WORKSHOP ON TECHNOLOGY LICENSING, VALUATION AND ACQUISITION FOR BIOTECH SECTOR

Program

Day 1

REGISTRATION **9.30 A.M. to 10.00 A.M.**

INAUGURAL SESSION **10.00 A.M. to 10.45 A.M.**

Lecture 1: Overview and Evaluating Early Stage Technologies
I. Overview of early stage technology commercialization
II. The products that will result from a technology
III. Markets for those products
IV. Intellectual property aspects
V. First Look Technology Assessment

TEA BREAK **10:45 A.M. to 11.00 A.M.**

SECOND SESSION **11:00 A.M. TO 1:00 P.M.**

Lecture 2: Licensing and Marketing Strategies
I. Licensing strategies
II. Marketing documents
III. Technology marketing

Group Activity Session
Lithium Ion Battery Case Study

LUNCH BREAK **1:00 P.M. TO 2:00 P.M.**

THIRD SESSION **2:00 P.M. TO 3:30 P.M.**

Lecture 3: Negotiating a License
I. The initial connection
II. Term sheet
III. Option Agreement
IV. Principles and mechanics of negotiating

Lecture 4: Completing a License Agreement
I. Template agreements
II. Sponsored research agreements
III. License agreements
IV. Pre-existing rights
V. Unique aspects of university licenses

TEA BREAK **3:30 P. M. to 4:00 P.M.**

SESSION 4 **4:00 P.M. to 5:30 P.M.**

Group Activity Session:
Novel Inherited Cancer Gene Case Study

Lecture 5: Valuation Part 1
I. Overview
II. Valuation principles
III. Financial structure of a license

Preparation for Day 2
Attendees will identify problems, issues and situations for discussion on Day 2

Day 2

FIRST SESSION **10.00 A.M. to 10.45 A.M.**

Lecture 7: Valuation Part 2
IV. Cost method
V. Comparables
VI. Rules of Thumb
VII. Discounted Cash Flow

TEA BREAK **10:45 A.M. to 11.00 A.M.**

SECOND SESSION **11:00 A.M. TO 1:00 P.M.**

Group Activity Session:
Novel Inherited Cancer Gene Case Study

Lecture 8: Medical Devices- Regulatory and Technology Transfer
I. FDA Structure
II. Regulatory approval
III. Reimbursement

LUNCH BREAK **1:00 P.M. TO 2:00 P.M.**

THIRD SESSION **2:00 P.M. TO 3:30 P.M.**

Lecture 9: Patenting and Technology Transfer issues in Stem Cells
I. Issues with cell lines
II. Patent issues
III. Licensing issues

Group Activity Session
We will select discuss some of the problems, issues and situations submitted in Day 1

TEA BREAK **3:30 P. M. to 4:00 P.M.**

SESSION 4 **4:00 P.M. to 5:30 P.M.**

Lecture 5: Technology Acquisition In Biotechnology and Introduction to Export Controls
I. Acquiring technologies
II. Licensing issues
III. Export controls

Group Activity Session
We will select discuss some of the problems, issues and situations submitted in Day 1

Technology Licensing, Valuation and Acquisition for The Biotechnology Sector

Lecture 1: Overview and Invention Evaluation

Biotechnology Industry Research Assistance Programme
Department of Biotechnology

February 11/12, 2013 Bangalore
and
February 14/15,2013 New Delhi

Dr. Ashley J. Stevens
Past President, Association of University Technology Managers
and
Lecturer, Health Sector Management Program
School of Management
Boston University

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Trivia

- Who is the most famous Professor who's ever been a member of Boston University's faculty?

Clues:

- Not known for his scientific discoveries or learned writings
- Applied a 50 year old scientific discovery to meet unmet consumer needs
- Couldn't interest the leading company in his industry to take up his ideas
- Founded his own company, with his father-in-law, to commercialize
  - Just a typical prof doing what it takes to get his stuff commercialized

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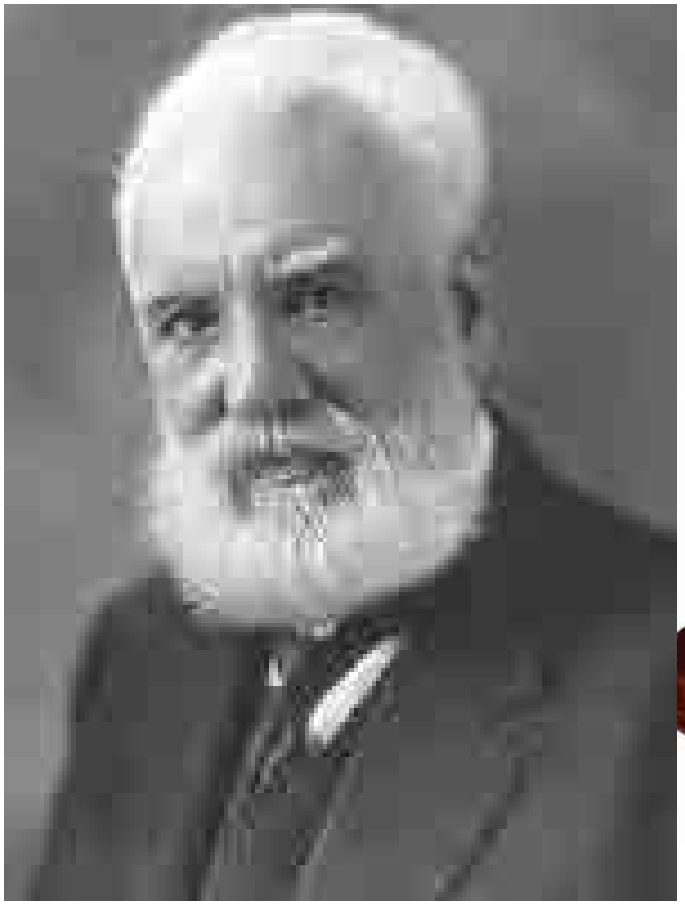

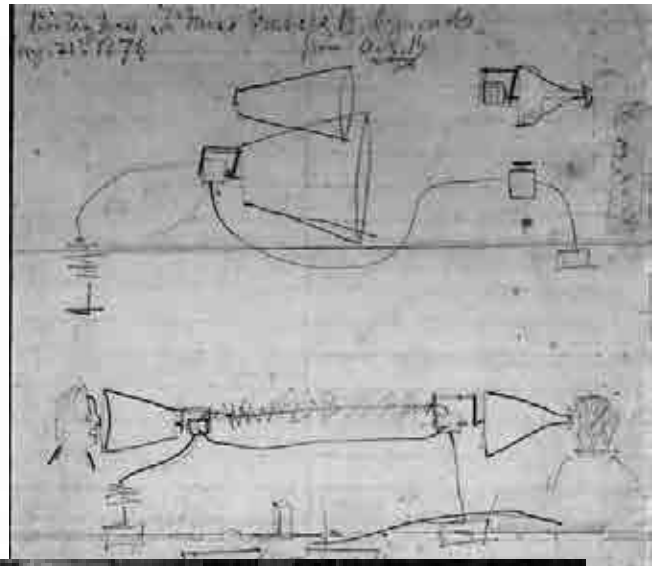

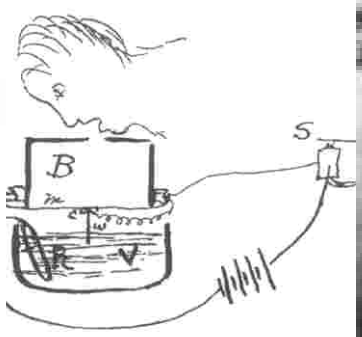
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Alexander Graham Bell

1873 Appointed Professor of Vocal Physiology and Elocution at Boston University

1874 Started experimenting with electricity; worked on a harmonic multiple telegraph system

1875 Dean Lewis Monroe advanced him one year's salary

1876 Patent prepared January 15 - February 13; filed morning of February 14; Elisha Grey filed caveat in afternoon

Interference declared February 19; dissolved February 25

US Patent 174,465 issued March 7;

"Mr. Watson -- come here -- I want you" March 10, 1876

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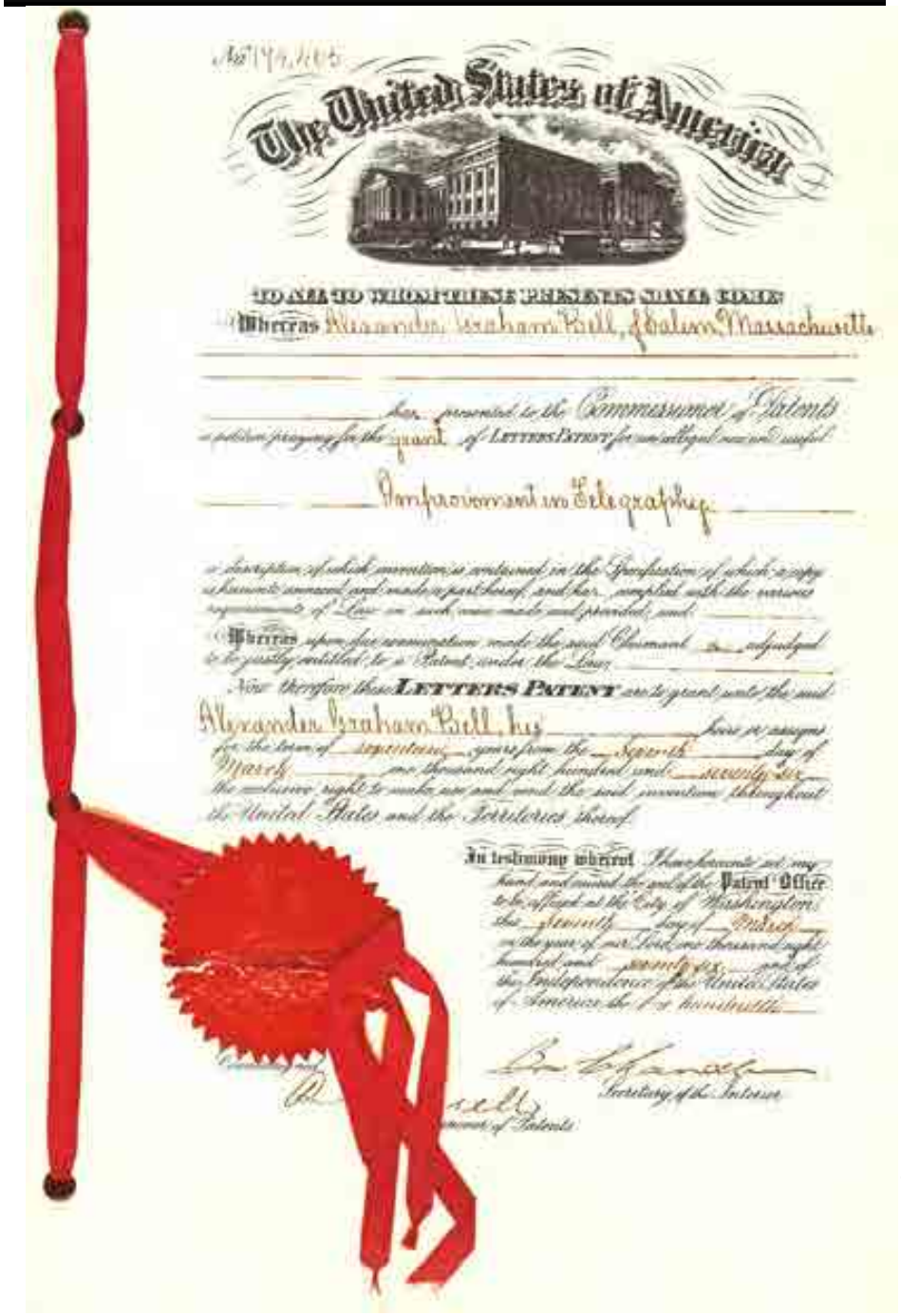


The United States of America

TO ALL TO WHOM THESE PRESENTS SHALL COME:

Whereas Alexander Graham Bell, of Salem, Massachusetts

has presented to the Commissioner of Patents a petition praying for the grant of LETTERS PATENT for an alleged new and useful

Improvement in Telegraphy

a description of which invention is contained in the Specification of which a copy is hereunto annexed and made a part hereof, and has complied with the various requirements of Law in such case made and provided; and

Whereas upon due examination made the said Claimant is adjudged to be justly entitled to a Patent under the Law;

Now therefore these LETTERS PATENT are to grant unto the said Alexander Graham Bell, his heirs or assigns for the term of seventeen years from the Seventh day of March one thousand eight hundred and seventy-six the exclusive right to make use and vend the said invention throughout the United States and the Territories thereof.

In testimony whereof I have hereunto set my hand and caused the seal of the Patent Office to be affixed at the City of Washington this seventh day of March in the year of our Lord one thousand eight hundred and seventy-six and of the Independence of the United States of America the one hundredth.

Secretary of the Interior

Commissioner of Patents

2 Sheets—Sheet 1.

A. G. BELL.

TELEGRAPHY.

No. 174,465. Patented March 7, 1876.

Fig. 1

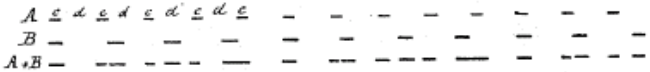


Fig. 2.

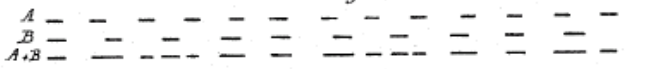


Fig. 3.

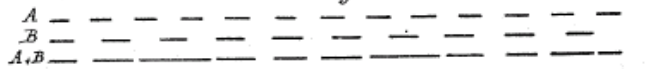


Fig. 4.

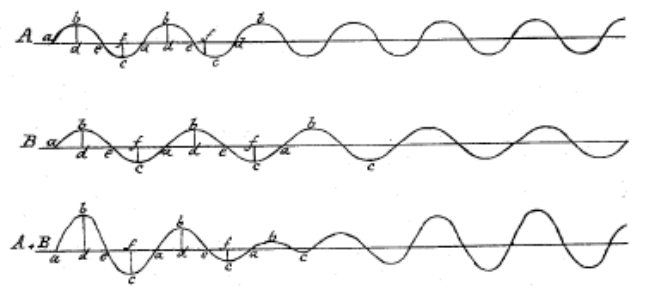
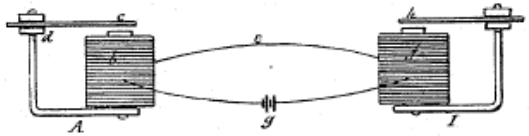


Fig. 5.



Witnesses

Ewell A. Brock

N. T. Hutchinson

Inventor:

A. Graham Bell

by Pollock & Bailey

And Now, the Rest of the Story…….

- Spent the next 17 years defending the patents
- Over 600 lawsuits 1876 - 93
- Defended by Frederick Fish
- Only finally confirmed by 4 – 3 vote of the Supreme Court in 1887

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The Aftermath

- Sold his Bell System stock fairly early
- Was involved in the early days of the airplane
  - Aligned with Curtiss in the Curtiss-Wright Brothers patent battle

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Oh, and what did BU get out of it?

- Nada
  - Didn't have any patent policy in place at the time
- US Universities taught rather than researched back then

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The Modern Day Equivalent

- The University of Illinois Urbana-Champaign
- Invented the Internet as we know it
  - Eudora
    - The first email program that could attach documents
  - Mosaic
    - The first web browser
      - Now Internet Explorer
- Made about $6-7 million from it all
  - $250k for Eudora
  - $6 million in royalties from Mosaic
- Spawned Netscape
  - Upset Marc Andreessen so much they made nothing from Netscape
    - Sued him for Trade Secret theft
    - $2 million settlement

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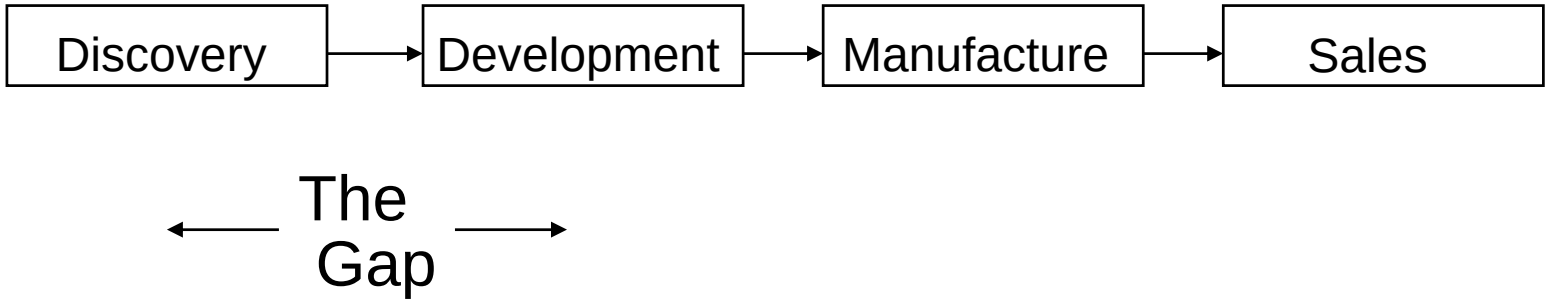
The Technology Translation Gap



At not-for-profits
Funded by Gov.
No return expected

Conducted by companies
Privately funded
Return on investment expected

- where the gap occurs moves as financial markets change
- in general has moved deeper into the development phase
- how do you pay for the Gap phase?

