

Device Development Session



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The Pennsylvania Convention Center

Program Chair
Course Chair
SAGES President

Adrian Park, MD
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COURSE OUTLINE AND TABLE OF CONTENTS

Title: Device Development: From Concept to Cash

Date: Thursday, April 10, 2008

Time: 7:00 AM – 12:00 PM

Course Chair: Steven D. Schwartzberg, MD

Description:

This postgraduate course will provide a comprehensive view of device development. The speakers will take the audience through the journey from the idea to a potentially successful enterprise. Each of the speakers will bring their experience in this field to educate the audience on each of the many steps necessary to go from *concept to cash*.

Objectives:

During this session, participants will be exposed to:

- Successfully protect innovative ideas.
- Understand the process by which patents are obtained and what their value is.
- Understand the relevance of a physician's employment contract with respect to intellectual property.
- Understand when procedures or devices need to be considered by the Institutional Review Board for research considerations.
- Recognize potential conflict of interest as it applies to the innovator and device developer.
- Appreciate the trials and tribulations of managing a clinical career and entrepreneurial venture.
- Understand the relative financial value of innovative concepts.

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WHY SHOULD SURGEONS INNOVATE?

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OVERVIEW

Many of the phenomenal breakthroughs over the past 50 years were conceived and born in university laboratories. The intellectual horsepower of university labs, the faculty and perhaps most importantly, the university students, is an unrivaled national resource. Many believe that universities have a fundamental stewardship and indeed responsibility not just to discover, but to “transfer innovation to the marketplace to truly make a difference to society” (C.L. Max Nikias, PhD, Provost, University of Southern California).

HISTORICAL CONTEXT

It wasn't always so. A recent review [1] traces the critical role of university research in the aftermath of World War II. The success of the Manhattan Project emphasized the increasingly technical nature of national defense which translates not only to military but to economic arenas as well. By 1980 the U.S. government held title to some 28,000 patents as a result of federal funding for research but fewer than 5% were commercialized. Modern day technology transfer from university research to commercialized traces to the Bayh-Dole and Small Business Patent Procedures Act (PL 96-517) enacted December 12, 1980. This legislation fundamentally altered the ownership paradigm of intellectual property developed with federal funding; federal ownership was transferred to grantees to enhance public access. It *de facto* created an implied duty for government grantees to translate research discoveries and commercialize inventions. Furthermore it explicitly encouraged academic-industry collaborations to this end ... but without specifying mechanisms – thus birthing conflicts of interest. Bremer comments in Innovation's Golden Goose [2] that the Bayh-Dole Act is “perhaps the most inspired piece of legislation to be enacted in America over the past half century. This unlocked all the inventions and discoveries that are made in the laboratories throughout the United States with the help of tax payer's money. More than anything, this simple policy measure helped reverse America's precipitous slide into industrial irrelevance.”

COMPONENTS IN THE PROCESS

As we consider the surgeon's role, the sequence from discovery to invention to innovation to entrepreneurship requires explicit definition.

Discovery

The greatest advances in medicine have been the result of unfettered investigator-initiated scientific inquiry and discovery. Recombinant DNA, synthetic human insulin and surfactant are but a few examples of fundamental discoveries successfully translated to phenomenal clinical utility and enormous patient benefit.

However, the vast majority of devices, drugs and hybrid devices are neither as lucrative nor touted, but in aggregate they are at least as profound.

Invention

An invention is an object, process or technique that has an element of *novelty*. That said, most inventions are usually based on a previous development or idea then modified or transformed into an invention, e.g., 1) Tom Fogarty didn't invent the balloon but he did invent its application with his Balloon Catheter, and 2) The Starr Edwards Cardiac Valve - the collaboration between a young surgeon and an experience engineer may have been inspired by the patent of a bottle stopper (1858). Some inventions represent a radical breakthrough in science or technology that extends the boundaries of human knowledge (e.g., LASERS).

Innovation

While an invention begins as a theoretical concept, an innovation is an invention put into practice. Simply put, an invention is an idea, and an innovation is an application. In his book They Made America [3] Harold Evens comments: "A *scientist* seeks understanding, an *inventor* a solution, and an *innovator* seeks a universal application by whatever means. Thomas Edison is thought of as America's foremost inventor, but his most important work was translating the insights of invention into the practical reality of innovation through the long process of development and commercialization." In most cases, the process of innovation is usually more important than the idea of an invention.

Entrepreneurship

An entrepreneur is a person who undertakes and operates a new enterprise or venture and assumes considerable responsibility for its success. The entrepreneur seeks independence, autonomy and control to maximize the likelihood of success in a risky (defined) and uncertain (ill-defined) venture (note similarities with traits frequently ascribed to surgeons). For an in depth analysis and synthesis of the process of innovation and entrepreneurship, the reader is directed to the following comprehensive books. [4-7]

SURGEONS AS PROBLEM SOLVERS

The fundamental and unique relationship between surgeon and their patient cannot be overestimated. Patients never crowd the surgeon's pre-op office and then report "all is well". Instead, specific problems amenable to mechanical solutions predominate.

What is a Surgical Operation?

What is Surgery?

"Surgery is not a place, not an event – rather it is fundamentally an intellectual discipline, frequently involving a surgical procedure, but most importantly characterized by an attitude of responsibility towards the care of the sick. The closed reduction of a fracture is part of orthopedic surgery, the non-operative management of a splenic injury or of gallstone pancreatitis is still clearly within the purview of the field of surgery and the surgeon's care." [A conversion with Mark M. Ravitch, MD, 1982]

Dr. Ravitch's precise definition of "surgery" suggests a concomitant need to precisely answer the question: "What is a surgical operation?" A surgical operation can be defined as "any act performed with instruments or by the hands of a surgeon". This entails two components, that of an image and a manipulation. Manipulation derives

from the Latin word “*manu*” for hand and hand manipulated tools, but now involves a variety of other energy sources. The image no longer need only be that of an unaided eye.

