandatory Programs for Federal Agencies with >\$100 Mio annual budget
- NIH (DHHS), NSF, DOE, DOD, NASA, ...
- SBIR: 2.5 % of annual budget of agency
STTR: 0.3% of annual budget of agency
(similar chance of funding)
- FY 2015 NIH:
 - ❖ SBIR \$622 Mio
 - ❖ STTR \$95 Mio

SBIR (Small Business Innovation Research)

- Popular funding mechanism for start-ups
- Does not dilute equity; patent rights remain at company (patents resulting from grant must be reported)
- PI (Principal Investigator) employed >50% at company
- Phase I: max. 33% of budget for subcontracts (e.g. academic institution, consultants)
- Phase II: max 50% of budget for subcontracts

STTR (Small Business Technology Transfer)

- Phase I & II:
 - >40% budget to company
 - >30% budget to single academic partner
- Chance of funding similar SBIR/STTR

Available Budget

- Phase I: Proof of Concept/Feasibility
 - ❖ SBIR: \$150k / 6 months
 - ❖ STTR: \$100k / 1 year
- Phase II: Technical and Commercial Merit
 - ❖ Requires Completion of Phase I grant
 - ❖ SBIR: \$1-1.5 Mio / 2 years
 - ❖ STTR: \$ 750k / 2 years
 - ❖ Direct-to-Phase II: Phase I research through other funding sources
- Fast-Track: Combined Phase I/II proposals
- Phase IIB
 - ❖ \$3 Mio / 3 years (requ. Prior Phase II)

Other issues

- Grant submission requires 5 registrations of company (can take 6-8 weeks)
 - ❖ EIN
 - ❖ DUNS
 - ❖ System for Award Management (SAM)
 - ❖ Grants.gov
 - ❖ NIH eRA commons
 - ❖ SBA company registry
- Omnibus announcement (all institutes) or Targeted announcement (institutes vary)
- Submit early to correct error/warning messages

General guidelines

- Application layout similar to academic research applications
 - ❖ Specific Aims, Research Strategy
 - ❖ Biosketches with personal statement
 - ❖ Phase I:
 - ★ 6 page research strategy
 - ★ Very early stage project, but preliminary data helps
 - ❖ Phase II:
 - ★ 12 page research strategy (incl. Phase I progress report)
 - ★ 12 page Commercialization plan (!!)
- People good with academic grants are usually good SBIR/STTR grant writers (with some business input)

SBIR/STTR Review Panel

CENTER FOR SCIENTIFIC
REVIEW
SPECIAL EMPHASIS PANEL
ZRG1 ETTNK

NDI MEDICAL

BOSTON UNIVERSITY

ARIZONA STATE UNIV

NEUROBIO TEX

BRIGHAM AND WOMEN'S
HOSPITAL

PRONGHORN SCIENTIFIC, LLC

OREGON HEALTH AND
SCIENCE UNIVERSITY

VANDERBILT UNIVERSITY

CLEVELAND CLINIC MAIN

DUKE UNIVERSITY MEDICAL
CENTER

BOSTON SCIENTIFIC

UNIVERSITY OF CALIFORNIA
SAN FRANCISCO

UNIVERSITY OF UTAH

ACCELEREYES, LLC

CALIFORNIA INSTITUTE OF
TECHNOLOGY

WASHINGTON STATE
UNIVERSITY

UNIVERSITY OF MIAMI

**CLINICAL
NEUROPHYSIOLOGICAL
SERVICES, LLC**

JOHNS HOPKINS UNIVERSITY

UNIVERSITY OF CINCINNATI

UNIVERSITY OF KENTUCKY

UNIVERSITY OF NEW MEXICO

THE UNIVERSITY OF CHICAGO
COMPUTATION INSTITUTE

PALO ALTO VETERANS
AFFAIRS HOSPITAL

UNIVERSITY OF ROCHESTER

INDIANA UNIVERSITY

BOSTON UNIVERSITY

UNIVERSITY OF ILLINOIS -
CHICAGO

COLUMBIA UNIVERSITY

General guidelines

- Innovative & novel
- At beginning of R&D phase
- Commercially feasible (esp. Phase II)

- Academic Reviewers like to see publications record for key personnel

- Key personnel should include ideally:
 - ❖ Business expertise
 - ❖ Clinical expertise
 - ❖ R&D / Scientific expertise

NIH SBIR/STTR success rates

SBIR ¹ /STTR ²	Phase ³	Number of Applications Reviewed	Number of Applications Awarded	Success Rate ⁴
SBIR	Fast Track	337	66	19.6%
SBIR	Phase I	3,425	514	15.0%
SBIR	Total Phase II	823	241	29.3%
SBIR	Regular Phase II	442	163	36.9%
SBIR	Direct Phase II	347	65	18.7%
SBIR	Phase IIB	34	13	38.2%
STTR	Fast Track	61	10	16.4%
STTR	Phase I	911	149	16.4%
STTR	Total Phase II	87	31	35.6%
STTR	Regular Phase II	87	31	35.6%

Submission Deadlines

Submission Dates* Phase I & Phase II	National Technical Merit Review	Advisory Council/ Board Review	Estimated Award Date
September 5	October/November	January/February	March
January 5	February/March	May/June	July
April 5	June/July	August	September or December

- Expect ~2 years until funding (revisions)

Non-NIH SBIR/STTR

- SBIR/STTR innovation summit
 - ❖ Nov 29 – Dec 1 (Austin, TX)
 - ❖ Focused on defense, but includes some biomedical



- ❖ Submission platform tutorials
- ❖ Proposal development workshops
- ❖ 1-on-1 meetings with program staff

Resources

- NIH SBIR/STTR resources:
 - ❖ <https://sbir.nih.gov/>
- Innovation summit:
<http://defenseinnovation.us/sbir.html>
- NIH award data:
 - ❖ <https://sbir.nih.gov/statistics/award-data>

Questions?

Charleston, SC



Availability of slides

- Slides to be made available on the TC website
 - ❖ Technical Committee on Therapeutic Systems and Technologies
- Search for:
 - ❖ “Embs therapeutics tc”
 - ★ Or go to
 - ❖ <http://tc-therapeutic-systems.embs.org/>