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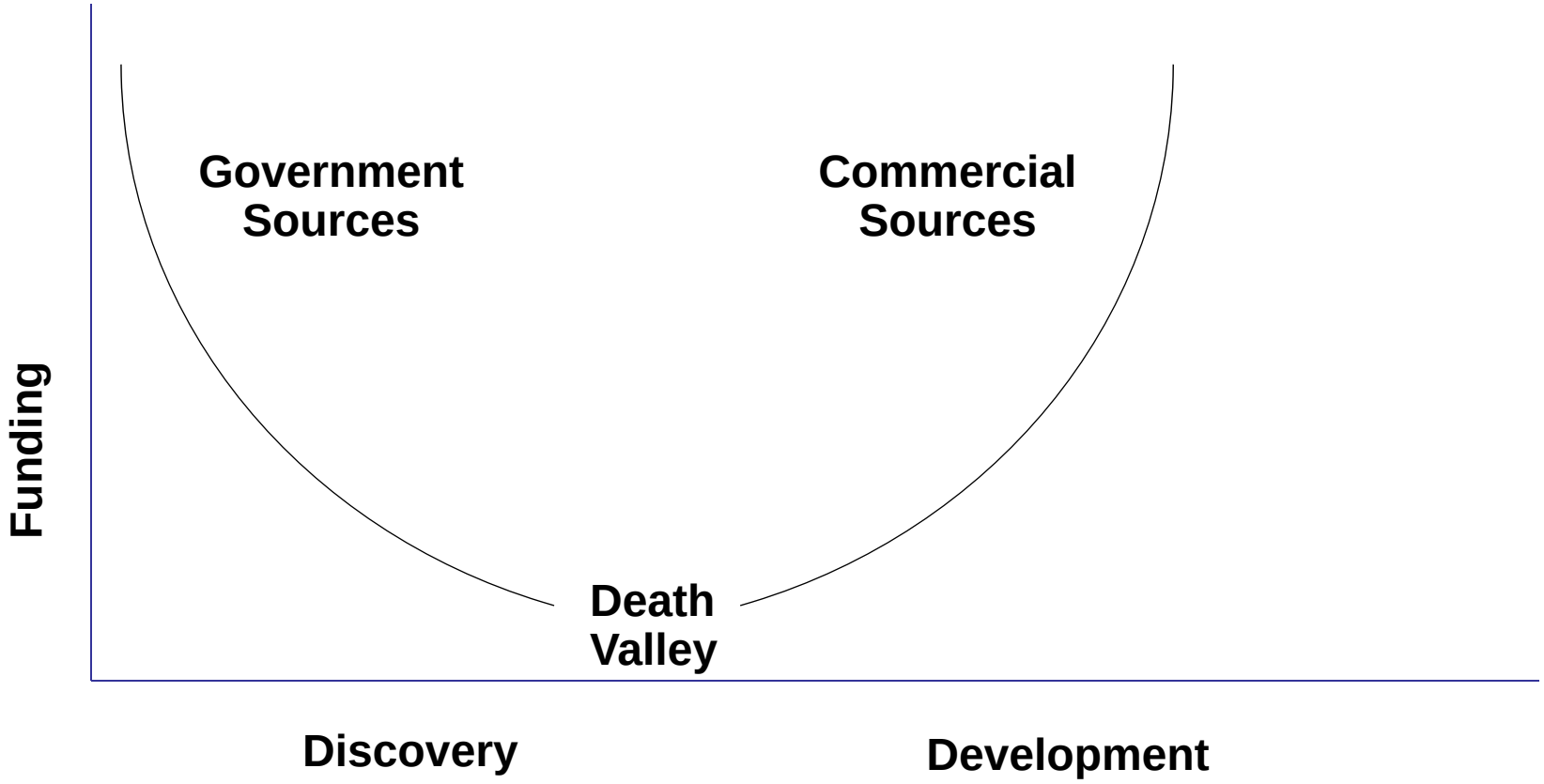
Academia's Death Valley



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Everyone has their own Death Valley

- Academia — Transition from basic science funding to commercial funding
- Start-ups — Transition from Seed Round to Series A
- Biotechs — Transition from Phase 2 to Phase 3

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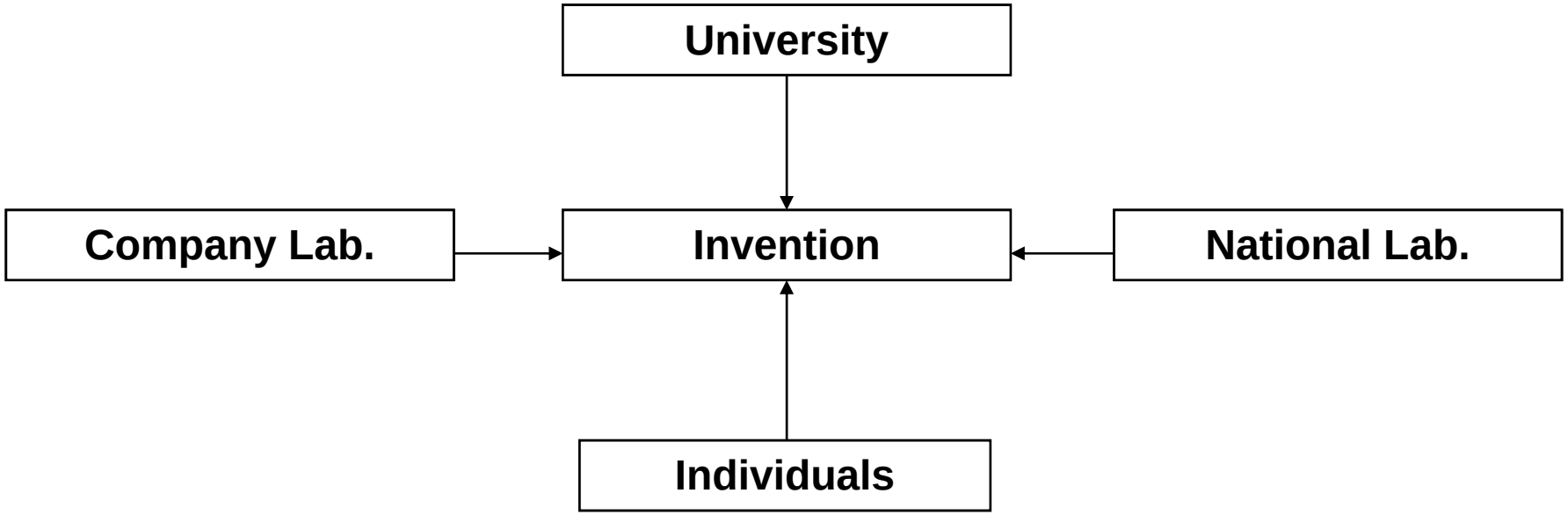
Where Do Inventions Come From?



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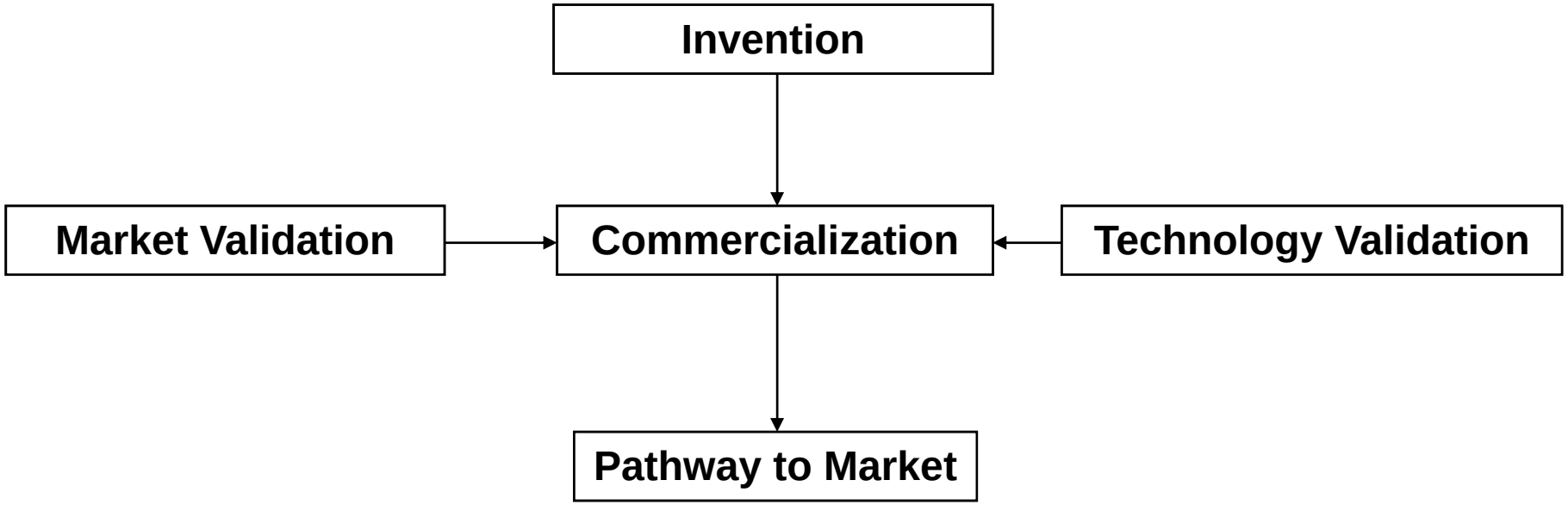
The Technology Commercialization Process



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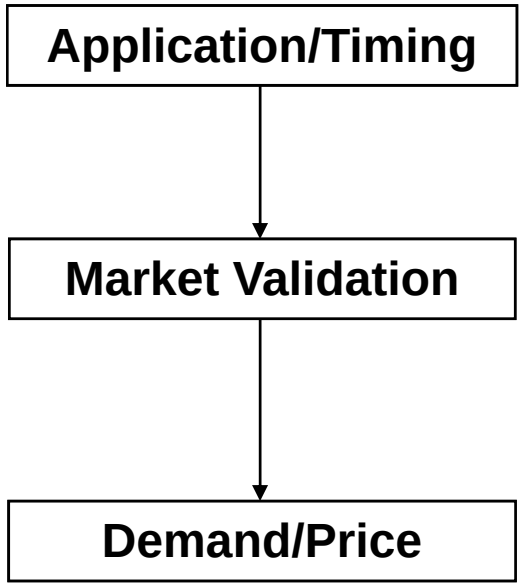

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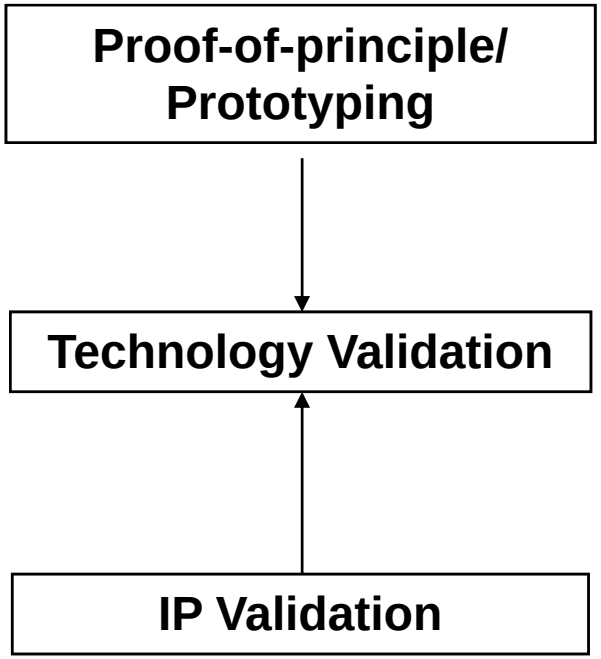

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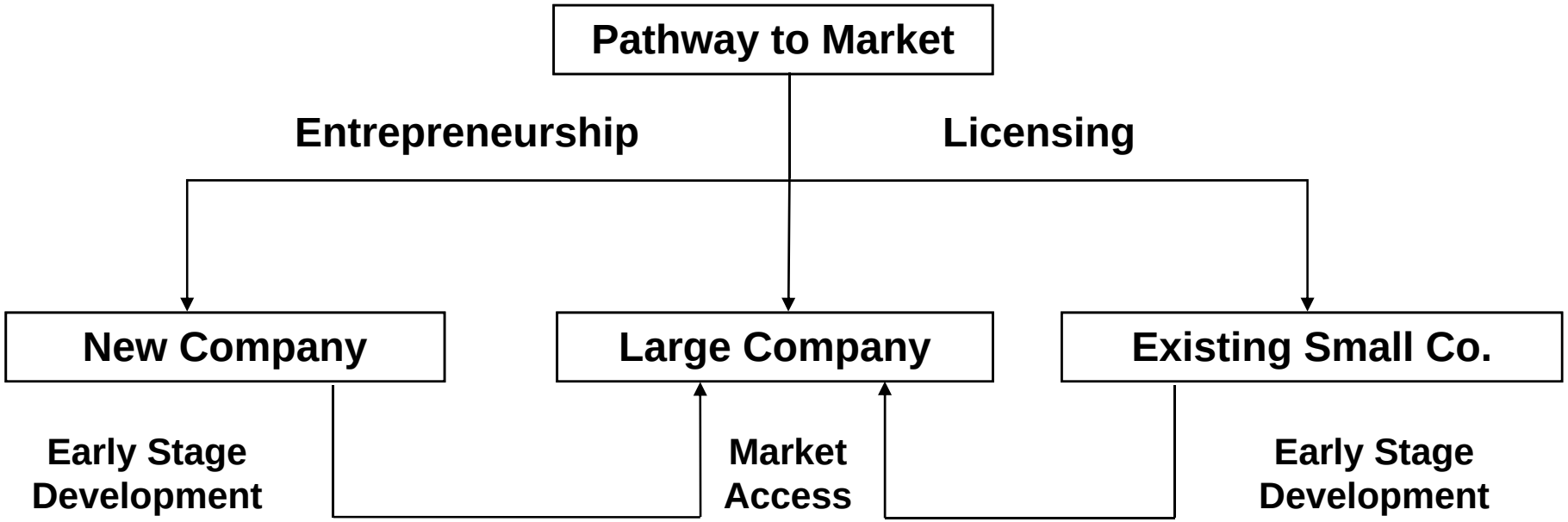

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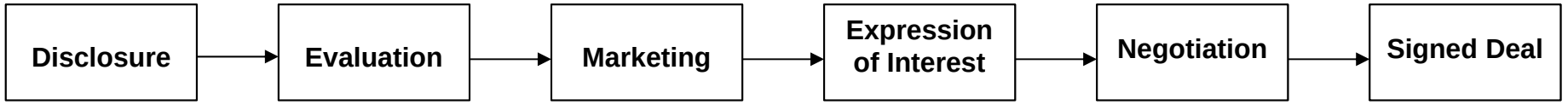
The Technology Transfer Process



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Step 1: Evaluating the Disclosure

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Four Key Questions

1. What are the Products or Services that will result from the invention?
2. How big are the markets for those Products or Services?
3. How likely are we to get a patent on the invention?
4. What are the key next steps to reduce the technical risk in the invention?

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1. The Products and Services

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Evaluating Early Stage Technology

- It's all about visualizing the products the science leads to
- Scientists send us raw disclosures:
  - Detailed science
  - Light on technology
  - Hints of a product
  - Devoid of a value proposition
- Industry buys products:
  - User oriented
  - Need clear benefits
    - The Value Proposition
  - Must be competitive

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Step #1: Focus on the underlying value of the science

- Understand the technology

  (Requires meeting with the inventor or graduate student to grasp the problem(s) the technology solves, what it does, how it does it etc…)

- …having an understanding of the technology will enable you to imagine what kinds of products can be created from it (sometimes different from inventor e.g., the DNA Extraction project) and to effectively communicate the value to others

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Step # 2: Give the Customer a reason to buy

- Look at everything through the eyes of the Customer
- The most important decision is the decision to buy
- To a Customer, a product is a collection of need satisfying attributes

  hurting → buy pain killer
- **The challenge is to match the value of the science to the Customer's needs**
- The more closely aligned the need is to your technology, the stronger the **value proposition**

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So, Who is the Customer?

- Different people in different markets
  - The person who **pays for your product/service**
  - The person who **uses your product/service**
  - The person who **recommends your product/service**
  - The person who **delivers your product/service**

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Step #3: Communicate the Value Proposition

- Briefly describe how the technology works
  - What is the product?
- Focus on the unique scientific merits of the technology that distinguish it from what currently exists
  - What is the unmet need?
- Avoid getting into great detail and using scientific jargon
- Don't give away all the enabling details

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The Value Proposition

- Value = Benefits received/perceived by the Customer
- The Customer defines and evaluates Value

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The Value Equation

- The Value Equation:

Value = Benefits – Costs

- How can you increase Value?