A tabulation of this conceptualization of both our image and our manipulation is outlined in Table 1. The most direct and traditional operation involves a direct visualization of an area of the body and a direct two-handed manipulation. Improvements in visualization with operating loupes or the operative microscope have permitted us to scale down the size of our operation. The addition of video camera to laparoscopy allowed a brilliant image to be projected to all in the OR, permitting assistants to actively participate. This expanded the field from a simple diagnostic maneuver to an array of increasingly complex surgical procedures. The inherent restrictions of laparoscopic surgery (2D visualization, fulcrum effect and others) ultimately helped drive the development of surgical robotics.

It’s now clear that many other images, an ultrasound, a CT scan or an MRI, can be manipulated with a variety of energy sources including heat or cold, radiofrequency energy or photodynamic therapy. The nascent field of frameless, stereotactic radiosurgery must not be missed by surgeons. The pre-emptive extirpation of the non-cancerous but high risk thyroid gland based on RET proto oncogenes might be thought of as a gene-directed image.

What’s next remains to be seen, but the notion of improvements in the quality or type of the image and in the nature of the manipulation provide a useful framework for speculation, thought and development. Given the evolution we’ve seen thus far, there is no reason to believe that the end is in sight.

The principles discussed above might be best summarized in what I would term “Ravitch’s Rules”. (Table 2) These rules provide a useful framework for clarity in understanding the past and, I believe, illuminate the road ahead. Most critically, surgeons must be thoughtful in how they define themselves and ignore technological advances at their own peril.

UNDERSTANDING THE UNSOLVED PROBLEM

If surgeons are problem solvers, then the “unsolved problem” requires surgeons to seek novel solutions through discovery, invention, innovation and entrepreneurship. The history of progress in our field is dominated by the creative and ingenious surgeon seeking a solution to an unsolved problem. Tom Fogarty watched senior surgeons perform groin-to-knee arteriotomies to extract clot; invariably these patients returned for an amputation. The clinical need was obviously but perhaps unspoken. His development of a balloon catheter using a finger cot and fly tying techniques has achieved iconic status in the history of surgical innovation and arguably created the field of catheter-based endovascular “surgery”.

The chance discussion between a young surgeon, Lazar Greenfield and an oil pipeline engineer took a curious turn. Dr. Greenfield was trying to sieve clots in the vena cava, a problem long ago solved filtering oil debris and sludge using conical filters in oil pipelines – voila, a whole new approach to venous thromboembolic disease was borne.

One of the most creative and ingenious surgeons of the past half century, Judah Folkman elucidated the basic processes of neovascularization and the field of angiogenesis. In an assortment of collaborations with industry, he moved beyond the scientific discovery to the treatment of a huge number of patients through the understanding and the control of angiogenesis. Each of these surgeons was inspired by an unsolved clinical problem.

WHAT TO DO?

To understand and solve the next generation of “unsolved problems” for patients, all of these processes – discovery, invention, innovation, entrepreneurship – are necessary in some combination. Creative, successful innovation almost always requires both inquisitive people and a permissive environment. Imagine Steve Jobs, arguably one of the most creative and ingenious talents of our age, in your Department of Surgery. Would he be tolerated? Encouraged? Embraced? Bludgeoned? At the beginning, and at the end of the quest for innovation is the recruitment, inspiration and retention of creative people. Are you and your department ready for the discomfort of such creators?

SO YOU HAVE A GREAT IDEA, NOW WHAT?

Many physicians and surgeons have great ideas; few of these are ever translated to improvements in patient care because of a failure to understand “the next step”. An extensive review of the process was presented in the monograph “Advanced and Emerging Technologies in Pediatric Surgery and the Process of Innovation” [8] as well as in a forthcoming chapter “From Idea to Bedside: The Process of Surgical Invention and Innovation” in the textbook Key Topics in Surgical Research. [9]

In most every case, the next step towards a solution of an “unsolved clinical problem” is actually a step backwards to understand the real problem. Once the clinical need is really understood, an effective path forward can then be derived. This pathway involves an appreciation of many issues, including intellectual property ownership, regulatory pathways, finance and clinical trial strategies.

TRAINING THE NEXT GENERATION OF SURGEON-INNOVATORS

Given both the imperative for innovation and its complexity, it seemed reasonable to consider a formal training program in the process, teaching the path finding skills of successful discovery, invention, innovation and entrepreneurship. Beginning 7 years ago, Stanford began a systematic training program in medical device innovation (<http://innovation.stanford.edu>). The Stanford Biodesign Innovation Program for the first time addressed medical device innovation as a discipline, specifically teaching the process in a way not previously achieved in existing graduate and post-graduate programs. This type of translational education provides an early career opportunity for an amalgam of surgeons, engineers and entrepreneurs to develop the talents that translate basic discoveries into important new treatments.

As currently constructed, the Biodesign Innovation Program applies a specific and proven methodology for teaching the knowledge and skills for biomedical technology innovation and translation. It includes

- A two-month boot camp
- An introduction to the techniques of clinical needs finding and characterization
- Surgical specialty immersion
- Needs analysis, validation and specification
- A systematic approach to inventive solutions (brainstorming)
- Early prototyping
- Methodic process for planning regulatory and reimbursement pathways
- Pre-clinical testing
- Clinical testing

After the first year of core knowledge acquisition, surgical trainees move forward in their second year to characterize and test their most promising inventions, beginning the process of technology translation and initiating a set of studies that carries them into the next phase of their career. This project-based methodology is modeled on other project-based educational programs and mimics such a process in our doctoral and

post-doctoral research laboratories. Thus the most important output is not a product or a technology but the education of the next generation of surgeon-innovators.

Image

Direct visual
Operative Microscope
Video image

US, CT, MR
RIGS
PET

Manipulation

2 hands direct

2 hands long tools,
robots

cryo, thermal
radiofrequency
PDT
ESWL

What's Next?

Table 1. Surgical Operation – Image & Manipulation

-
1. Surgery is not an operation, but an intellectual discipline.
 2. Surgical procedures are characterized by both an image and a manipulation.
 3. Surgeons can and should be active participants in the ethical introduction and use of technology.
 4. Surgeons must be thoughtful in how they define themselves.
 5. Surgeons ignore technological advancements at their own peril.