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2. Market Assessment

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A Two Step Process

- Secondary research ➔ Primary research
  - Secondary research = OPR (Other peoples' research)
  - Primary research = MR (My research)

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Stay skeptical

- Assume everything already exists
- First search for things that destroy your opportunity, then search for things that support it.
  - A quick kill of a project early in the process is preferable to wasting time on a dead end.
  - People (mistakenly) tend to focus their attention on supporting evidence
  - Investors look for ways to say NO

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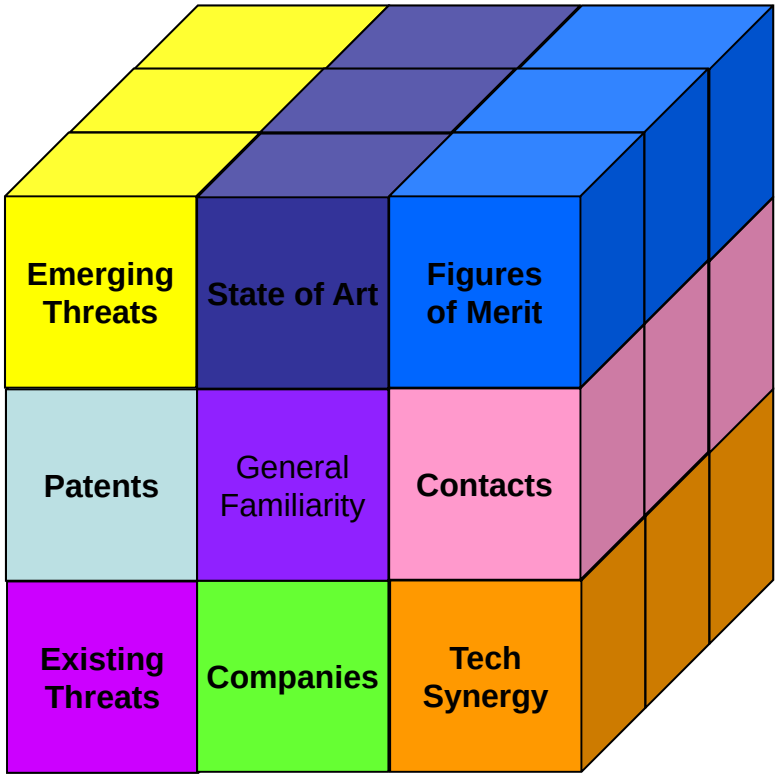

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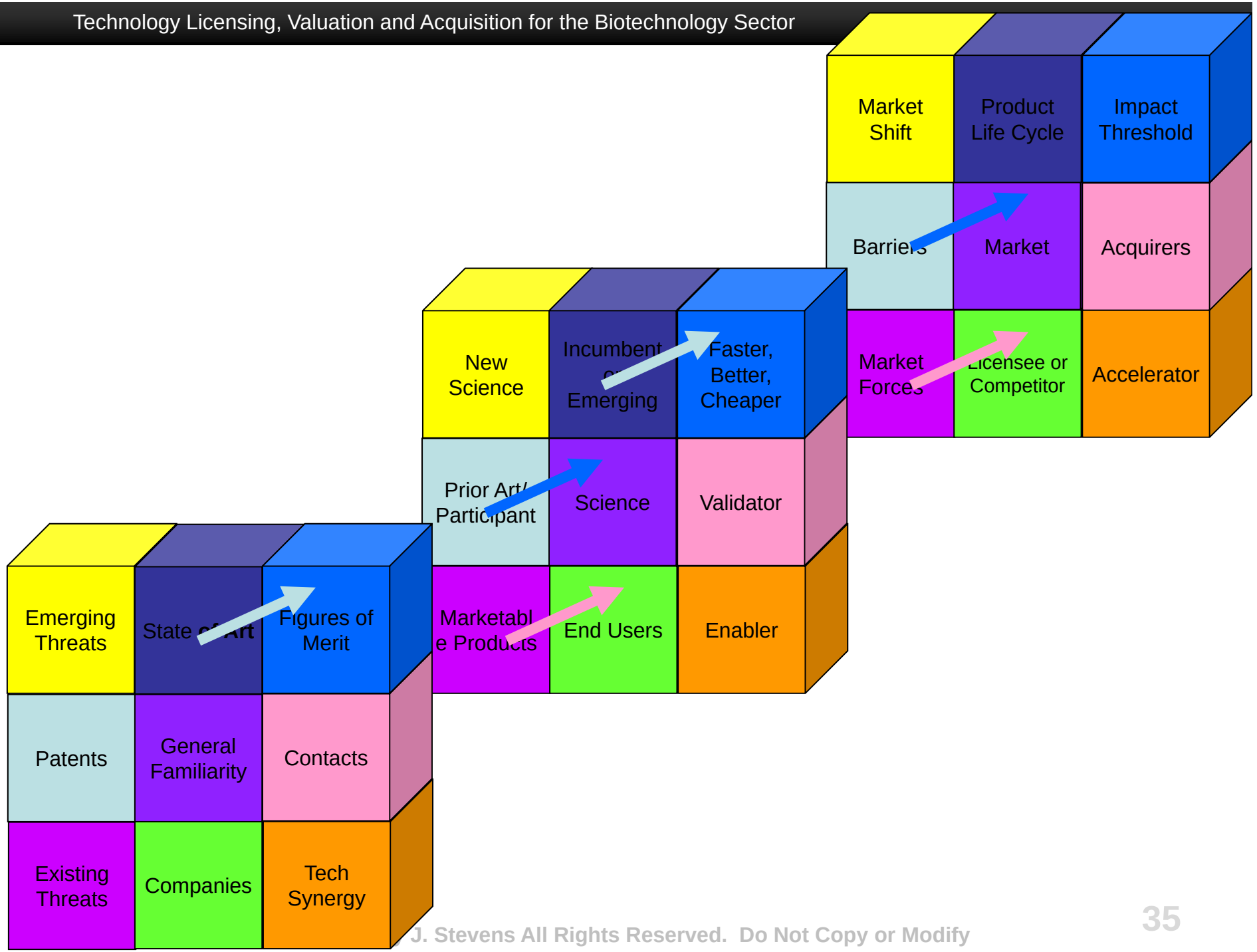

Secondary Research Resources

- Google
- Pardee Management Library
- Subscription Services
  - T2+2
- See Handout

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Healthcare

- Much easier than physical sciences/IT/Software
  - Need is more obvious
  - Addressable market size is easier to estimate
  - Range of possible products is usually constrained

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Healthcare

But… horizons vary

- Drugs
  - Stage of development is earlier
  - Leads to far reaching assumptions about performance
- Devices
  - Returns are usually much lower than drugs
  - Therefore risk must be much lower
  - Translation: 510K, replace an existing therapy, has an established reimbursement code
- Diagnostics
  - Market is highly competitive (many solutions, many entry points…)
  - Incumbents require compelling data
  - Expectations on performance are much higher (clinical samples)

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Physical Sciences & IT

- Many possible products
- Many possible markets
- Varying levels of competition
- Value chains not clearly defined
- Market data harder to identify

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Physical Sciences & IT

- But…horizons are usually within reach

- Must act quickly
- Time to market is critical
- Promise or Performance?

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Primary Research

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Trust, but verify

- Validate your assumptions
  - Pick up the phone…
  - Open ended questions…
    - What is driving the move towards molecular diagnostics?
    - What are the top three challenges your are facing?
    - What reimbursement codes do you use for xx procedure?
    - What are the biggest time constraints in xx protocol?
  - Followed by direct questions…
    - Would a product that is taken orally and relieves these symptoms improve the lives of your patients?
    - Would a diagnostic that provides instant readout from a clinical sample change your clinical practice?

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Contact Experts and Companies

- Call identified contacts for their expert opinion
- Emphasize invention's potential benefits
- The best contacts usually are in marketing or R&D or Open Innovation….. Why is this????
- Don't forget about the Trade Press

Contact Both Scientific & Business Experts

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Personal Interview Advantages

- Provides background data on the marketplace
- Answers specific questions
- Ensures the right experts are contacted
- Examines corporate buying behavior
- Validates novelty of technology
- Identifies industry trends
- Has a flexible structure that can be modified
- Identifies other players to contact
- Ensures various viewpoints are pursued

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Goals of Personal Interviews

- Better understanding of the problem
- Use open ended questions and conversations to uncover:
  - Perceptions, opinions, beliefs and attitudes
- Understand the motivating buying factors
- Qualitative data that informs the quantitative research

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Learn the Customer's Language

- Never assume you know what they are talking about
- Question every nebulous term
- Don't be afraid of asking the obvious
- They are the experts, acknowledge that and use it to your advantage

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Listen to the Voice of the Customer

- Understand what is really important
- Understand customer motivations
- Understand the buying cycle and how decisions are made
- Provide a sanity check to the internal perceptions of the technology
- Begin to understand the value of your technology and what it is worth

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Features vs. Benefits

- Really easy to focus on ***Features***
  - Ask yourself “So what?”
- Importance is the ***Benefits***
  - Features that help and so matter to the customer
  - Maybe a consequences of features

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Getting Feedback on Benefits

- Expected level of quality of the product
- Linear performance quality improvements may not be enough
- Exciter qualities are the real sellers
  - May not be the obvious ones to the technology developer
  - May become expected qualities over time
- In their opinion, what would be a step-change improvement

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Types of Responders

- Yeasayer - Only tell you the good
  - Ask them to pin down why it is good
  - What would a benefit mean to them?
- Naysayer - Only tell you the bad
  - Ask why a benefit or feature isn't important
  - Ask for suggestions on how to make it better
  - Use them to identify barriers and improvements to the technology

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Information Collection Tips

- Reconfirm data collected from secondary research
- When asking about potential market size, offer scale examples based on an educated guess
- Test your current knowledge beliefs against theirs
- Usually only 7 to 10 *productive* calls are needed for a First Look study.

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Identify Barriers and Opportunities

- Define the hurdles that the technology must overcome
  - Market barriers
  - Technology barriers
- Outline potential ways to overcome the barriers
  - Resource requirements
  - Cash requirements

In many cases, these turn into milestones

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3. Will we get a patent?

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Patent Due Diligence

- Two Levels of Analysis
  - Patentability
    - Us
    - Likelihood of getting our patent issued
      - Prior Art
      - Obviousness
  - Freedom to Operate
    - Them
    - Dominating patents
      - Will need a license to them to be able to practice our patent

FLTA

FLVA

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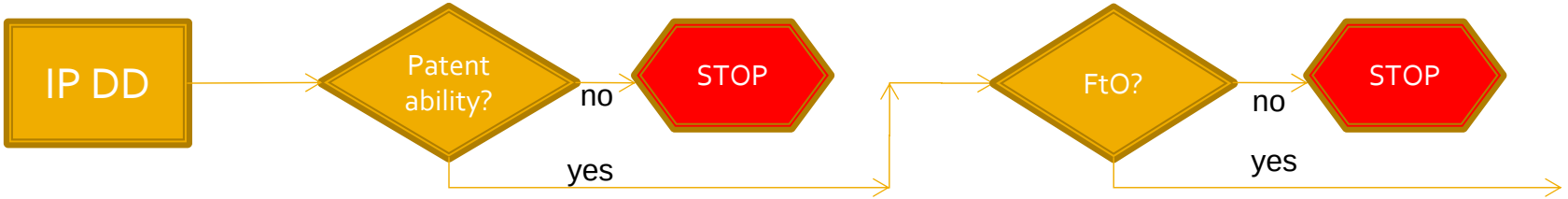
First Questions: Why, What and When?

But no simple flow chart should tell you what to do…



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Prior Art Searching

- One of the first steps in evaluating a technology
- Are we going to be able to get the right sort of patent to protect the products we envision?

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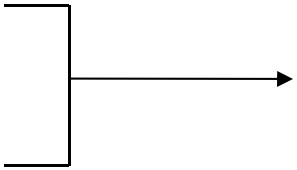
Criteria for patentability

- Novelty
- Utility
- Non-obviousness



Prior art search

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The wrong vs. right question…

~~"Is the technology even patentable"?~~

~~"What's the spurs game of Tuesday"?~~

"What claims might get issued"?

Are they broad enough to effectively exclude a competitive approach?

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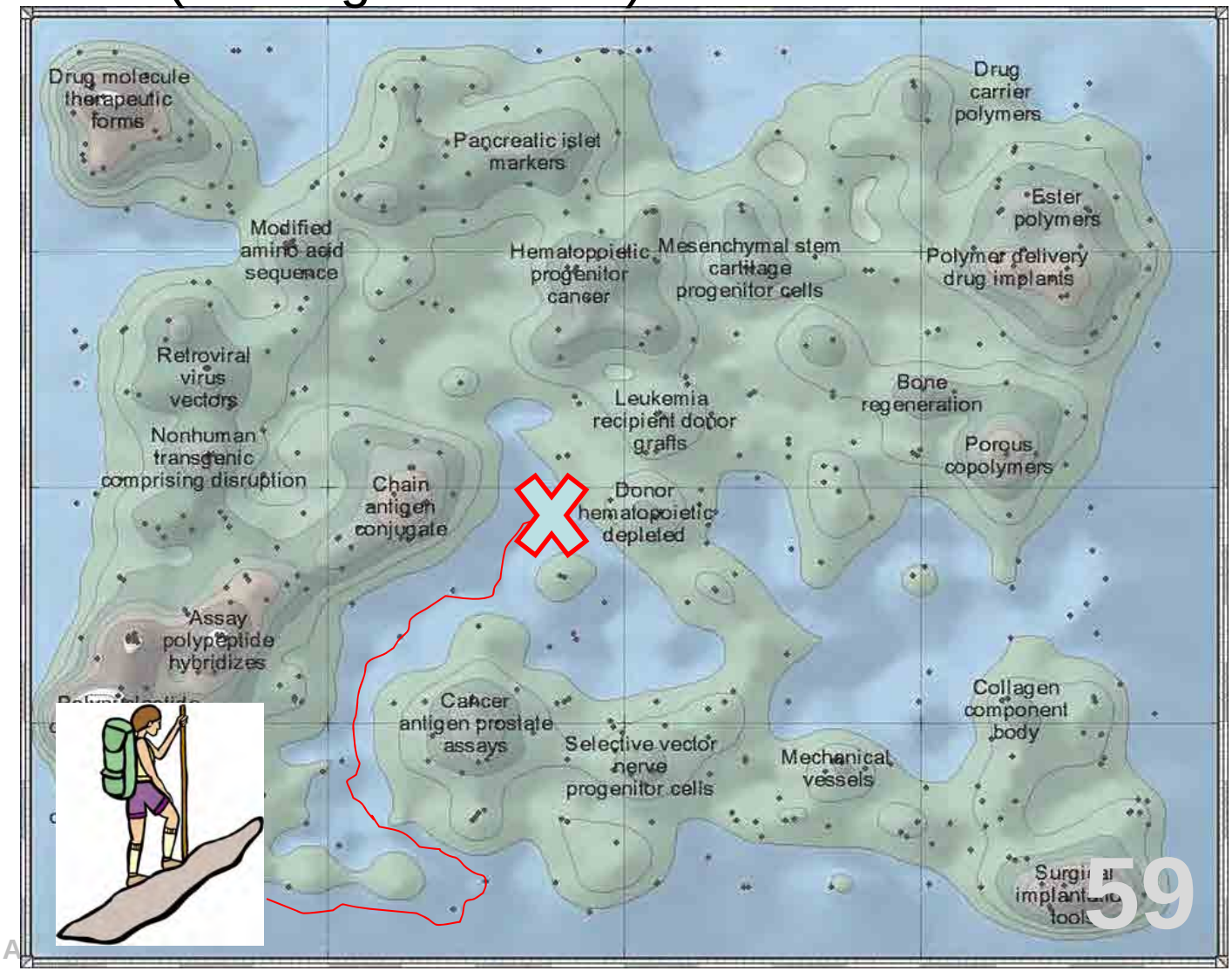
…what claims might get issued? (The 'right' answer)



A deep analysis and careful navigation of the patent landscape will get you there…

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…what claims might get issued? (my answer)

In the old days

<u>Depends on</u>

- How deep are your pockets?

Today

<u>Depends on</u>

- How deep are your pockets?
- (Currently) uncertain examination rules
- Whim/competency of examiner

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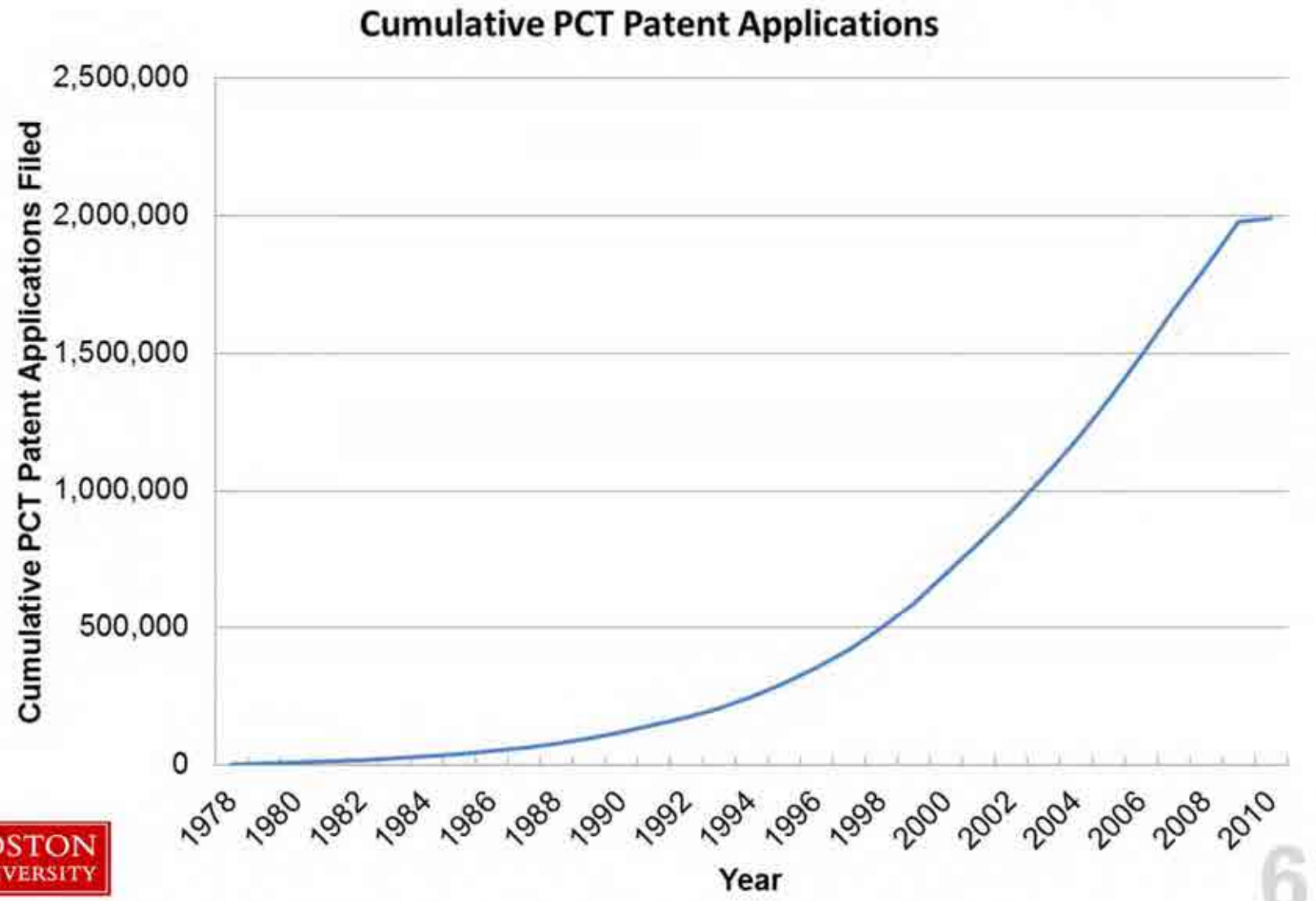
… in other words…

There's a lot out there, and growing…



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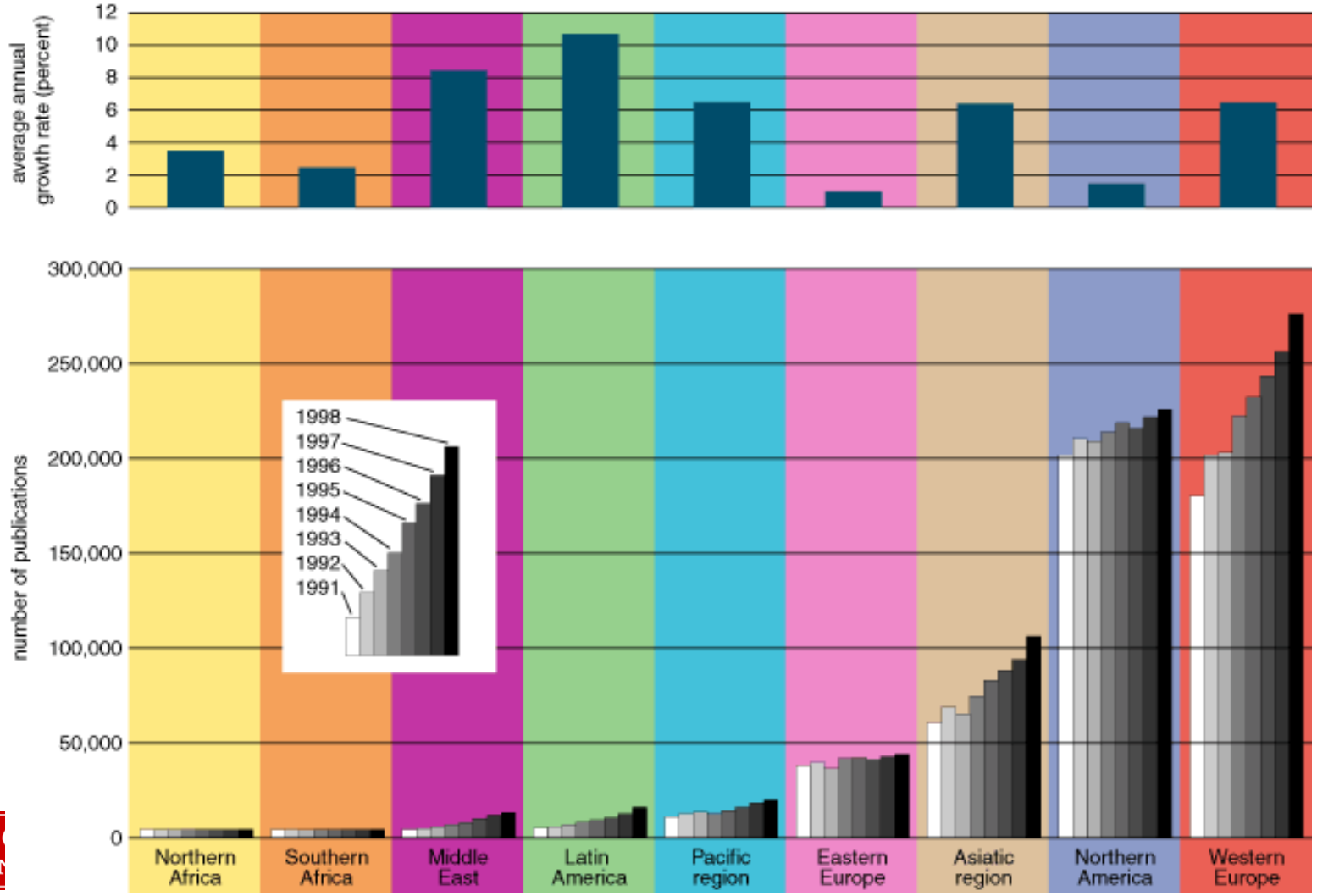
Less than half of scientific publications are in N. America



Mechanics of IP searching

- Search engines
- Search terms
- Search strategies

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Types of Searches

- Patent Searches
  - USPTO
  - WIPO
  - EPO
- Non-Patent Searches
  - "Literature"
- Searching services

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What tools are used to search patents?

Finding Patents

- **USPTO** – www.uspto.gov/patft/index.html
- **WIPO** – www.wipo.int/pctdb/en/search-adv.jsp
- **European Patent Office** – worldwide.espacenet.com/
- **Google Patents** – www.google.com/patents?hl=en
- **Prior Smart –** www.priorsmart.com
- **Patentlens** – www.patentlens.net
- **FreePatentsOnline -- www.freepatentsonline.com**

Search Terms:
Work with the Inventors!

- Use alternative terms
  - e.g. “steerable needle”=“manipulator”
  - “nanowires” = “thin channels”
- Names of competitor academic labs
  - PIs have best information (but still may not be enough)
- Names of competitor companies
  - PIs, patent assignees, licensors

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Identifying the right Key Terms is NOT trivial! (example later)

- Create alternative terms **with the inventor**
- Identify critical scientific phrases
- Identify major labs to search by author/inventor name
- Identify if there are major companies in the area and explore their websites

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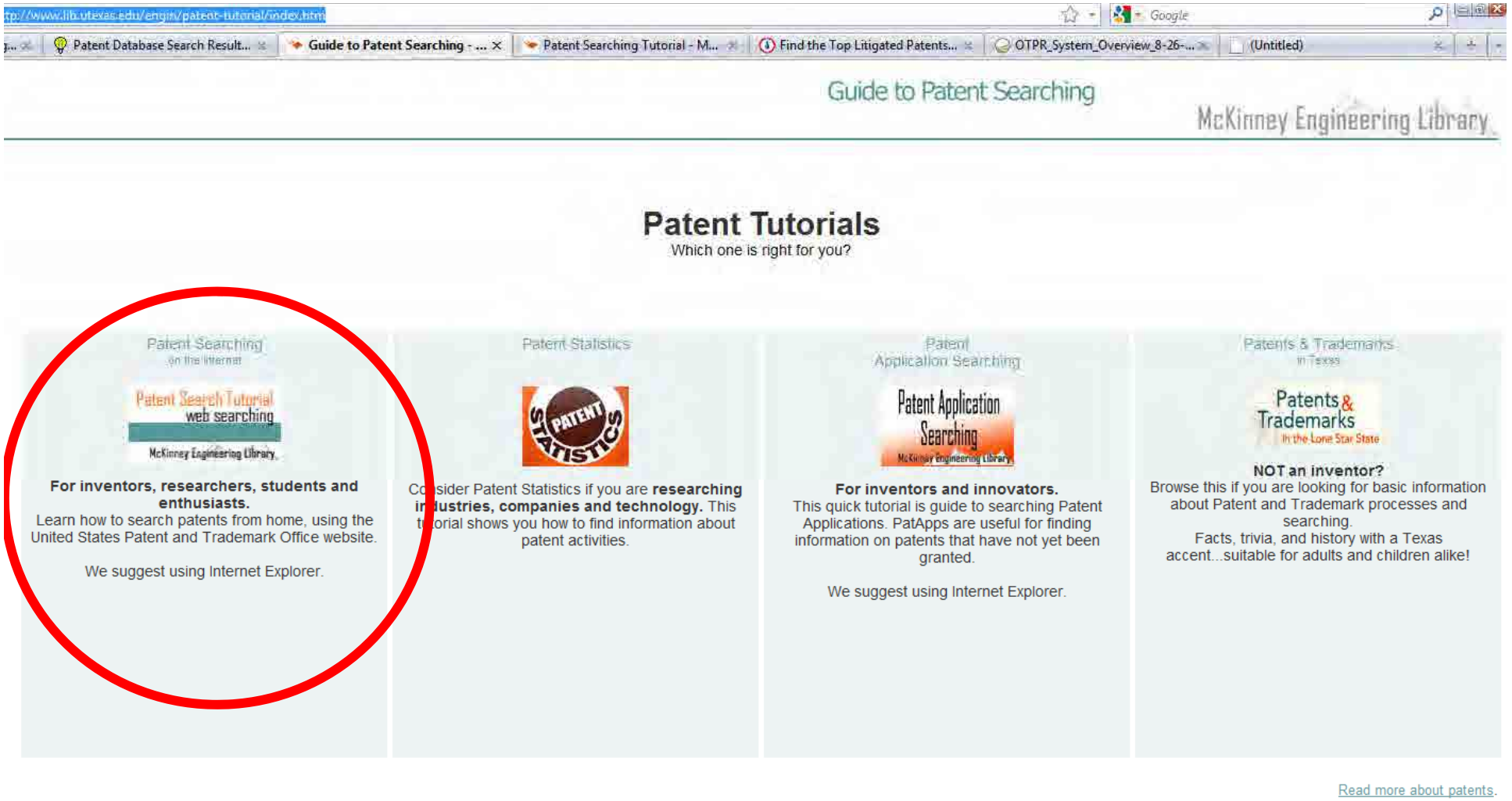
Search Classification

- Great resource at the University of Texas McKinney Engineering Library
  - www.lib.utexas.edu/engin/patent-tutorial/index.htm



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Purpose and Instructions

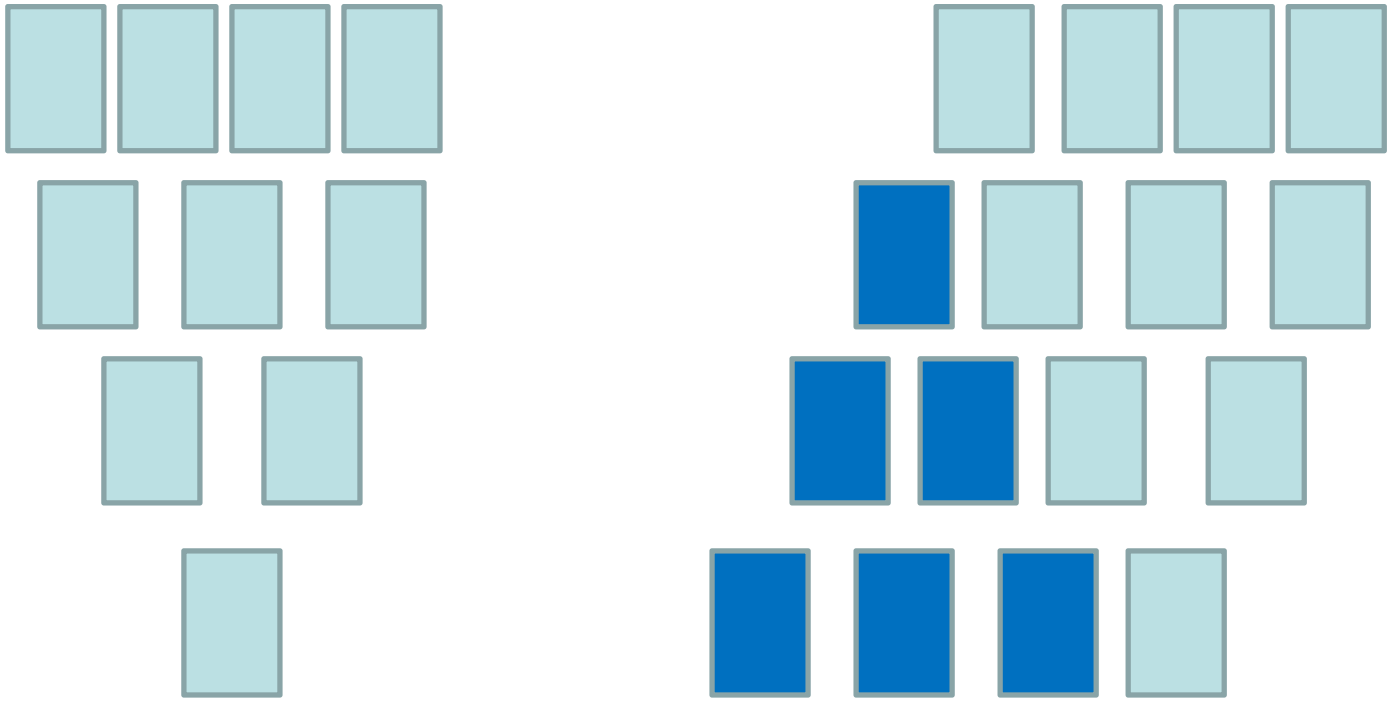
The purpose of this tutorial is to give users a hands-on, interactive patent searching experience utilizing the United States Patent and Trademark Office's website.

For our purposes the long, narrow area on the left side of the window will display the instructions that will guide you through the tutorial. At the bottom of each set of instructions is a link to the next step of the tutorial. Each of these links is also available at the top of the window; this allows you to move around the tutorial at will instead of sticking to the prescribed order. Finally, the large frame to the right will contain the USPTO website, which is the focus of this tutorial. **Please note** that the USPTO website is more compatible with Internet Explorer, therefore this tutorial works best with IE.

This tutorial was brought to you by McKinney Engineering Library, The University of Texas Libraries.

Step 2: Introduction >

Dominos



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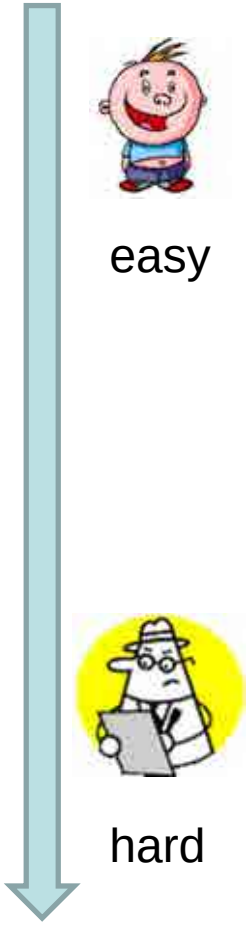
Patent search fields: by Concept

- **Title**
  - Usually not very revealing
- **Abstract**
  - Somewhat more revealing
- **Claims**
  - Creates blocking prior art
- **Description/Specification**
  - Creates non-blocking prior art



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Patent Search Fields: by Competition

- **Assignee**
  - Who owns it at time of issuance
- **Inventor**
  - The evil genius competing with you
- **Attorney**
  - Sometimes helpful

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What should you expect?

- Pioneering invention, little related art
  - Search as broadly as possible
  - Use “any field” to look for terms
  - Use as few terms as possible
- Well-populated field, great deal of art
  - Design highly specific search
  - Use very restricted fields – abstract, title
  - Include as many terms as possible

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Pulling It All Together

The First Look Technology Assessment (FLTA)

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First Look Technology Assessment

Report Content

1. Technology Description and Resulting Products
2. Potential Benefits
3. Potential Commercial Markets
    i. Prioritization
4. Development Status of the Technology
5. Intellectual Property Status of the Technology
6. Market Interest
7. Competing Technologies and Competitors
8. Barriers to Market Entry
9. Recommendations
10. Commercial Potential Rating

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Technology Rating

Factor	Weight	Score (1-3)
Market Potential	25%	
Market Maturity	15%	
Technology Development	30%	
Competitors/Patents	30%	
Total		

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Outcomes

- Go
- Conditional Go
- Conditional Kill
- Kill

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Questions?

astevens@bu.edu

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Technology Licensing, Valuation and Acquisition for The Biotechnology Sector

Lecture 2: Licensing and Marketing Strategies

Biotechnology Industry Research Assistance Programme
Department of Biotechnology

February 11/12, 2013 Bangalore
and
February 14/15,2013 New Delhi

Dr. Ashley J. Stevens
Past President, Association of University Technology Managers
and
Lecturer, Health Sector Management Program
School of Management
Boston University

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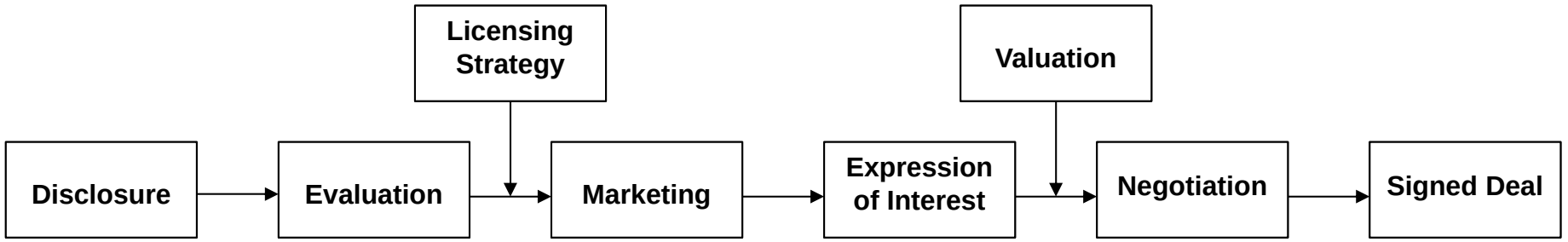
The Technology Transfer Process



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Step 2: Develop the Licensing Strategy

Develop the Licensing Strategy

- The fundamental question:
  - Are we going to license this to an existing company?
  - Or a new company?
- Truly revolutionary inventions frequently need a new company
- Incremental inventions are licensed to existing companies

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Develop the Licensing Strategy

- Are there multiple products that come from the technology?
  - If answer is “Yes”, which market is most attractive?
  - Do we need separate sets of patent claims to protect each market?
- Are the products used in the same industry?
  - If so, can the same company exploit them?
  - If answer to either is “No”, then we will need to license by field of use and find multiple licensees

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Develop the Licensing Strategy

- The next question:
  - Does the license(s) need to be exclusive?
    - Maximizes the incentive to the licensee
    - Maximizes the risk to the licensor
    - Maximizes the potential return to the licensor
- Does the technology provide everything that's needed for a finished product?
  - If so, do we want to provide the maximum incentive for a licensee to invest in developing the technology?
    - Exclusivity provides that
- Is there a clear market leader?
  - They may be the most attractive/only viable licensee
- Is it a crowded market?
  - If so, #2 or #3 may be a more motivated licensee

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Licenses Granted

- 15% start-up companies
- 53% small companies
- 32% large companies

- 37% exclusive
  - Start-Ups almost always need an exclusive license to all fields of use
- 63% non-exclusive

AUTM Annual Licensing Activity Survey 2011

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Develop the Licensing Strategy

- What are the key steps the licensee needs to do to get a product into the market
  - These will become your due diligence mechanisms
  - Should have at least one milestone each year
    - Perhaps more in first year
    - Ensure that licensee is developing the technology
      - Terminate the license if not
  - If start-up, include corporate development milestones
    - Fund raising
    - Hiring of key individuals

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Step 3: Marketing the Technology

Marketing Documents: Quad Charts & NCD's

- The vehicles for communicating the value proposition
  - Makes sure **you** understand the technology
- Used to market technologies through the website, targeted marketing campaigns and at trade shows

Boston University

Interactive Life Science Project Space

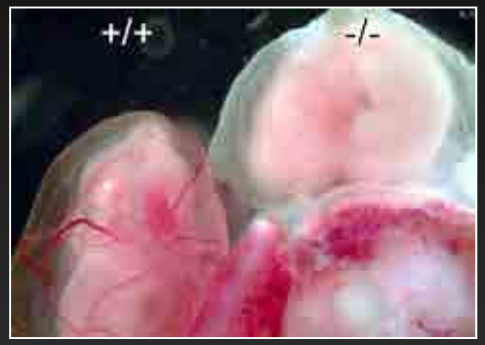
DEspR: A New Receptor in Angiogenesis & Monoclonal Antibody Therapy

Value Proposition

- A novel antibody therapy against tumor angiogenesis

Description

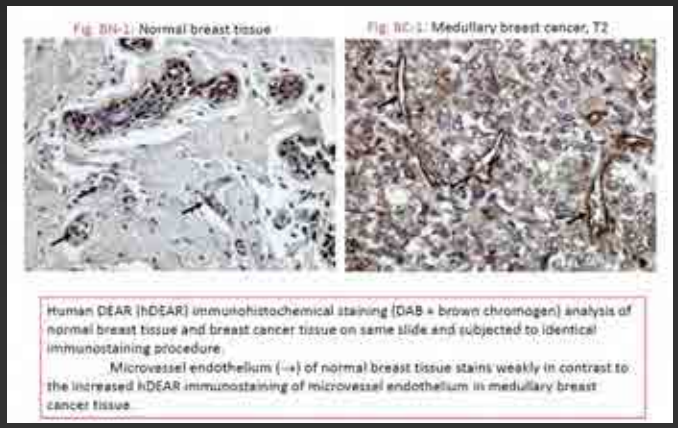
- The DEspR homozygous knockout mouse is embryonic lethal due in part to a lack of blood vessels in the placenta, yolk sac and embryo, highlighting the importance of this receptor in developmental angiogenesis (picture top right). The inventors have further demonstrated that administering antibodies to DEspR substantially reduces tumor growth, since tumors are also angiogenesis-dependent.