Table 2. Ravitch's Rules

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I Have a Good Idea – How Do I protect it?

Dmitry Oleynikov, M.D.

• A patent is a property right granted by the Government of the United States of America to an inventor “to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States” for a limited time in exchange for public disclosure of the invention when the patent is granted

• What **can** be patented – utility patents are provided for a new, nonobvious and useful:

- Process
- Machine
- Article of manufacture
- Composition of matter
- Improvement of any of the above

• What **cannot** be patented:

- Laws of nature
- Physical phenomena
- Abstract ideas
- Literary, dramatic, musical, and artistic works (these can be Copyright protected). Go to the [Copyright Office](#).
- Inventions which are:
 - Not useful (such as perpetual motion machines); or
 - Offensive to public morality

- Invention must also be:
- Novel
- Nonobvious
- Adequately described or enabled (for one of ordinary skill in the art to make and use the invention)
- Claimed by the inventor in clear and definite terms

• Next, a **search** of all previous public disclosures (prior art) including, but not limited to previously patented inventions in the U.S. (prior art) should be conducted to determine if your invention has been publicly disclosed and thus is not patentable. A search of foreign patents and printed publications should also be conducted. While a search of the prior art before the filing of an application is not required, it is advisable to do so. A registered attorney or agent is often a useful resource for performance of a patentability search. After an application is filed, the USPTO will conduct a search as part of the official examination process.

• Patent searching is a learned skill. The best advice for the novice is to contact the nearest [Patent and Trademark Depository Library](#) (PTDL) and seek out search experts to help in setting up a search strategy. If you are in the Washington, D.C. area, the USPTO provides public access to collections of patents, trademarks, and other documents at its [Search Facilities](#) located in Alexandria, Virginia. These facilities are open weekdays (except holidays) from 8:00 a.m. to 8:00 p.m. For further information on search services offered at the USPTO, please refer to [Public Search Services](#) offered by the USPTO.

How Long does the Patent Last?

- For applications filed on or after June 8, 1995, **utility** and **plant** patents are granted for a term which begins with the date of the **grant** and usually ends 20 years from the date you first applied for the patent subject to the payment of appropriate [maintenance fees](#). **Design** patents last 14 years from the date you are granted the patent. No maintenance fees are required for design patents.

How much does it cost to get a patent?

- There are three basic fees for utility patents:
- The filing fee, which is non-refundable whether or not a patent is granted. (This is the cost to have your invention "examined" by the US Patent and Trademark Office - remember, you may or may not get a patent!)
- The issue fee (you pay this only if your application is allowed)
- Maintenance fees (paid at 3 1/2, 7 1/2, and 11 1/2 years after your patent is granted - these fees "maintain" your legal protection).
- Additional fees may be required.

Filing a provisional application. (More information)	\$100
Filing a non-provisional application. (More information)	Approximately \$150*
Issue fee	Approximately \$650
Maintenance fees: Due at 3 1/2 years Due at 7 1/2 years Due at 11 1/2 years	Approximately \$450 Approximately \$1150 Approximately \$1900

What is a PCT application?

- The Patent Cooperation Treaty (PCT) is an international agreement for filing patent applications having effect in many countries around the world. Although the PCT system does not provide for the grant of “an international patent”, the system simplifies the process of filing patent applications, delays the expenses associated with applying for patent protection in foreign countries, and allows the inventor more time to assess the commercial viability of his/her invention. Under the PCT, an inventor can file a single international patent application in one language with one patent office in order to simultaneously seek protection for an invention in the PCT member countries.

I Work for a University – Who Owns my Head?

Roger de la Torre, M.D.

Did Not Submit Syllabus

I Built This in My Garage Do I Really Need to Go to the IRB?

S. D. Schwaitzberg M.D.

There is sufficient federal law that covers just about every unimaginable situation in this regard. The branch of the federal government the deals with this most directly is The Food and Drug Administration Center for Devices and Radiologic Health. (<http://www.fda.gov/cdrh/>).

Medical Device Definition

A medical device is defined within the Food Drug & Cosmetic Act as "...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Medical devices distributed in the United Sates are subject to General Controls, pre-marketing and post marketing regulatory controls.

General Controls include:

1. Establishment Registration by manufacturers, distributors, repackages and re-labelers,
2. Medical Device Listing with FDA of devices to be marketed,

3. Manufacturing the devices in accordance with Good Manufacturing Practices,
4. Labeling medical devices in accordance with the labeling regulations, 21 CFR 801 or 21 CFR 809,
5. Medical Device Reporting of adverse events as identified by the user, manufacturer and/or distributor of the medical device.

Pre-marketing controls are device and device classification specific. Pre-marketing controls for a medical device may include: clearance to market by 510(k) or approval to market by Pre-Market Approval (PMA). Post marketing controls include Device Listing, Medical Device Reporting (MDR), Establishment Registration and Quality System Compliance Inspection.

Device Classification

There are 3 FDA regulatory classifications of medical devices: Class I, Class II and Class III. The classifications are assigned by the risk the medical device presents to the patient and the level of regulatory control the FDA determines is needed to legally market the device. As the classification level increases, the risk to the patient and FDA regulatory control increase. Accessories to medical devices, devices used with a medical device to support use of the device, are considered the same classification as the medical device.

Class I medical devices have the least amount of regulatory control. Class I devices present minimal potential harm to the user. Class I devices are typically simple in design, manufacture and have a history of safe use. Examples of Class I devices include tongue depressors, arm slings, and hand-held surgical instruments. Most Class I devices are exempt from the premarket notification and may be exempt from compliance with the good manufacturing practices regulation.

Class II medical devices are devices where General Controls are not sufficient to assure safety and effectiveness and existing methods/standards/guidance documents are available to provide assurances of safety and effectiveness. In

addition to compliance with General Controls, Class II devices are required to comply with Special Controls. Special Controls include:

- Special labeling requirements,
- Mandatory performance standards, both International and United States
- Postmarket surveillance
- FDA medical device specific guidance

Class II devices typically require pre-market notification by submission and FDA review of a 510(k) clearance to market submission. A few Class II devices are exempt from the premarket notification. Information on Class II exempt devices is located within the device regulation, 21 CFR 862 through 892. Examples of Class II devices include physiologic monitors, x-ray systems, gas analyzers, pumps, and surgical drapes.