Status

Proof of Concept: The anti-human DEspR antibody:

- Shrinks tumors *in vivo* (including pro-malignancy nuclear grade)
- Detects DEspR in human cancer tissues
- National Applications filed – US, EPO, Canada, Japan, Australia



Note: DEspR previously called DEAR

Next Steps

- Make humanized anti-DEspR antibody, license or NewCo

Inventors

Dr. Victoria Herrera & Dr. Nelson Ruiz-Opazo

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Technology Available for License

Office of Technology Transfer – 108 Bay State Road Boston, MA 02215
(617) 353-4550 Fax: (617) 353-6141

Sensory Prosthetic for Improved Balance Control

Invention

Researchers at the Neuromuscular Research Center at Boston University are developing a sensory substitution prosthetic device designed to improve balance [illegible].

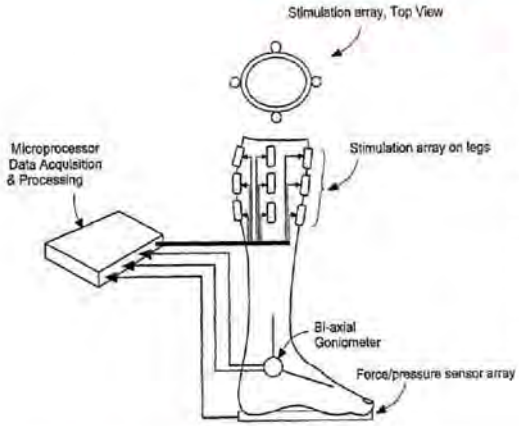
Advantages

- **Improved upright balance control**
- **Reduced risk of falls and associated injury**
- **Easily integrated into unconscious postural control system**

Potential Applications

- **Balance aid** – patients suffering from gait and balance problems due to peripheral sensory neuropathy and other balance sensory deficits
- **Countermeasure device** – to reduce plantar sole hypersensitivity resulting from prolonged bed rest, reduced weight bearing, or microgravity exposure
- **Artificial sensation** – virtual environment, for sports training or rehabilitation

Wearable Sensory Substitution Device



This is a feedback device for measuring balance related information, and for producing a stimulation of the skin that encodes the information in a way that is useful to the wearer of the device. At least one sensor detects balance information and transmits at least one balance information signal to a signal processing subsystem. The signal processing subsystem converts the received balance information signal into at least one stimulation control signal. The signal processing subsystem then transmits the stimulation control signal to at least one stimulator, which provides stimulation to a wearer of the device reflecting the stimulation control signal received from the signal processing subsystem.

Intellectual Property

Published US utility application (US 20050131317)

Inventors

Lars Oddsson and Peter Meyer

Contact

Sean Lee
Tel: (617) 353-4567 ♦ Fax: (617) 353-6141 ♦ Email: seanlee@bu.edu ♦ Website: http://www.bu.edu/otd

Ref #: BU 05-54, BU00-67

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Ref #: BU02-57
updated: 2/15/2008

BOSTON UNIVERSITY Technologies Available for License
Office of Technology Development

A New Receptor in Angiogenesis: Dual Endothelin-1/VEGF-signal peptide Receptor (DEspR)

Invention: The inventors discovered DEspR, a cell surface receptor that has a key role in angiogenesis related physiology and pathology. DEspR-knockout experiments reveal that DEspR is critical to angiogenesis, acting downstream to, and distinct from VEGF-mediated pathways.

Background: The inventors have shown in an animal model that alterations in the *DEspR* gene contribute to hypertension susceptibility. Additionally, the DEspR homozygous knockout mouse is embryonic lethal due in part to a lack of blood vessels in the placenta, yolk sac and embryo, highlighting the importance of this receptor in developmental angiogenesis (picture, left). The inventors have further demonstrated that administering antibodies to DEspR substantially reduces tumor growth, since tumors are also angiogenesis-dependent.

Applications: DEspR ***antagonists***, such as anti-DEspR antibodies or small molecules could serve as viable treatment options for angiogenesis-dependent diseases including cancer, macular degeneration, diabetic retinopathy and restenosis by inhibiting blood vessel formation. DEspR ***agonists*** could stimulate angiogenesis and vascular networking in conditions such as diabetic ischemia, impaired wound healing and myocardial infarction where neovascularization is important.

Stage of Development: PROOF OF CONCEPT: An anti-human DEspR antibody has been made.

The anti-human DEspR antibody:

- ✓ Detects DEspR in human cancer tissues and cell lines
- ✓ Inhibits angiogenesis of primary human microvascular endothelial cells and human umbilical vein endothelial cells – this is an anti-angiogenic effect
- ✓ Inhibits the invasiveness property of an aggressive human breast cancer cell line that expresses DEspR – this is an anti-metastatic effect

Inventors: Victoria Herrera, Nelson Ruiz-Opazo

Intellectual Property: National Applications filed – US, EPO, Canada, Japan, Australia

Publications: Herrera et al, *Physiol Genomics* (2005) 23:257-68; Kaneko et al, *Physiol Genomics* (2005) 20:157-164; Ruiz-Opazo et al, *Mol Med* (1998) 4:96-108

Contact: Rick Clark
• Tel: (617) 358-4208 • rclark@bu.edu • Website: http://www.bu.edu/otd

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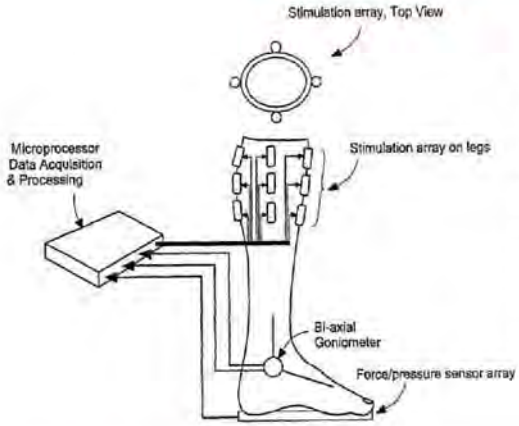

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Ref #: BU 05-54, BU00-67

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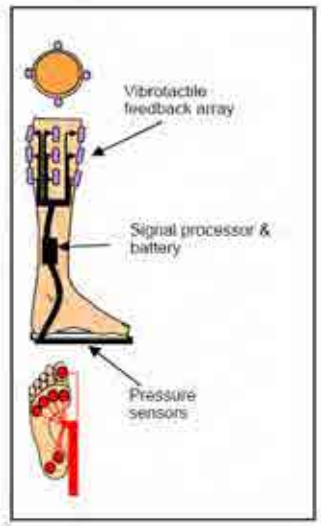
The *SmartSleepSock*

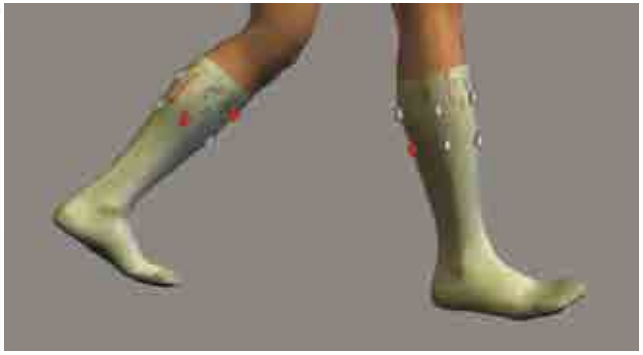
Value Proposition

- A wearable, low-profile, low-cost device for preventing falls.

Description

- A sock with pressure sensors underfoot and vibrotactile devices about the calf.
- The device enables sensory substitution - such that the calf experiences the pressure underfoot
- Improves balance and reaction time





Status

- Prototypes fabricated and tested (initial data on human subjects available)
- Business plan and pitch created
- US Utility application filed on method and apparatus

Next Steps:

- Identify entrepreneur
- Seek investment
- Form new entity

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Titles are Important!

See if you can tell what technology they are asking you to license?

Would you be compelled to read further?

1. A Method of Preventing Flower Loss and Increasing Crop Yield
2. Design and Synthesis of Robust Alternating Maleimide-vinyl Ether Copolymer with Phosphonate Side Groups
3. Composite Electrolyte Containing Surface Modified Fumed Silica
4. Fish Behavior Inducer
5. Low Energy, Self-Cleaning Air Purification
6. Materials and Methods for Detection and Treatment of Insulin-Dependent Diabetes

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Applications Clarify Potential Use

- Describing the applications for the technology makes it easy for potential licensees to understand its applicability to their industry
- Applications help to define the target market
- If applications are diverse, you may want to create separate NCDs/Quad Charts for specific target markets
  - Incorporate specific features and benefits targeted to each market segment

Features vs Benefits

A Feature or Fact	A Benefit
Can be Proven	Should be specific to a customer's need
Is Specific	Show a clear value to your customer
Is True	A reason to buy

If in doubt, apply the "So What?" test

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Features vs Benefits

- Features don't automatically communicate the resulting benefits
  - Our unique sensor can detect ppm level of NO in % level of O_2

- Benefits give a reason to buy
  - The sensors are highly sensitive to specific gases, providing accurate and in-depth diagnosis of pollutants

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Features vs Benefits

- Down the road, benefits will translate into pricing
  - What is the value of those benefits to the customer
    - Increased revenues
    - Decreased costs
    - The “goodness”
  - How much of that value can I include in my price and still leave the customer with an incentive to buy
    - How much do I have to “leave on the table”

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Value Proposition is communicated in the benefit (low-cost, wearable, low-profile)

The *SmartSleepSock*

Lars Oddsson

Value Proposition

- A wearable, low-profile, low-cost device for preventing falls.

Description

- A sock with pressure sensors underfoot and vibrotactile devices about the calf.
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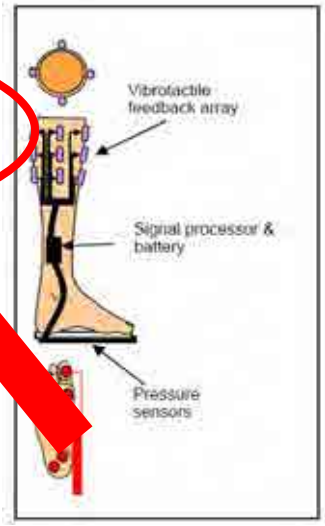

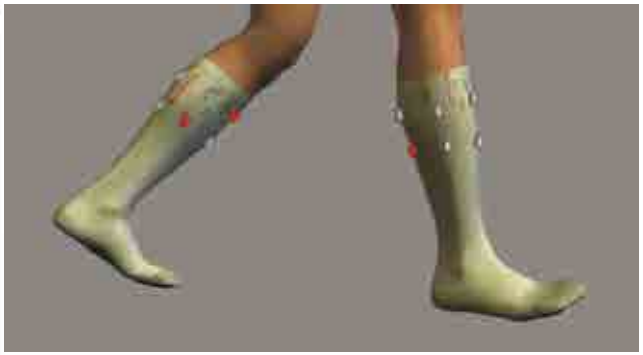

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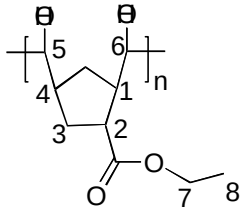
Novel Polymers for Viscosupplementation and Bulking Agents

Value Proposition

- Easy delivery, provides proper lubrication, and lasts longer (fewer injections)



Description

- A low cost synthetic polymer
- A new class of polymers with properties that may lead to longer residence time
- Can be used to treat osteoarthritis (reduce pain) or as a bulking agent (cosmetics or urinary incontinence)

Status

- Polymer has been produced and mechanical properties tested
- Initial cytotoxicity tests have been completed
- PCT patent application pending

Next Steps:

- Start-Up company (Flex Biomedical) established 11/07; seeking 1st round of VC funding

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Semiconductor Nanosensor Arrays

Value Proposition:

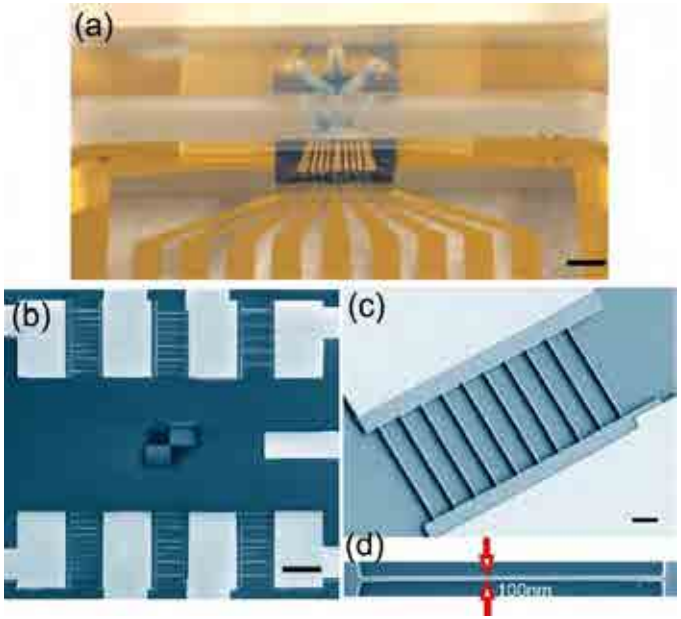
- Low cost, high sensitivity and specificity arrays that can provide patient-specific therapy

Description:

- Nanosensor arrays built with semiconductor methods that provide manufacturable sensors.
- Less expensive, portable, faster, measured in real-time
- Easier large scale manufacturing vs.traditional optical detection methods..
- Clinical need: Breast cancer. Detecting the unique "biomarker fingerprint" for breast cancer tumors can help lead to a specialized and more effective course of treatment for the more than 1.1 million cases of breast cancer are diagnosed each year.

Status:

- PCT filed in November, 2007 covering the sensor platform.
- Launch Award received from Office of Technology Development
- Proof of principle completed in multiple platforms.



Next Steps:

- Design and fabrication of breast cancer biomarker specific arrays.
- Detection of serum biomarkers.
- Ninth Sense, Inc. formed; seeking initial funds including VC, SBIR or STTR funding.

Contact:
Shyamsunder Erramilli, Ph.D.; 617-353-1271; shyam@bu.edu

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Osteoarthritis Knee Brace

Value Proposition

- A soft good with the performance of a rigid brace
- Low profile, light weight, ease of use, attractive gross margin, easy to manufacture

Description

- Pneumatic knee brace (inflatable air-bladder maintains a constant force to counteract the adduction moment throughout the full range of motion of the knee)

Status

- Modeling complete
- Prototype fabrication complete
- Provisional patent application pending

Next Steps:

- Impact analysis on existing businesses; visit to DJO scheduled for 2/08.
- Renewal application submitted to test prototype in a gait lab.

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Getting Started

- Start with the quad chart
  - Fewer words
  - Makes you focus on what's really important
- Do the technology description first
  - Now you've got that out of the way, everything else will be the value proposition
  - Value proposition isn't technical features
    - It's customer benefits

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Technology Marketing

- It's not like marketing a product…and……. it's not like sales
- What is it?
  - Putting the right information…..into the right hands…..at the right time
- Why is it important?
  - Technology /IP does not sell or license itself……(even "good" technology)
  - Technology Transfer without technology marketing…..is like one hand clapping

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We Market Technology Two Ways

- Passive Marketing
  - Shot gun marketing
  - Putting the NCD/Quad chart out on the web
    - Hope somebody finds it
  - Necessary first step
    - Generates things for second step
- Active Marketing
  - Rifle Shot
  - Fire off the NCD/Quad Chart to:
    - Carefully selected contacts
      - at carefully selected companies
  - Labor intensive
  - Second priority

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Passive Marketing

- Your own website
- Other peoples' websites
  - Portals
    - Don't pay for access to a portal
    - Which portals do companies visit?

Some Technology Portals

- AUTM GTP — gtp.autm.net/
- Biopharmalife — www.biopharmalife.com
- Flintbox — www.flintbox.com
  - Foliodirect — foliodirect.net
- iBridge — www.ibridgenetwork.org
- Inngot — www.inngot.com
- Innovaro — www.innovaro.com
  - Knowledge Express — www.knowledgeexpress.com
  - Pharma-Transfer — www.pharma-transfer.com
  - Pharmalicensing.com — pharmalicensing.com
- Tech Transfer Online — www.techtransferonline.com
- Technology Market (APCTT) — www.technology4sme.net
- Tynax — www.tynax.com
- Yet2.com — www.yet2.com

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Technology Marketing

- AUTM Global Technology Portal ("GTP")
  - Launched in March 2012 at Annual Meeting
    - The one portal all companies visit!
  - 22,000 technologies
    - Biggest portal world wide
  - Must have one member of AUTM in good standing to list your technologies
    - $285
    - Best investment you'll ever make!

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Active marketing

- Research to identify companies who should be interested
  - Professor's input critical
  - He knows:
    - Where his graduates now work
    - Who co-publishes with his competitors
    - Who's at the conferences he goes to
- Market Assessment will have identified potential licensees
- Founded on person-to-person contact
- Professional relationships
- Networking is the key!