Class III medical devices have the most stringent regulatory controls. For Class III medical devices, sufficient information is not available to assure safety and effectiveness through the application of General Controls and Special Controls. Class III devices usually support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury to the patient. Typically a Pre-Market Approval (PMA) submission to the FDA is required to allow marketing of a Class III medical device. A few Class III medical devices are required to only have a 510(k) cleared by the FDA to be marketed. Examples of Class III devices that require a PMA are: replacement heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators.

Let suppose you really did just build a medical device in your garage. After classifying it, there are several other ways to categorize the new device you just built. The most common distinctions would be *experimental* versus *investigational*.

An experimental/investigational device refers to an innovative device for which "absolute risk" of the device type has not been established (that is, initial

questions of safety and effectiveness have not been resolved, and the FDA is unsure whether the device type can be safe and effective.

A nonexperimental/investigational refers to a device for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of the device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

Another way to categorize your new device is by risk. Risk assessment is performed by an IRB in order to determine what the approval pathways are.

Non- significant risk – This is an absolute, not relative assessment.. If this determination can be made the IRB has great latitude in the approval process. The approval can be granted by an expedited review the IRB chair, bypassing the often time consuming full committee process. In addition if this determination is made a waiver of the documentation of informed consent can be requested. Examples of these devices would be external diagnostic devices such as EKG patches, dressings, new handheld open surgery instruments.

Minimal Risk – This is a relative assessment and require a value judgment by the investigator and confirmed by the IRB. A minimal risk device protocol can also be approved by expedited review but generally requires informed consent. An examples of this would include a novel intravenous catheter . A variant of this would minimal incremental risk. Previously approval devices, even those with significant inherent risk, that are modified in some way where the risk profile is altered but n a minor way can be considered for expedited review. A modification to a ultrasonic coagulator might meet this criteria.

Significant Risk – These devices are often novel introductions to the field. These devices require full IRB review and informed consent. The introduction of the ultrasonic coagulator into surgery required this level of review .

An another way to categorize your new device is by approval status. This is helpful in classifying the nature of a potential research project.

Approved – These devices have been approved for marketing by the FDA This approval is tied to specific indications for their use. Thinking up new ways to use these devices could render their use investigational and could also invalidate any warranties.

Cleared – The devices can be sold after FDA clearance. Often they fall into low risk categories such as dressing sponges. This is common for Class I devices.

“510k” approved - Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers to notify FDA, at least 90 days in advance, of their intent to market a medical device. . It allows FDA to determine whether the device is equivalent to a device already approved or cleared. This is a relatively short pathway to marketing approval if granted. If this is accomplished many device developers still study their new device in a clinical trial prior to marketing. The advantage of garnering this status is the ability to label the device as investigational (ie approved) rather than experimental.

PMA - Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of experimental Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a premarket approval (PMA)

application under section 515 of the FD&C Act in order to obtain marketing clearance. (<http://www.fda.gov/cdrh/devadvice/pma/>) .

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device. The PMA owner, however, can authorize use of its data by another. This is a lengthy process that culminates with a review by the FDA staff and an FDA panel of outside experts in a public forum.

HDE - A Humanitarian Device Exemption (HDE) is an application that is similar to a premarket approval (PMA) application, but exempt from the effectiveness demonstration requirements.. FDA approval of an HDE authorizes marketing of an Humanitarian Use Device (HUD). As defined in 21 CFR 814.3(n), a HUD is a “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.”

Conclusion;

If you built a tongue depressor (or other Class I device) in your garage and meet the requirements of General Controls. You can go out and sell it. If use assemble a novel device out of even Class I components and cannot meet this requirement then at the very least this would be considered investigational if not experimental and would require IRB approval. The same would be true of a home modification of an existing Class II or III device. As noted above this need not necessarily be a high barrier if the absolute or incremental risk is low.

I Want to Publish and Profit – Can I do Both?

Mark Talamini, M.D.

University Research and Inventions: Why Patent?

- The university encourages broad utilization of the results of research **“not only by scholars but also in practical application for the general public benefit.”**
- University research is conducted for the primary purpose of gaining new knowledge.
- However, innovative research often leads to **patentable inventions** as by-products of the research.



What is Patentable?

- Any new, useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof.
- Must be “non-obvious” to one who is skilled-in-the-art.



Biological Patentable Subject Matter

- Organisms and methods for making
- Isolated versions of naturally occurring sequences
- Methods to isolate and identify
- Synthetic sequences and methods of making
- New uses for known compounds
- Methods of treatment



Non-biological Patentable Subject Matter

- Software
- Algorithms
- Circuits
- System architecture
- Mechanical assemblies



Why Patent?

- You reveal your invention in a patent application. In exchange, the government grants you a limited period (20 years) of exclusivity.
- An issued patent represents a *right to exclude* others from making, using or selling your invention in the country in which your patent issues.



Invention Disclosure to UCSD

- Patenting action can't be taken until formal Invention Disclosure (ID) is made to TechTIPS.
- Ideally, ID should occur prior to any **public disclosure** of the invention.
- If not, disclose ASAP afterward.



Can Publish AND File Patent Application

- If you publish prior to filing a patent application, US patent rights may still be available to you for 1 year from the publication date.
- However, if you publish before filing in the US, then **foreign patent rights are lost**.



Biological Patentable Subject Matter

- Any abstract, journal article, letter to the editor, seminar, poster presentation, or oral presentation.
- A grant application abstract (keep it vague).
- Operating your invention in public.
- Transfer of your invention unless it's under a UC agreement.
- Sale of your invention.



Patent Protection

- If you publish prior to filing a patent application, US patent rights may still be available for 1 year from publication date.
- However, if you publish before filing in the US, then **foreign patent rights are lost**.
- If you file FIRST, you can publish ANYTIME without losing patent rights.
- Publication delay for filing is never more than ~ 60 days, and less if you need it.