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The "Right Hands"

- Obvious company/technology fits
- Non-obvious company/technology fits
- Initial contacts: upper-level management
  - VP (R&D, Business Development, Licensing, Open Innovation)
  - Licensing professionals (e.g. STEM, LES, AUTM)
  - Marketing department
- Contacts in professional settings/networking
- Meetings and conferences
- Technology brokers
- Scanning trade journals, other media
- Eventual linkage with technical evaluators
- Orchestrating the technical, business contacts

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Social Networking

- Tools:
  - LinkedIn
    - Groups to market
    - Find contacts
      - Ask for introduction if only two or three “degrees of separation”
  - Twitter
  - Facebook

Technology Marketing "Facts of Life"

- It's practically impossible to predict (despite thorough research) if a company will or will not be interested in a particular technology.
  - Successful technology transfer is probabilistic
  - However, the technology marketing professional can improve the probabilities significantly

The "Right" Time

- It is very difficult to predict the "right" time for any given company and a particular technology
- Look for obvious potential for strategic positioning:
  - Entry into new market
  - New product in existing market
  - Enhance current product portfolio

Sources of Leads that Resulted in Licenses

Source	%
Inventor	56%
Marketing efforts of OTT	19%
Company called university	10%
Research sponsor requested license	7%
Unknown	7%

Source: "Where do the leads come from? Source data from six institutions" Jansen and Dillon, Journal of the Association of University Technology Managers, 11, 1999

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Questions?

astevens@bu.edu

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Licensing Strategy and Valuation Case Studies

Case Study – Improved Lithium Ion Batteries

written by

Richard Cahoon, Ph.D.
BioProperty Strategy Group, Inc.

and

Ashley Stevens, D.Phil. (Oxon)
Lecturer, School of Management
Boston University

Past President
Association of University Technology Managers

Background:

A professor in your Electrical Engineering Department has sent you a disclosure that contains several ideas for novel technologies that appear promising to produce improved lithium ion batteries. Specifically, he has used sulfur nanoparticles in battery cathode formulations. The use of these nanoparticles in lithium battery cathodes eliminates the problem of cathode disintegration caused by repeated charge/discharge cycles. This disintegration is the cause of lithium battery failure and shortened lifetime. In addition, the method of manufacturing cathodes with sulfur nanoparticles also eliminates the problem of high-defect ratios in manufacture of lithium batteries larger than 10 cubic centimeters. This high-defect problem has made the manufacture of large lithium batteries prohibitively costly. Lowering the defect rate can lower production costs by 10% or more.

Lithium batteries are currently a $2 billion/year global business. The market for small batteries is projected to expand annually at between 5% and 10% over the next ten years. Sales of large Li batteries could exceed small batteries if the yield problem is solved.

There are currently twenty manufacturers of lithium batteries world-wide. Five are in the US, three in Europe, five in Japan, two in Taiwan, two in China, two in India, one in Russia. Two of these have annual sales of $100+ million, five have

This case study is based on an actual situation. The names and the science have been altered sufficiently to maintain anonymity. A number of academic institutions have provided material for these case studies.

annual sales of $50-$100 million, three have sales of $15-$50 million, and ten have sales of less than $15 million per year. No company is selling lithium batteries larger than 100 cubic centimeters.

The market is highly competitive, and pre-tax profit margins are less than 10%.

The Intellectual Property Portfolio:

The invention is covered by two PCT patent applications, both filed six months ago. Patent #1 covers a method for making lithium battery cathodes with sulfur nanoparticles; Patent #2 covers lithium batteries larger than 10 cubic centimeters with sulfur nanoparticles in the cathode. The PCT application designates all countries. The research group that invented it has amassed significant data on various means of manufacturing small, prototypes.

Current Stage of Development:

Proof of concept experiments have been successfully completed and the manufacturing process has been demonstrated at pilot scale. No working models have been constructed of a 10cc or larger battery due to the cost -- it is estimated that at least $1 million will be required for these.

Strategy Questions:

1. How many discrete, licensable inventions are there here?
2. Which is more valuable?
3. Which licensees are appropriate for each invention?
4. What licensing strategy will be appropriate for each invention

Valuation Questions:

1. What would be the financial terms for each invention?
2. What would be the due diligence milestones for each invention?

Technology Licensing, Valuation and Acquisition for The Biotechnology Sector

Lecture 3: Negotiating an Agreement

Biotechnology Industry Research Assistance Programme
Department of Biotechnology

February 11/12, 2013 Bangalore
and
February 14/15,2013 New Delhi

Dr. Ashley J. Stevens
Past President, Association of University Technology Managers
and
Lecturer, Health Sector Management Program
School of Management
Boston University

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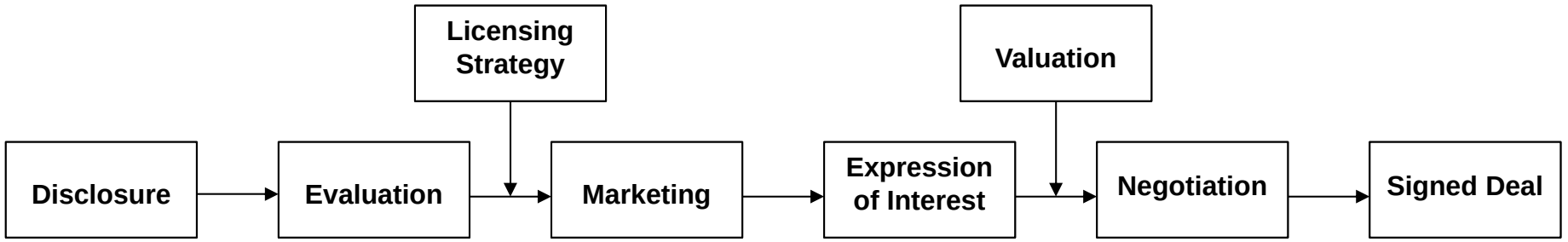
The Technology Transfer Process



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The Mechanics of Negotiating

Activity **Intensity of Negotiation** **Medium**

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The Connection

- Sources
  - From faculty
  - From passive marketing
  - From active marketing
  - They find you
- Initial discussions electronically
  - Email
  - Conference call

The Connection

- If serious interest, follow with a personal meeting
  - Dedicated trip
    - They visit you
      - Get to meet the scientist
  - Meet at a convention with partnering focus
    - BIO
    - AUTM Annual Meeting
    - AUTM in Asia

Confidentiality

- Initial discussions non-confidential
  - Published materials
    - Scientific papers
    - Published patent applications
- Later discussions confidential
  - Recent scientific data
  - Unpublished patent applications
- Never insist on a CDA and then send them something that's in the public domain

Interest Begins to Solidify

- As their interest develops, discussions of valuation creep in
  - Be gentle
  - Don’t frighten them away
  - Let their interest gel
    - No terms till after a personal meeting
- At some point, discussion will turn to a Term Sheet
  - You propose
  - They ask
- You’ll know when the time is right!

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Step 6: Expression of Interest

The Term Sheet

- Term Sheet
  - 4-5 pages
  - Non-binding
    - No payment associated with a Term Sheet
  - Encapsulates the deal
    - Identifies all the different agreements that make up the deal:
      - License, sponsored research, equity, etc.
    - Detailed business arrangements
      - IP involved
      - Business terms
      - Development commitments they'll make
        - Due diligence provisions
    - Summary of the legal aspects
- English is the standard for international agreements

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The Term Sheet

- Who goes first?
  - If you're really sure of your valuation, go first
    - If not, let them make the initial proposal
  - Remember:
    - The seller (licensor) can only go down in price
    - The buyer (licensee) can only go up in price
- After the initial proposal, there will be counterproposals back and forth
  - Negotiation tennis!
    - You may not get a second serve
    - Once it's in the net or out of court, the game's over.

The Term Sheet

- Never withdraw your own proposal
  - Except in response to one of their changes
- If you realize you've made a mistake, keep it to yourself
  - Look for an opportunity to correct it in in return for one of their requests
  - Every term of an agreement is a financial term
- Always have a reason for what you ask for

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The Term Sheet

- Mechanics:
  - Exchange MS Word documents
    - Clean copy + Track changes
    - Make sure each file is clearly named
      - Clean copy/Redline versus what version
      - Identify each draft by it's date and the side it came from
      - Draft number optional
    - Header or footer repeating this information
      - Not always updated
    - Use Comment boxes to give reasons for significant changes
  - Follow up with telephone discussion
  - Be clear about your negotiating authority:
    - "Yes, we can accept that"
    - "I agree with that and I think we can accept it"
    - "I think that's fair and I'll do my best to get it approved"

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“Trust but verify”

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The Term Sheet

- Do your own redline
  - Particularly before final
- Verify their changes
- Mistakes do happen
  - Yeah, right!
- Should be able to get to a deal in 3-4 rounds of back and forth
  - Be prompt
  - One to two days turnaround at this stage
    - The business person is in control of this stage
  - 2–4 weeks total from expression of interest
- Both sides sign
  - Even though non-binding
    - And final paragraph saying it’s non-binding

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Step 7: The Option

The Option

- Gives them rights to negotiate for the technology for some period of time without risk of losing the technology to someone else
  - Allows them to do due diligence
  - Time for negotiations
  - 6 months generally adequate
  - Longer if they want to do experiments to confirm/proof of concept/prototype
- Binding
- Must involve a payment
  - Cash
    - Non refundable but possibly creditable – upfront fee
  - Patent costs incurred during Option period
- Should have a Term Sheet attached
  - Make sure both sides have the same expectations

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The Option

- The Option is Optional!
  - Not all deals include an Option
- Avoid a Right of First Refusal ("ROFR") at all costs
  - If you can't reach agreement on terms during the option period, then you can't offer it to someone else at a lower price for some period of time without letting the Optionee meet the new terms
    - Destroys your ability to negotiate with someone else in good faith
    - Having a Term Sheet in the Option strengthens your hand to refuse a ROFR
- If you already have a signed Term Sheet, Option should be very quick to complete and sign
  - Particularly if an Option and the payment terms was included in the Term Sheet

Principles of Negotiation

“In Business as in Life,
You Don't Get What You Deserve
You Get What You Negotiate”

Dr. Chester L. Karrass

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Negotiating

- Life is a negotiation
  - “What shall we have for dinner tonight?”
  - “If you finish your homework, we’ll go for ice cream.”
  - “I’d like to go to Europe this summer.”
  - “We’re prepared to offer you $500,000 for this house.”
  - “I’m frankly disappointed in a merit increase that low after the contribution I made to the business this year.”
- We are the sum of the choices we’ve made
- In technology transfer, our portfolio is the sum of the choices we’ve made.

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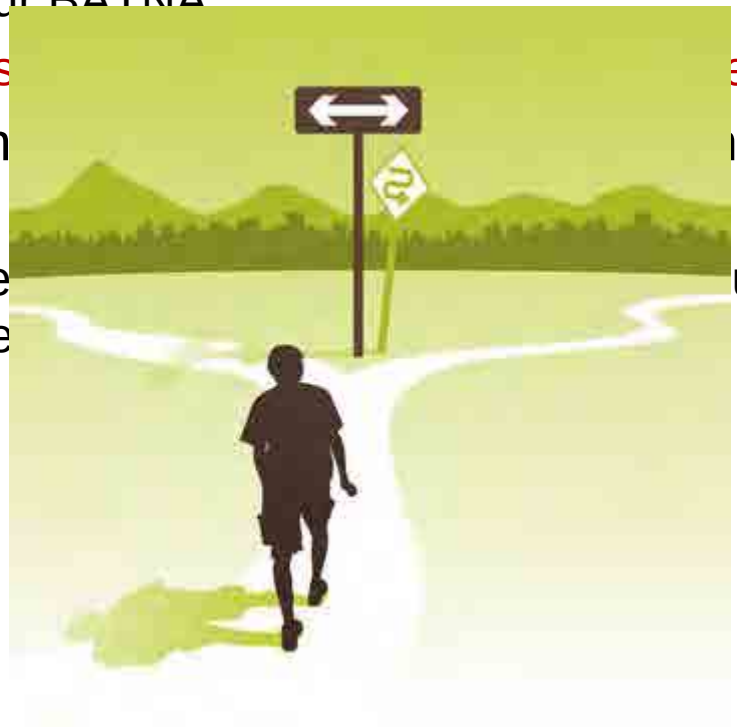
Negotiating

- It's all about choices and alternatives
  - If you can't get this deal done, what will you do next?
    - This is your BATNA
      - Bes ement
  - Your strongest n walk away from this deal
    - You have a se up your sleeve begging to lice



The realities of technology transfer

- Well established, mature offices license 25% of the inventions they get

"A hot academic technology is one that two companies are interested in"

Lita Nelsen, MIT
1998

- Most offices are happy to get one qualified prospective licensee
  - Start negotiations exclusively with that licensee
  - Stop looking for alternatives
    - No BATNA
- Drastically weakens your negotiating position

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The nature of academic license negotiations

- You're not just doing a transaction
  - – you're creating a relationship
- Patents last for 20 years
  - If the technology is successful, the relationship will last 20 years too!
- Must be win-win
- The deal will almost certainly need to be renegotiated
  - Changes in the technology
  - Changes in the marketplace
  - Changes in the licensee
- So if you don't get everything you want, there'll be additional opportunities to get them

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Negotiation is not a skill

If it were:

- You could learn it from a book and go do it
- There would be fixed ways to address issues
- You could cut and paste to get the final deal
- Big deals would be as easy as small ones
- Everybody would be just as good at it
- You would feel like an accountant!

The Negotiating Problem

1. The Problem
   - Discomfort
   - Uncertainty
   - Suboptimal results
     - Missed opportunities
     - Protracted negotiations
2. Possible diagnoses
   - Poor measures of success
   - Poor preparation
   - Poor process
   - Inadequate negotiating skills
   - It's difficult

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The Negotiation Problem

- Poor measures of success
- Poor preparation
- Poor process
- Inadequate skills
- It's difficult

- Measure success systematically
- Prepare! Thoroughly and systematically
- Think as much as possible about process
- Practice and *review;* keep a negotiation journal
- No guarantees of success! Ask "How do I make the best use of available resources

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How to measure success?

- Winning?
  - They make more concessions?
  - Break their bottom line?
  - Get the last possible dollar?
  - They hurt *more?*
- Not losing/Maintaining relationships
  - Equally unhappy?
  - Above our bottom line?
  - Won't be criticized?
- Avoid confrontation?
- Wise, efficient, amicable?

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A good outcome

- Is better than our BATNA
- Satisfies Interests
  - Ours well
  - Theirs acceptably
  - Others' tolerably
- Is an elegant, no waste solution: among the best of many Options
- Is Legitimate – no one feels taken
- Includes Commitments that are well planned, realistic and operational
- Is reached efficiently – the result of effective Communication
- Helps build a good working Relationship

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Prepare for the seven key elements

- Alternatives
  - What's our BATNA? What's theirs?
- Interests
  - What are ours? What are theirs?
  - Are there third parties to consider?
  - Which interests are *shared,* which are just *different*, and which *conflict?*
- Options
  - What possible agreements might creatively satisfy both sides interests?
- Legitimacy
  - What standards might a judge apply?
  - What "ought" to govern an agreement?
  - What will *they* argue? Our response?

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Prepare for the seven key elements

- Commitments
  - What is our authority? Theirs?
- Relationship
  - What kind would we like to have? What can we do that would be *unconditionally constructive?*
- Communication
  - What do we want to learn from them?
  - How can we improve our listening?
  - What will be persausive to them? How do we ensure that our messages are clear?
  - What's our agenda and plan?
  - How will we begin?
  - How will we handle disagreement?

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The "Negotiator's Dilemma"

- To create value, you need to reveal your interests

BUT

- Revealing your interests can put you at a disadvantage in distributing value

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Managing the Negotiator's Dilemma

- Prepare. Consider what you *can* reveal
- Reveal the *nature* of your interests, but not the *intensity*
- Share information reciprocally, in bite-sized bits
- Promote a framework of side-by-side joint problem-solving
- Use independent standards to guide questions of distribution

The Two Extreme Negotiating Styles

- Soft on Everything
- "Have to talk"
- Insist on maintaining relationship
- Open with a reasonable position
- Concede generously
- Focus on what you *will* do; Make offers

- Hard on Everything
- "Don't have to talk"
- Insist on agreement to your position
- Open with an extreme position
- Concede stubbornly
- Clarify what you *won't* do; Make threats

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Negotiate on the merits

- Soft on Everything

  "Have to talk"

  Participants are friends; the goal is agreement.

  Make concessions "for the relationship" (soft on the people *and* the problem)

  Open with a reasonable position

- Hard on Everything

  "Don't have to talk"

  Participants are adversaries; the goal is victory

  Demand concessions to have a relationship (hard on the people *and* the problem)

  Open with an extreme position

Solution: Principled

Depends on your BATNA

Participants are problem-solvers; the goal is a good outcome

Distinguish relationship and substance: Be soft on the people and hard on the problem

Avoid positions, clarify interests. Listen

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Negotiate on the merits

- Soft on Everything

  Concede generously

  Make offers – avoid a contest of wills

- Hard on Everything

  Concede stubbornly

  Make threats – win by a contest of wills

Solution: Principled

Don't concede anything. Invent options

Ask why? Use standards

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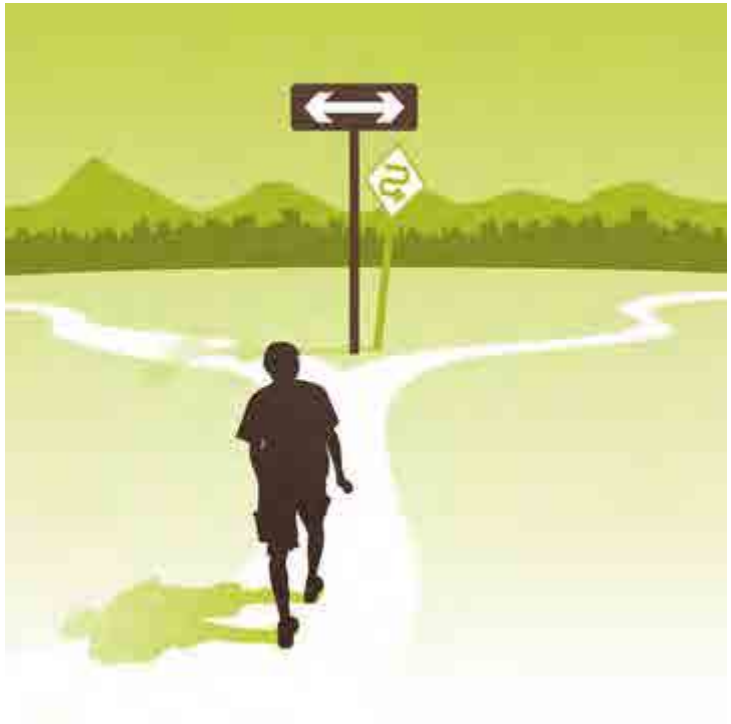
Some of the core principles of negotiating

Principle 1

- You’re never alone with a BATNA by your side



Principle 2

- Honesty is the best policy
  - You don't have to strip down to your underwear
  - But make sure you find out what you need to
  - Caveat emptor

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Principle 3

- "There are two sides to every question"

  Protagoras, Diogenes Laerius, (Greek philosopher, 485 – 421 BC)

  - Put your self in the head of the other side
  - What are t
    - Do the
    - Or only
  - Help them ou're halfway there.