Lost Opportunities

- When an invention is publicly disclosed without patent protection, it is considered to be “in the public domain.”
 - Public disclosure generally prevents *anyone* from patenting the invention.
 - Companies rarely develop unpatented technologies.
 - In this case, only scholars benefit.



Commercialization Benefits to Researchers

- ALL inventors receive a portion of the income from the license, and possibly:
 - Consulting arrangements (per UC policy),
 - Sponsored research,
 - Collaborations,
 - Clinical research opportunities, etc.



Revenue Distribution from Licensing Activity

- Revenue Distribution (1997 Policy)
 - Inventor Shares at 35%
 - Research Shares at 15%
 - 60% to PI's Lab
 - 40% to PI's Home Academic Unit
 - Residual Pool at 50%
 - Campus Share 50%
 - General Fund Share 50%



UC Encourages Disclosing Inventions

- Invention disclosure is required by UC policy and federal law on NIH/NSF funding.
- Disclosures can facilitate obtaining future state, federal and *commercial* research funding.
- Patent protection enhances publication and encourages commercialization of innovations for the *public benefit*.



I Have a Company. Should I Give Up My Day Job?

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This is a very personal account of what happened to me, when I set out to build a surgical robotics company:

In the fall of 2001, I had what I thought was a great idea. Based on over twenty years of clinical experience as a general and endoscopic surgeon in New York, I was convinced that the world needed a robotic scrub nurse or technician. Of course, this robot would be the perfect assistant for the surgeon, always at the ready with requested instruments and even being able to anticipate what the surgeon would need next. I was convinced that such a device would be a great thing to have in the OR, and would fulfill many needs, such as freeing the OR staff from the tedious and error-prone task of counting the surgical instruments as the case was closing. I even dreamed that such device might lead to even greater things, such as robots that could really do surgery on their own. What a boon that would be to wounded soldiers or perhaps even someday to interplanetary space travelers! Certainly my notions were greeted (by most people) at the time as complete science fiction, but I had a sort of missionary zeal for making this dream come true. I was on a mission to convince the skeptics and change the world.

And so, while maintaining my day job as a general surgeon at a small affiliate hospital of NewYork-Presbyterian, I set out to build the first crude prototype of the robotic scrub technician. At least from the technical standpoint, I was not starting completely from scratch in this endeavor. I have many years of experience as a designer/inventor of surgical devices, and also have an excellent working knowledge of many disciplines relevant to surgical devices, including mechanics, computer, electronics and many craft skills that go into building prototypes. My background as a young man was in physics and I obtained my MS degree in this field. Physics was a great platform to enable me, in subsequent years, to study other relevant knowledge areas that contribute to building surgical robots. I have also been a compulsive inventor and tinkerer all of my life. My clinical office was always filled with gadgets and projects in various stages of completion. I would work on these projects when I was on-call at the hospital. My loyal secretary of many years regarded my inventions as

harmless eccentricities. My real job was to take care of patients. I accepted this duality of purpose, and, even as I was planning the first prototype of Penelope (the robot scrub technician), I continued to perform my clinical duties faithfully.

Nevertheless, as the idea of the robot scrub technician grew in my imagination and actually began to take first shape, I began to become impatient. I had spent years trying to create and invent surgical devices, in a sort of part-time way. Frustrated with this half-way thing with my projects and inventions, I finally decided that the time had come to start my own company and really raise some money to do it right. Just doing another research project with a grant was not what I wanted to do. I really wanted to establish a going concern, one that would be financially self-sufficient at least, and which would be the platform upon which this new type of surgical robot could be built. I really admired other people that I knew in the surgical/medical device industry, particularly Yulun Wang, the inventor of the AESOP robot (Computer Motion, Inc.) and also the telepresence robot that his new company, InTouch Health, is making and marketing quite successfully. This was my mind-set when I founded RST in the spring of 2002. I certainly had lofty goals, but other than my burning desire, I knew basically nothing about starting a business or raising money or any of that necessary business stuff. However, I was convinced that I could learn what I needed to learn, to build and run a business. Others had done it, so why not I?

In order to realize my dream, money was clearly a key ingredient. One of my first steps toward raising money was to apply for a small grant offered by United States Surgical. I got that money, and this enabled me to pay a young but very talented mechanical engineer, a very recent graduate from a prestigious university, to work with me. This was the first time I had really collaborated with anybody on my projects. I sensed that I could go further if I had some help. In fact, this intuition was correct, and we made great progress in less than a year. As a result of that initial burst of output, we were able to construct a crude but working prototype of the robotic scrub technician, which we named Penelope. As elementary as this machine was, it was enough of a proof of concept to get us funding from the US Army. The US Army was interested in applying robotics to battlefield care of wounded soldiers. I had no idea of this when I started the project. The US Army funding was a great boost, and provided me the opportunity to acquire some other helpers. We eventually went on to raise over a million dollars in government funding, much of it from the National Science Foundation.

In July of 2003 after our first NSF funding came in, I decided to step away from the day job of doing surgery and dedicate myself full time to RST. Columbia University was very nice about letting me take a sabbatical, which was of course unpaid but which did allow me to keep my affiliation, even though I was not doing surgery. So, I had in effect, walked away from my day job, although I was expecting to return. This was a huge step for me. It caused a lot of stress at home, as my wife was horrified at what I was doing. Fortunately, the children

were nearly though college, and except for the youngest one (of three), the money for their educations had already been allocated. For my own part, I was prepared to live, rather frugally, on the small salary that the grants afforded me. My wife had her own salary, and should be able to take care of herself.

The company's money quickly became a major concern of mine. Things were always very, very tight. Basically all of the money went into the salaries of my team (who made more money than I did, though still not a lot) and basic expenses of the company, "overhead" costs. Against my wishes, I began to get very involved in the day to day financial operations of the company. I had hired someone with an MBA degree to manage the books of the company. This person, though well intentioned, was not able to really get the job done, in terms of allowing the company to get to its goals with the money that we had. At one point, he said that, with our current expenses, we were shortly going to go bankrupt. I had to step in and start micro-managing our cash flow, in order to keep the company from going under. Ironically, at the start of this adventure, I could barely manage my own check book. At the present time, I have become quite skilled at this sort of thing, so much so that it amazes me sometime. This is not where I wanted to go when I started the company. I just wanted to build surgical robots. But this is where it ended up. One of the other key ingredients for a successful company, besides having money, is knowing how to manage it as efficiently as possible. I believe, that when one is starting out in a new company, that this is one of the most important tasks, and one that must be taken to heart.

Early in 2004, we were invited to join a Defense Department project that was being launched under the DARPA flag. This DARPA project, called "Trauma Pod", had as its goal the development of a completely unmanned robotic surgical system for trauma care on the battlefield. This project was the brainchild of Richard Satava. Although we were delighted to join the Trauma Pod team, we progressed in our work with Penelope, building more advanced versions of Penelope. From the solitary grad student that I started with, RST now had four skilled computer science and engineering employees. Things really seemed to be rolling along. In the summer of 2005, we did a clinical case with Penelope at NewYork-Presbyterian Hospital. We received amazing media coverage. In those heady days, it was hard at times for me to believe how far my dream had come in just a couple of years. The joy I derived from seeing my ideas take reality more than offset the aggravation caused by having to watch out for every cent that we spent. This was just three years after I founded the company.

At present, I am still working full time for the company, although receiving basically no salary. The company itself is struggling along, but is still alive and kicking. I suffered a very serious injury shortly after we did our first and only case with Penelope. This injury, which changed my life, has made it difficult for me to really return to the rigors of clinical surgery. So, for the time being, I am more or less stuck at RST, where I wanted to be.

But it is touch and go for now. Although Penelope made a great splash in the OR, it has been elusive to translate that event into outside funding. I think my accident also hurt the company, in that it was extremely difficult for me to keep things going. My little team would deny it to this day, but I believe that it was very hard for them to keep going, when there was a good chance that I was not going to make it out of the hospital alive. My subsequent recuperation even after the hospital was very slow, and it is only very recently that I feel that I have got back my old accustomed energy level. As the money got tighter, I was forced to let go a couple of people that we had hired, who simply were not contributing what the company needed. This was very painful for me, and for them too. I also convinced the remaining team members to allow us to take on some experienced business people, to help us with fund-raising and to advise us on what we should do to make the company successful. These business people, the leader of whom I have known for years as a successful entrepreneur and Columbia business school academic, have taken RST through a complete make-over. I had to be humble enough to let these folks fix up RST so that RST could survive. My original vision is still more or less there, but it has been radically altered. Being an optimist, I still think that the company will prosper. But it will take a lot more hard work and sleepless nights. This is just a hard a job as doing surgery, believe me!

In summary, I think that what I did was definitely risky. It was also somewhat selfish, in terms of my family and also the patients whom I had to leave behind. It was possibly foolish. But the way I look at it, is that if I had not done it, I would spend the rest of my life regretting my inaction. If someone really wants to do it, then I would say, just follow your heart and do it. But be prepared for a very bumpy ride, unless you are smarter and luckier than I have been.

“What is a good idea worth anyway?”

Andy Levine

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The process of taking a concept for a new idea from a thought to a marketable product is complex. It involves resolving not only technical hurdles, but even more importantly, market and business hurdles that are often overlooked by the new entrepreneur. My experiences as a medical device engineer and entrepreneur have exposed me to many “good ideas”, most of which do not make it to market. The ones that do make it have several common threads, the most important of which is that they solve REAL market needs and the market is receptive to them. As a co-founder of Seedling Enterprises, a medical device incubator company, I have been a part of teams that have taken dozens of products to market and formed several companies. Of course, not all of these have been successes and one of the best ways to learn is through failure, although when possible, someone else’s. The better one understands this process, the more economic value one will realize.

I like to categorize new product concepts into one of the following: the niche product, the novel technology and the new paradigm. It is imperative that the inventor realize where their product fits within this continuum. It is common for entrepreneurs to think that their product will have a bigger impact on the world than reality would dictate. This leads to unreasonable expectations for a return, excessive investment by the entrepreneur and friends, and can often kill the product as reasonable offers to acquire it are turned down. As one moves up this product continuum, the potential financial return to the entrepreneur goes up, but so does the risk, effort, time and money needed to realize that return. Establishing where your product lies in this continuum requires experience, a deep knowledge of the market place and honesty.

A niche product is the most common category. These are better ways of doing what one does now such as a novel laparoscopic instrument. It is unlikely that one would set up an entire company around a niche product, but that it would more likely fit into the bag of one of the companies already marketing similar products. The market potential is typically less than \$40 million. The amount of money needed to develop a niche product varies of course but one should expect to spend at least \$150,000 to fabricate prototypes, perform testing, submit patents and research the markets. One key is that the entrepreneur should identify who the acquirer of their product will be to make sure there is an outlet once the technology is developed. It is reasonable to look for a deal from an acquirer to get 1-3 times the amount of money you have invested back, and to then get a royalty payment over time. Royalty rates are quite variable but range from 2% for a moderate patent position, to 7% for a strong patent position. It is also possible to arrange for phased payments based on milestones such as FDA

approval, patent issuance and first product sale. A good business lawyer is helpful for these negotiations.

A novel technology is one that greatly improves current practice, and that has a large enough market potential that it presents an interesting revenue and profit opportunity for existing commercial players in the field, but that supporting ones own sales force could be challenging. Examples of novel technologies are the Harmonic Scalpel and the IsoCool non-stick electrosurgical instruments. These technologies are not likely to totally alter your practice, but may enhance greatly patient treatments. The market potential is typically \$40 to \$100 million.