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Principle 4

- Always have a basis that supports your proposals
  - Then you negotiate the bases
- Without a rational basis, you negotiate from emotion

Principle 5

- The Seller can only go down in price
- The Buyer can only go up in price

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Principle 6

- If you're sure you know what the ballpark should look like, make sure everyone plays in your ballpark
- If you're not sure what the ballpark should look like, let the other side take the first step in defining the ballpark
- Once the ballpark's defined, that's where you'll play
- Do you want to play here

or

here?

Principle 7

- For every “Quid” there’s a “Quo”
  - Keep track of those quids
  - There’s always a tomorrow
- Every term in an agreement is

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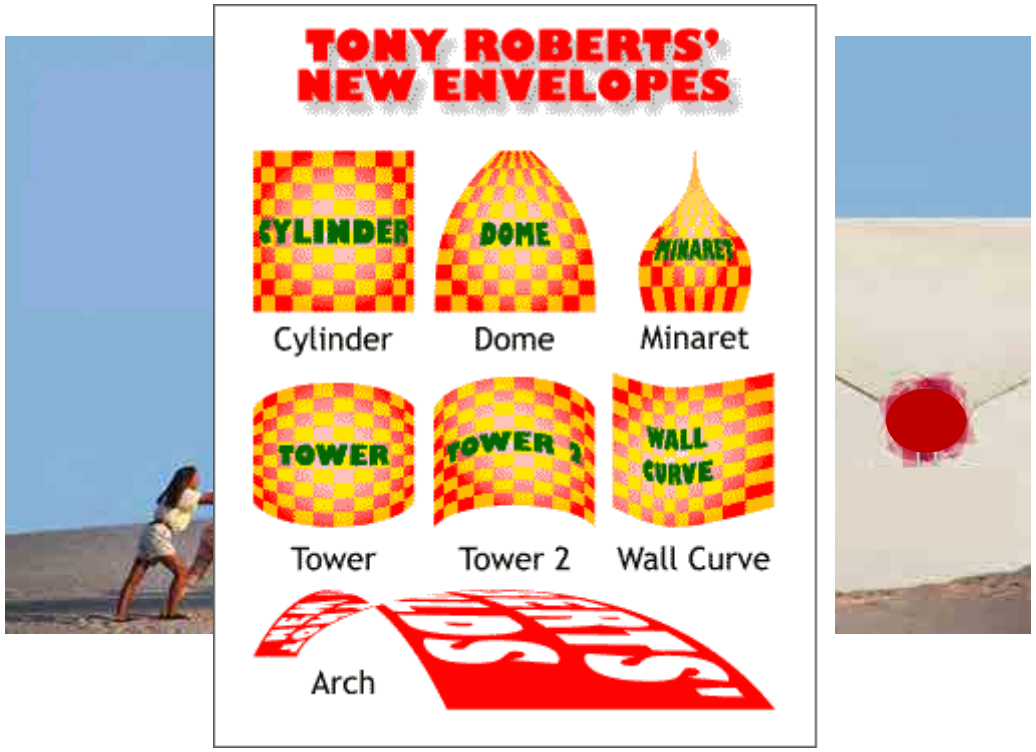
Principle 8

- You should always be trying to push the envelope
- You should be very careful about trying to invent a whole new envelope



Principle 9

- Those who think outside the box may never get back inside the box

"I can live with you not wanting to push the envelope, but your refusal to think outside the box..."

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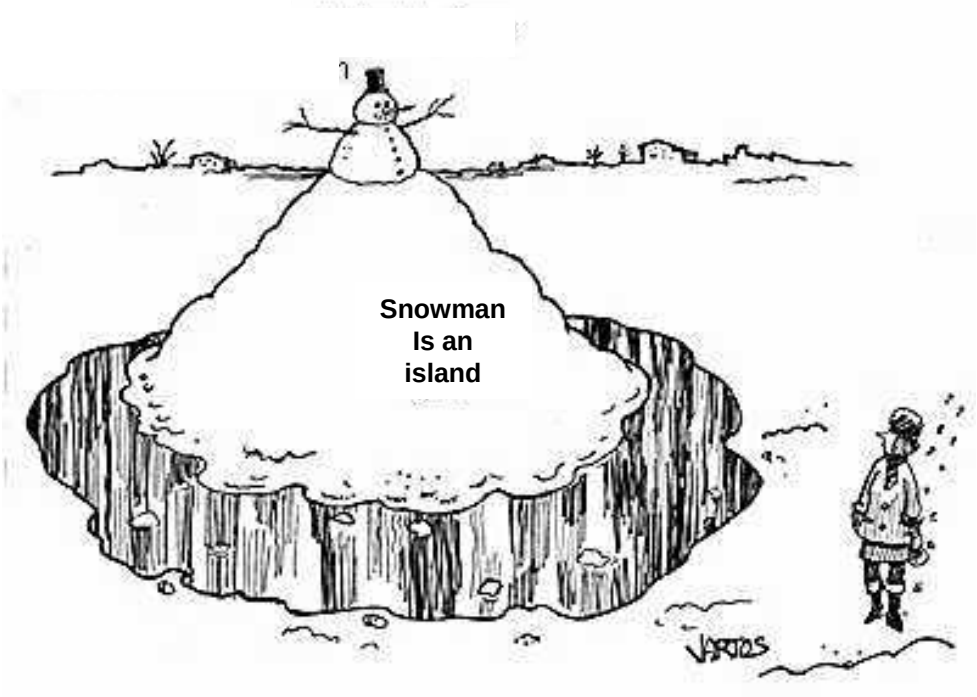
Principle 10

- No man is an island
  - You're much better off with two in the negotiating team



Principle 11

- The man behind the black curtain is your (best) friend.

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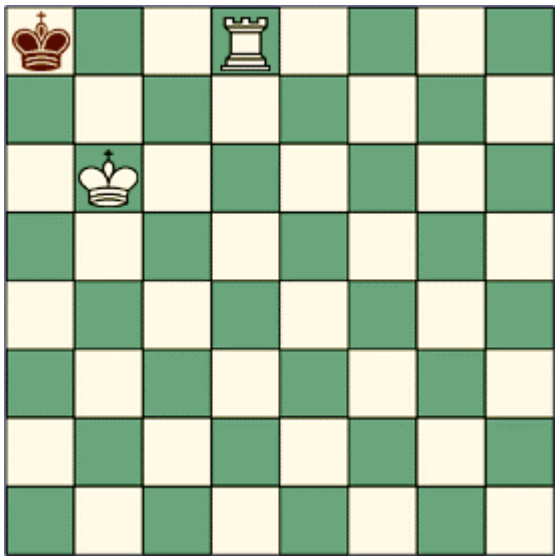
Principle 12

- Beware the end game



Principle 13

- Never enter a negotiation with your bladder full or your stomach empty

Principle 14

- Never push a man to the edge unless you're prepared to push him over

Principle 15

- "Sometimes, winning can be losing."
  - aka "Buyers Remorse"
  - Ancient Chinese Curse: "May [redacted]

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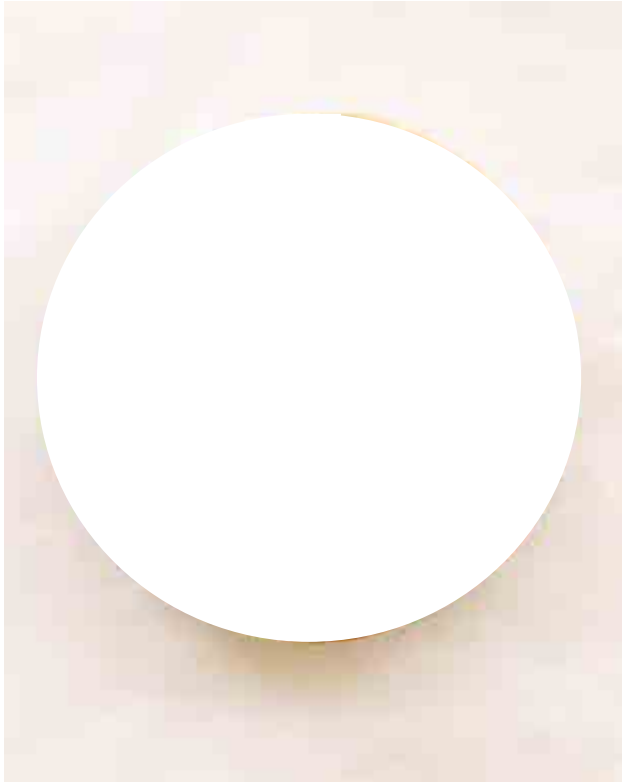
Principle 16

- 95% of something is better than 100% of nothing
  - i.e., Leave well enough alone



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Principle 17

- My word is my bond
  - Once you've agreed to something, you can't change your mind unless something else changes
  - This is the start of a relationship, not just a transaction

The final deal will probably be like the Curate's egg

It's very good in parts, sir

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Psych Out the Deal and Personalities

- Start by gathering FACTS:
  - What is the company like? How big is it? How successful? Do they have a good story?
  - Is this a big deal for them, or a tiny one?
  - What is their negotiator's education, job experience, family life, hobbies, politics, etc.?
  - What is this person's position in the org chart?
  - Who is their boss, the CEO, other key players?
  - Study competitors; what is the industry like?
  - Auto, medical imaging are hard-ball; biotech, green tech and agriculture are more relaxed

Sources for Fact-Gathering

- All over the web: Facebook, Linked-In, political contribution databases, dig to the 20th page of a Google search!
- Invite them to join your Linked-In network, and call those you may know in common!
- Talk to the inventors over coffee or lunch, they may know more than you think
- Talk to AUTM friends about this company and others in the industry

Select Your Opening Style, Then Adapt

- There are several basic negotiating styles:
  - Confrontational - “Take it or leave it”
  - Competitive - “I must win, you must lose”
  - Intellectual - “All of the facts support my view”
  - Collaborative - “Let’s find a middle ground”
  - Emotional - “If I don’t get this, I’m dead!”
  - Passive - “Well, I don’t know what to say”
  - Wounded Dove - “Could you help me out?”

Give Yourself a Break

- When you feel unsure of yourself, tell them you would like to take a short break
- If the boss or colleagues are available in person or by phone, bounce it off of them
- If someone else was with you in the room, comparing gut reactions can be incredibly valuable
- Make yourself a bullet list of where you are, you may find new openings or strategies
- If you need 20 minutes, so be it! After 10, tell them you apologize for the delay, but will be back shortly; or if by phone, that you will call back
- If you still don't feel ready to proceed, tell them you need to have some discussions internally, and ask to meet again

Don’t Let the Perfect Be The Enemy of the Good Enough

- Perfectionists don’t become master negotiators; all deals are compromises, and thus are imperfect
- After several rounds, you see diminishing returns
- Stop and ask yourself some questions:
  - What is the worst result if we just sign?
  - Are remaining issues likely to be important?
  - Would it be better to squeeze the last nickel out of this deal, or spend that time on another deal?
  - Has it taken over 3 months? Political consequences of delay may outweigh gains
  - Do you think this company will make it? If not, they will blame you, and you gain nothing!

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Keep the Issues in Perspective

- A big risk is that once the big issues are settled, the small ones start looking big, too
- Make it a conscious effort to distinguish big, medium and small issues, and treat them as such
- Most deals have few “gotta haves,” and you probably dealt with them early on
- When you reach that point of diminishing returns, you probably don’t need to give away much to get the deal done

One Last Rule for Success: HAVE FUN!

- There is no such thing as the perfect deal, so accept your lumps with humor and grace
- The only way to become a master negotiator is to keep negotiating!
  - You can't do that if you let it terrorize you or stress you out
- If you make 1,000 mistakes on the way to becoming a master, you are better than most!
  - Just learn from those mistakes
- Remember:
  a) As long as you do your best, you have nothing to regret, and
  b) It's not your money anyhow!

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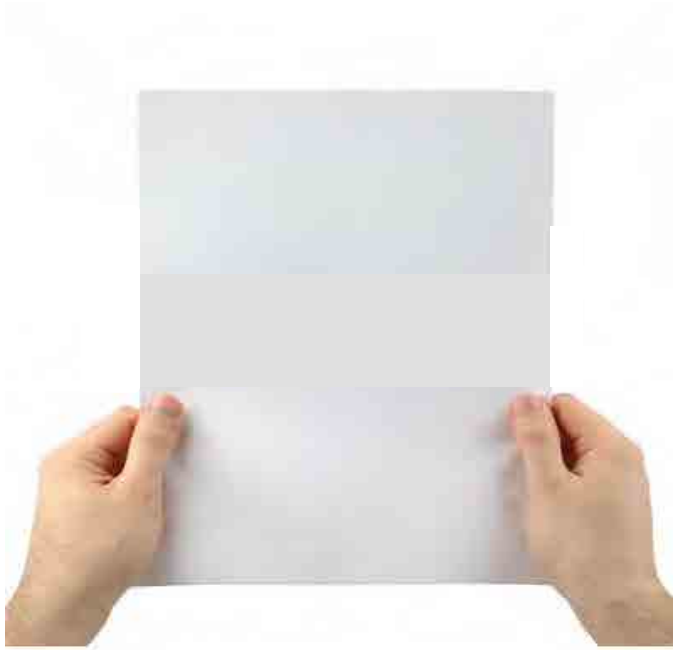
And Finally

- Remember: Every new deal starts with a clean sheet of paper
  - They won't know if you got snookered once before
  - Learn your lessons and apply them the next time



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Questions?

astevens@bu.edu

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Technology Licensing, Valuation and Acquisition for The Biotechnology Sector

Lecture 4: License Agreements

Biotechnology Industry Research Assistance Programme
Department of Biotechnology

February 11/12, 2013 Bangalore
and
February 14/15,2013 New Delhi

Dr. Ashley J. Stevens
Past President, Association of University Technology Managers
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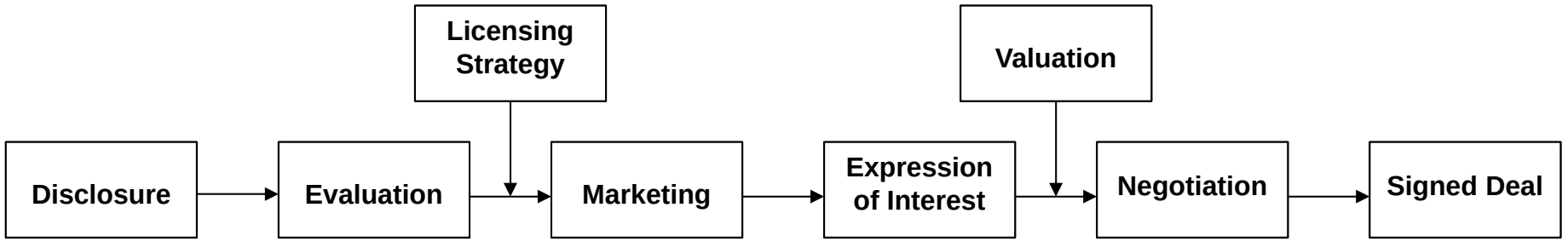
The Technology Transfer Process



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Step 8: The Legal Documents

The Legal Documents

- Terms of the Term Sheet get incorporated in a set of template agreements
- Always do the first draft using **YOUR** template
  - You know what you need in the document
  - You can see what changes they want to make to your language
- If you let them send the first draft using their template:
  - It'll be further away from where you need to finish up
  - You'll have to carefully check what's **NOT** in there that you need
    - As well as editing what is in there

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Templates

- You need template agreements to start from:
  - Invention Disclosure Form
  - Patent Assignment Agreement
  - Inventor Participation Agreement
  - Inventor Reassignment Agreement
  - Confidentiality Agreement
    - One way
    - Two way
  - Material Transfer Agreement
    - Inert material
    - Biological material
    - Invention Human tissue samples
    - Mouse
  - Consulting Agreement

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Templates

- Inter-Institutional (Joint Invention) Agreement
- Sponsored Research Agreement
  - Basic research
  - Clinical research
- Contract Research Agreement
  - Clinical trial
- Collaboration Agreement

Templates

- Term Sheet
- Option Agreement
- License Agreements
  - Exclusive Patent License Agreement
  - Non-Exclusive Patent License Agreement
  - Software/Copyright License Agreement
  - Enduser License Agreement
- Spin-Out Company Agreements
  - Stock Purchase Agreement
  - Shareholders Agreement

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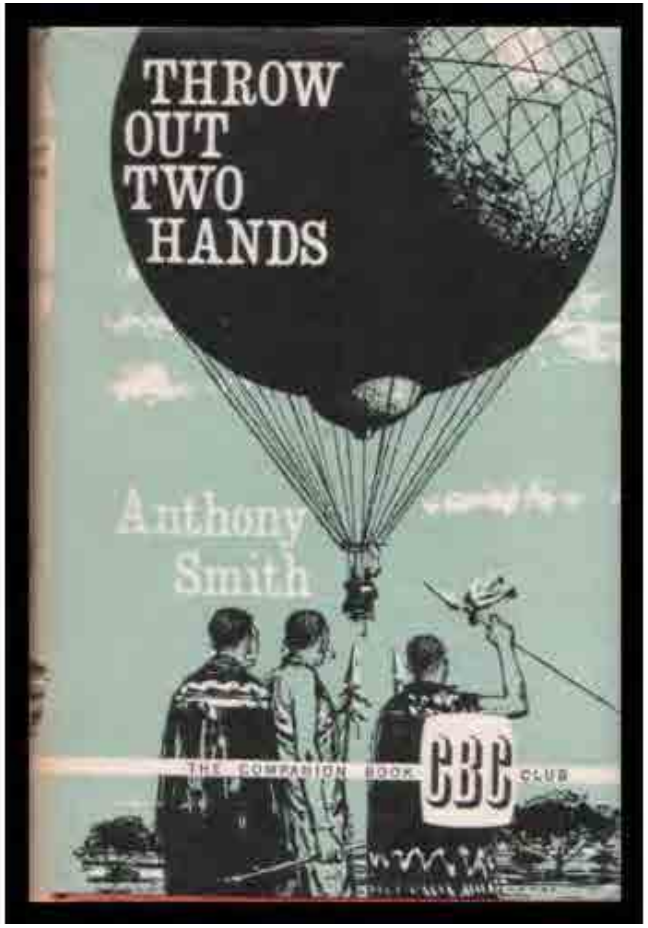

“The safety rules of ballooning are essentially a recapitulation of the accidents that have happened”

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"Those who ignore history are doomed to repeat it"

George Santayana

He actually said: "Those who cannot remember the past are condemned to repeat it."