The initial investment needed is similar to that which one puts into the niche product except that the technical development, testing and regulatory investments are more complex and therefore more expensive. One can expect to need \$300,000-\$1,000,000 in seed money to develop the initial technology. If the market opportunity is at the higher end of the \$40-\$100 million range, it is not uncommon for entrepreneurs to be more aggressive by forming a company, building a team and working to commercialize the product. Subsequent funding may be needed but will dilute the financial standing of you, your investors and your team. It is typical to have to raise \$20 million to get a novel technology to the point of a return which may take the form of a sale to a company. The reception you receive from the commercial players in the field will vary depending on how the device fits in their current business strategy and on the size of the opportunity. One could obtain a license fee in the millions of dollars and 4-7% royalty based on the strength of the intellectual property and the market opportunity.

A new paradigm is rare. These are the big ideas that can radically change your practice. Examples of these are cardiovascular stents, orthopedic bone anchors and perhaps, NOTES. These ideas require a lot of time and money but can bring the greatest return to those who stick them out. They typically do not fit into current companies or are actually threats to their existing business. As a result, the innovation must be taken to a fairly refined level, the market demonstrated to be large and the clinical need to be real. Companies developing new paradigms require tens of millions of dollars and 5-10 years to realize a return. If successful, returns can be 5-10 times the amount of money invested through Public Offerings, sales or mergers. There are many examples of very successful returns to entrepreneurs through buyouts of small, emerging companies by larger corporations or by IPO. Companies like Fox Hollow or its recent acquirer Ev3, Mitek and Trans1 in the orthopedic space are all wonderful examples of how you can make a great deal of money by pursuing a good idea to an extraordinary financial return. Keep in mind however, that these successes required enormous amounts of capital investment, time and energy to achieve this success.

The pathway to realize value from any of these product categories includes many similar steps. There are technical, market, business and regulatory considerations one

must be aware of and address thoroughly to optimize ones return. The better one understands each of these factors, the more likely the entrepreneur will appreciate the expected return he might achieve given the amount of financial and time resources he will have to expend.

The development of the technical attributes of one's idea is usually most well known to entrepreneurs. One must carefully and clearly identify the design attributes that are most critical to the functioning of the product. This requires a careful analysis and understanding of the problem one is solving. It also requires a thorough knowledge of the needs of the user, costs and market obstacles to using the product. Intellectual property, or patents, is needed as this protects the inventor or acquirer from others simply copying their idea. This can be very expensive, but is a vital part of the invention process and a good IP attorney is key to your success.

Probably the most important research an entrepreneur must do is to fully and completely understand the market their idea will play in and the clinical need being addressed. The first question one must truthfully answer is "who cares" about this problem. Is there a REAL clinical problem that this concept would solve, or is it just a cool idea? The best way to research this is to ask questions to independent users to ensure one is getting objective feedback, not friendly answers. In these days of cost containment, an idea must be better, faster and cheaper to the hospitals, payers or patients. A good understanding of competition is also critical.

Important business issues include how long will it take to get to market, how much money will it take and probably most importantly, who will I sell this to once it is done? The list of potential acquirers for new technology continually shrinks as the large companies buy up the smaller ones. In addition, the interest level of a major company in a small opportunity that does not move their revenue line appreciably is likely to be low. If you are ready to take a product to market and run a business forever, that is one decision. If you are planning to take a company public, that is another outlet. But most products and companies realize their financial return to the entrepreneur through acquisition by another company.

Finally, regulatory issues are important to the timeline and expense of developing medical devices. Regulatory requirements vary in order from simplest to most complex: class I devices that require no formal approvals, simple 510(k) products that require no clinical trials, 510(k) products that do require clinical trials, and class III devices that require extensive trials and a PMA. Again, one must get good advice from experienced regulatory specialists on where your product fits to fully understand how far you need to take it.

This is a simple overview of some of the issues one must understand in order to figure out what value your concept has. It is clearly not an easy process and along with

hard work, luck and good timing have much to do with success. It is always a good idea to talk to people who have done it before to get advice. Talk to your colleagues to find help. If you truly have a novel product or technology that really serves an unmet need, you have a good starting point. Be reasonable about your expectations, ask lots of questions and always keep in mind that it will take more money, time and hard work to realize a return on your concept than you think. Once you know this, it is extremely fun, exciting and rewarding.

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PEG
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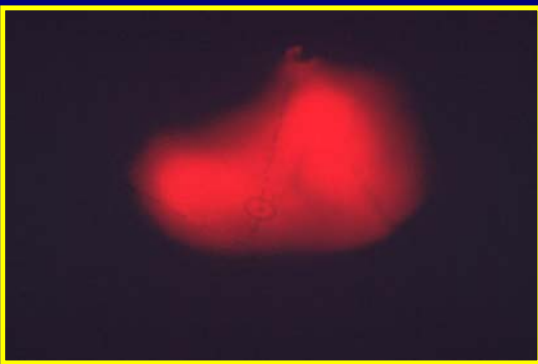




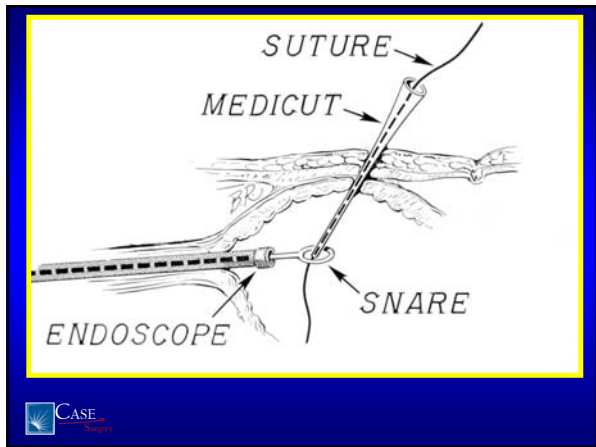
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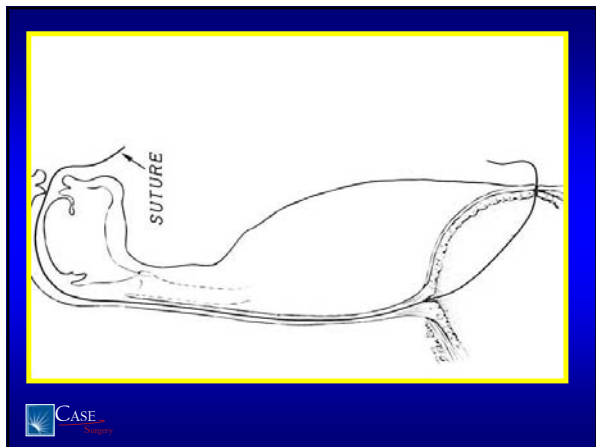
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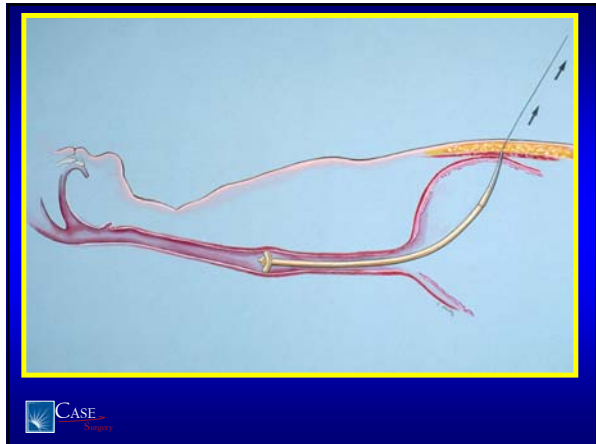


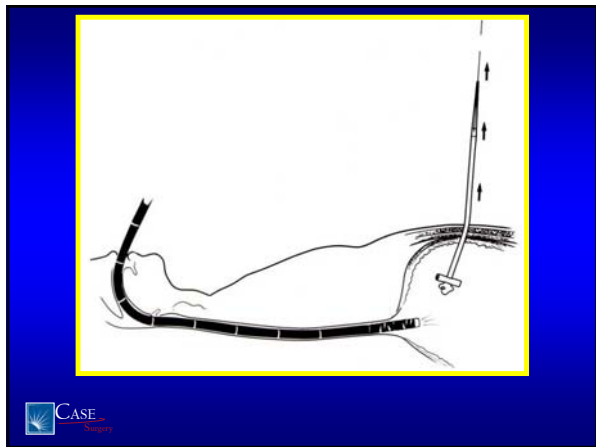
















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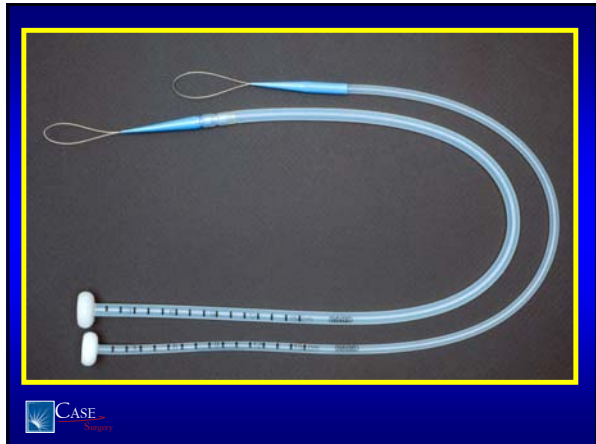


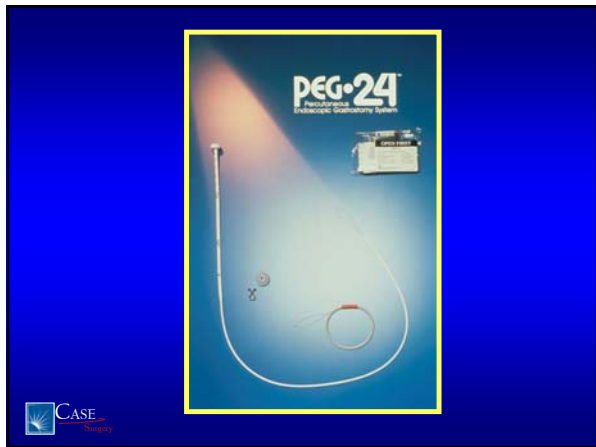
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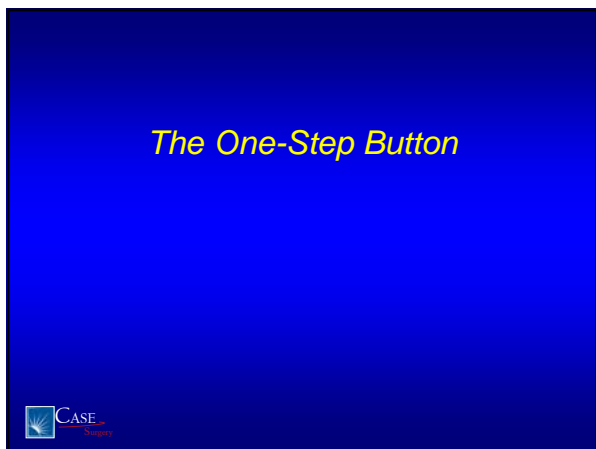

































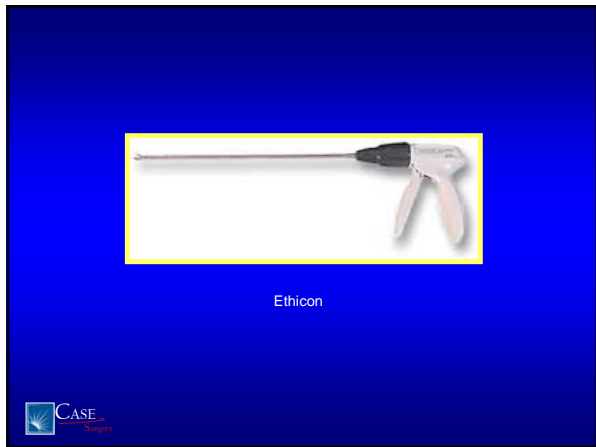


Importance of a Patent

- Pros:
 - Protects from copy cat
 - Ensures profits for 14 years
- Cons:
 - May limit market growth
 - May be bypassed







Another Approach

- Create new concept and product
- Allow for competition and market growth
- Develop best product and enjoy market share

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and,
if your lucky.....





Thank You