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Sources of Templates

- Inter-Institutional Agreement
  - MATTO/MTTC
- MTA's
  - AUTM
- Sponsored Research Agreements
  - UIDP
  - Lambert Agreements
- AUTM
    - Comprehensive collection of technology transfer agreements
    - Must be a member
      - Electronic membership is $50
      - Best deal you'll ever have

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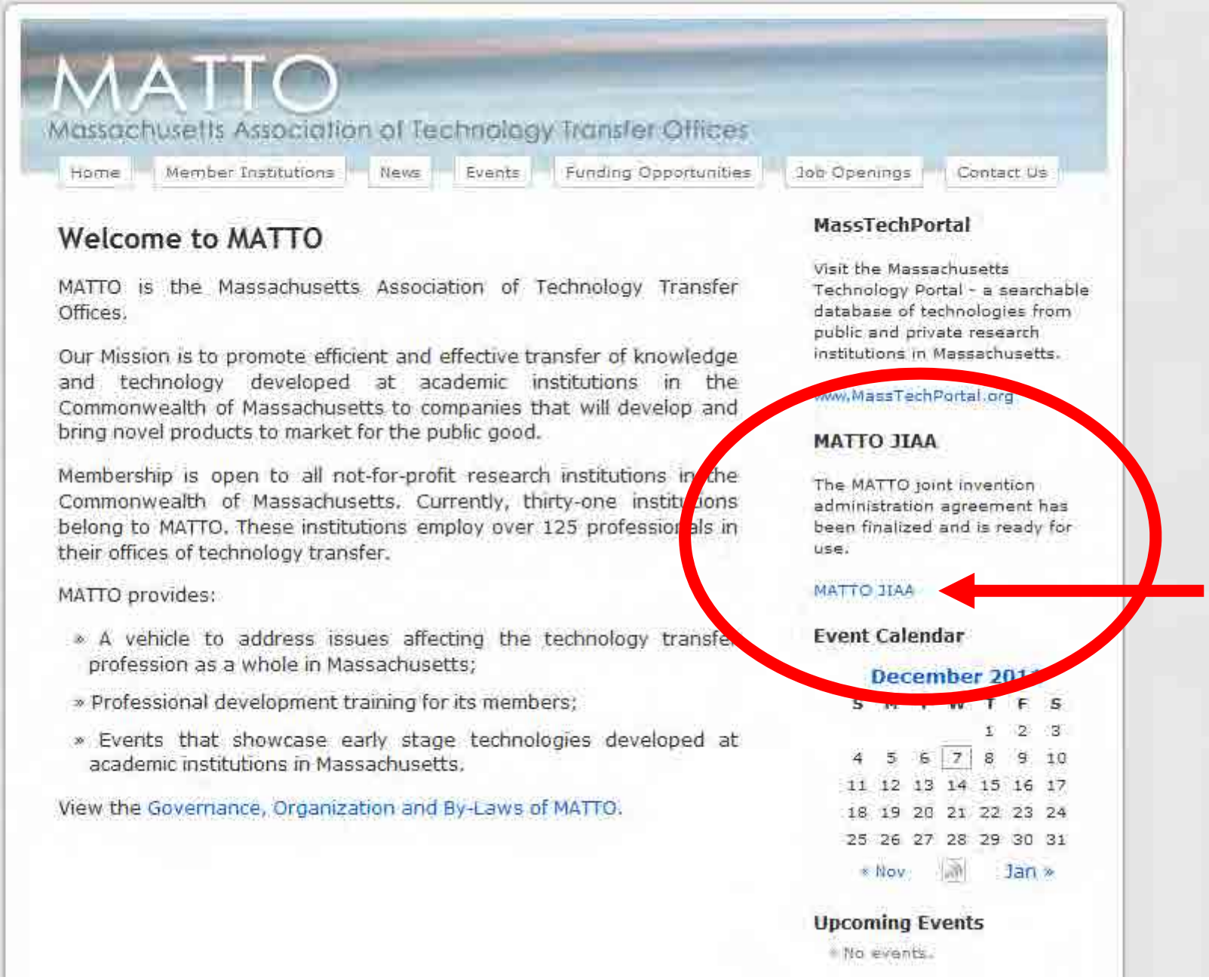
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Funding Opportunities
Job Openings
Contact Us
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Membership is open to all not-for-profit research institutions in the Commonwealth of Massachusetts. Currently, thirty-one institutions belong to MATTO. These institutions employ over 125 professionals in their offices of technology transfer.
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» Professional development training for its members;
» Events that showcase early stage technologies developed at academic institutions in Massachusetts.
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www.MassTechPortal.org
MATTO JIAA
The MATTO joint invention administration agreement has been finalized and is ready for use.
MATTO JIAA
Event Calendar
December 201
S M T W T F S
1 2 3
4 5 6 7 8 9 10
11 12 13 14 15 16 17
18 19 20 21 22 23 24
25 26 27 28 29 30 31
« Nov
Jan »
Upcoming Events
No events.

Sponsored Research Agreements – Key Issues

- Access to IP
  - Frequently the most contentious
  - Companies want free access to IP
  - IRS rules severely limit this
    - Research where the terms for access to the IP are defined in advance is considered “commercial research”
    - Can only devote 5% of space financed with tax exempt bonds to commercial research
  - Normal terms are:
    1. A royalty free license to make and use (i.e., a research license)
    2. An exclusive option to an exclusive license to make use and sell on terms to be negotiated when the option is exercised
  - Background rights need to be separately negotiated
    - May be problematic if invented by a different professor

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Sponsored Research Agreements – Key Issues

- Publication
  - Company gets to review publications for:
    - Patentable inventions
      - 30 day delay to file
    - Confidential company information
- Cost
  - Companies frequently resist paying full IDC

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IPO Home
Why use IP?
How and when should I use IP?
IP for education
IP in research and knowledge transfer
IP and Collaborative Research in the UK
IP and Collaborative Research in Europe
Lambert Tool kit
- News
- Introduction and background
- Model Research Collaboration Agreements
- Model Consortium Agreements
- Guidance notes
- Useful resources
- Contact the Lambert Working Group

Lambert Tool kit

The Lambert toolkit is for universities and companies that wish to undertake collaborative research projects with each other.

The toolkit consists of a set of five Model Research Collaboration (one to one) Agreements numbered 1-5 and four Consortium (multi-party) Agreements lettered A-D and documents that should help you to use and understand those agreements. The toolkit was prepared by the Lambert Working Group on Intellectual Property.

Innovation and Compromise

The aim of the model agreements is to maximise innovation. They have not been developed with the aim of maximising the commercial return to the universities; but to encourage university and industry collaboration and the sharing of knowledge. They do not represent an ideal position for any party; depending on the circumstances they are designed to represent a workable and reasonable compromise for both or all parties.

Model Research Collaboration Agreements (one to one)

There are five model Research Collaboration agreements devised by the Lambert Working Group. Their use is optional, [redacted]d help you save time and money when negotiating.

Model Consortium Agreements (multi-party)

The four model Lambert Consortium Agreements use the same terminology and have the same structure as the five Re[redacted]oration Agreements, but contain additional provisions to cover some of the complications that arise as a result of having more than two parties.

Decision guide

The Decision Guide consists of a series of questions to help you choose which of the five model research

Internet links

- AURIL
- Confederation of British Industry (CBI)
- CREST cross-border collaboration Decision Guide
- Institute of Knowledge Transfer (IKT)
- PraxisUnico
- Research Councils UK
- Technology Strategy Board

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Useful resources

IPO Home > Why use IP? > IP in research and knowledge transfer > Lambert Tool kit > Model Research Collaboration Agreements

Model Research Collaboration Agreements

There are five model Research Collaboration Agreements, covering one to one projects each providing a different approach in the key area of who is to own, and have the right to exploit, the intellectual property in the results or outcome of the collaborative project.

Lambert Research Collaboration Agreement	Terms	IPR
Agreement 1	Sponsor has non-exclusive rights to use in specified field/territory; no sub-licences	University
Agreement 2	Sponsor may negotiate further licence to some or all University IP	University
Agreement 3	Sponsor may negotiate for an assignment of some University IP	University
Agreement 4	University has right to use for non-commercial purposes	Sponsor
Agreement 5	Contract research: no publication by University without Sponsor's permission	Sponsor

The model agreements are merely starting points and their use is not compulsory, but by using them you may be able to reduce the amount of time and money spent negotiating.

You should decide which of the five approaches best suits your purpose and negotiate with the other party to achieve consensus and a signed agreement before work on the project begins.

Choosing the right agreement

To help you decide which of the model Research Collaboration Agreements most closely reflects the circumstances of your project, we have prepared a Decision Guide to lead you through some of the principles and criteria that you may wish to take into account when deciding on the ownership and rights to exploit IP. You may find it helpful to consult this before using any of the model Research Collaboration Agreements.

See Also

- Research Collaboration Outlin
- Decision guide

License Agreements

- You're creating a relationship which, if successful, will last 20 years
- Relationships are unequal
  - Licensor has made their investment
    - Looking for as return on that investment
  - Licensee is taking on substantial risk
    - Financial
    - Opportunity cost

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License Agreement Outline

- Recitals
- Definitions
- License Grant
- Fees, Royalties, & Payments
- Patent Prosecution & Infringement
- Obligations of the Parties
- Representations & Warranties
- Indemnification & Insurance
- Confidentiality & Publication
- Term & Termination
- Miscellaneous

Recitals

- The “WHEREAS” clauses
  - Establish the background to the current agreement
  - Establish the purpose and objectives of the parties
  - Non-Binding

Definitions

- Defined terms are either Capitalized or ALL CAPS
- A section of Definitions – either Article I or an Appendix

  Licensed Patents shall mean …….
- Some terms are defined in the text
  - In parentheses and quotation marks

    LICENSE AGREEMENT dated as of June 30, 2012 (the “Effective Date”), by and between Trustees of Boston University (the “University”) and …..
- Complex agreements can have over 100 Defined Terms

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License Grant

- University hereby grants an Exclusive License to make, have made, use, have used, sell, have sold and import Licensed Products under the Patent Rights within the Licensed Field
- Right to grant sublicenses
  - Don’t require prior approval of sublicensees
- No exclusivity for know-how (“technology”)
- Certainly no license to trade secrets
  - Everything must be publishable
    - Universities don’t have many trade secrets
      - Cell lines
      - GM animals
      - Seeds
- May not include rights to improvements
  - Certainly time limited

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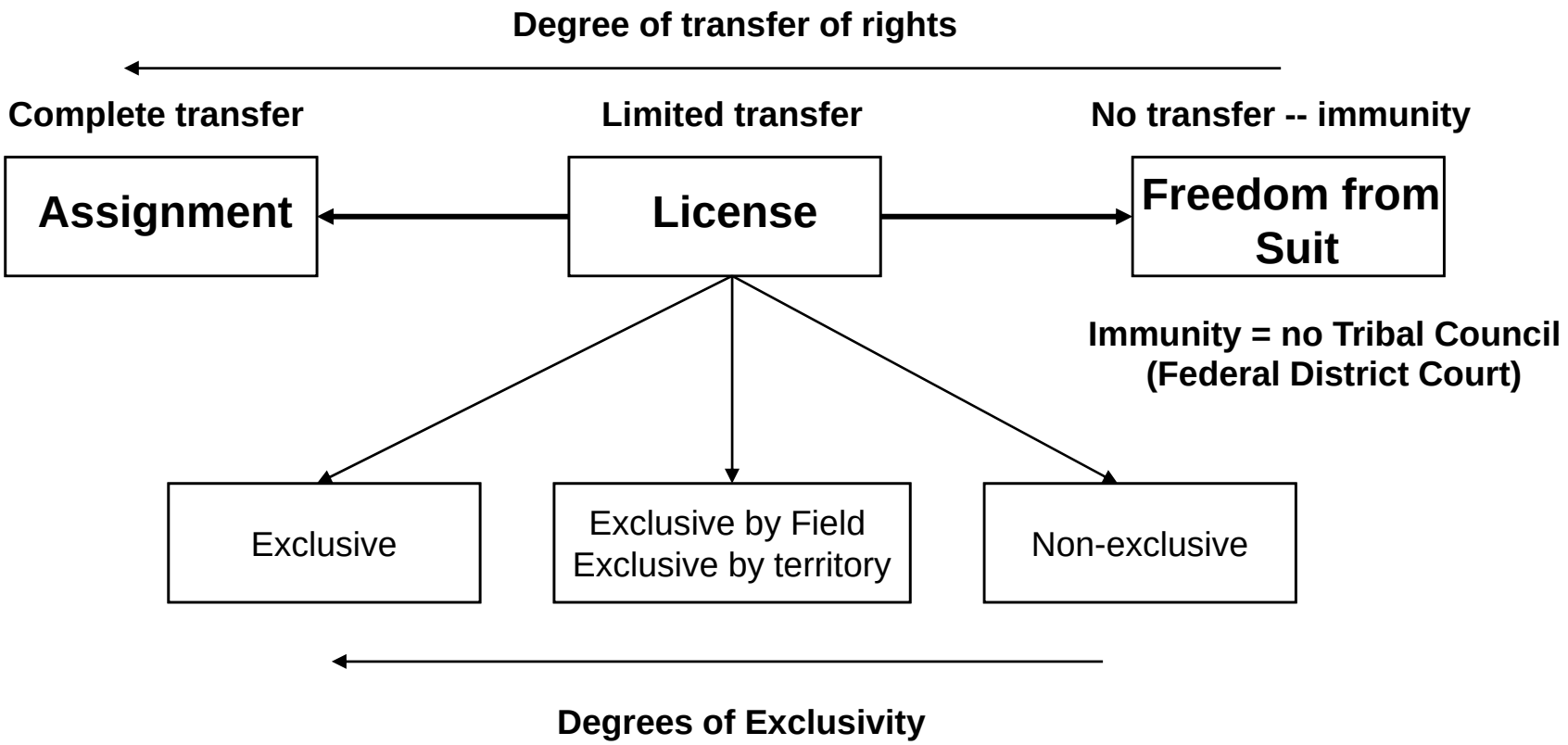
License Grant

Different Degrees of Rights Can be Granted



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Licensed Patents

- What the rights are being granted to
- Identified by number and title
- Mechanism to capture continuations, continuations-in-part and foreign counterparts

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Licensed Field

- The subset of all the possible uses of the technology that the Licensee is getting rights to
  - State what is affirmatively included
  - State what is affirmatively excluded
    - e.g., any planned or previously granted fields of use
      - Reproduce the exact wording of the other affirmative grants

      Licensed Field shall include all products intended for human therapeutic and prophylactic use

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      Licensed Field shall include all products intended for human therapeutic and prophylactic use, excluding any products in which a DNA construct is introduced into a human patient using a viral vector or by direct injection of a DNA construct ("Gene Therapy")

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Licensed Field

- The subset of all the possible uses of the technology that the Licensee is getting rights to
  - State what is affirmatively included
  - State what is affirmatively excluded
    - e.g., any planned or previously granted fields of use
      - Reproduce the exact wording of the other affirmative grants

      Licensed Field shall include all products intended for human therapeutic and prophylactic use, excluding any products in which a DNA construct is introduced into a human patient using a viral vector or by direct injection of a DNA construct ("Gene Therapy") and furthermore shall exclude all products intended for non-human animal therapeutic and prophylactic use ("Veterinary Uses")

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Territory

- Don’t include more than they can reasonably sell in
- Major territories:
  - US
  - Europe
  - Japan
  - China
  - India
- Make or sell?

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Equity

- In License Agreement
  - Shares of Stock to be issued instead of Up-Front Fees
- In Stock Purchase Agreement or Shareholders Agreement
  - Anti-dilution provisions
  - Information & visitation rights
  - Other rights enjoyed by founders
- Universities often do not take a seat on the board

Fees, Royalties and Payments

- Royalty base
  - Net Sales of Licensed Products
    - Net Sales are Gross Sales les certain standard deductions
      - Shipping
      - Insurance
      - Taxes (not income)
      - Distributor fees
      - Returned product

    or
    - Net Sales are Gross Sales less 5%
  - Kit deduction
    - Combination products
    - Apportion Net Sales in ratio of prices if sold separately
    - If not sold separately, apportion in ratio of fully burdened manufacturing cost

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Fees, Royalties and Payments

- Royalty payment = Royalty Base x (Royalty Rate – Offset/Stacking) – Deductions
- Non-Exclusive Licensees may demand a “Most Favored Nations” Clause
  - Nobody gets a lower rate
  - If they do, everybody gets the lower rate

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Licensed Products

- Either identified by name
  - If licensed at a late stage when products are known

or

- covered by a Valid Claim of a Licensed Patent

or

- which would, but for the license granted hereunder, infringe a Valid Claim of a Licensed Patent
  - Legally defined under the Patent Statutes (USC

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  - Legally defined under the Patent Statutes (USC

Patent Prosecution and Infringement

- University controls prosecution
- Reimbursement of patent expenses
  - Lawfirm bills university
  - University bills licensee
- Exclusive Licensee will want first right to sue for infringement
  - University has to join the suit
- Infringement costs paid by the company
  - Recovery distribution – (10% - 25% to University)
- University has second right to sue
  - Keeps all proceeds
- Non-Exclusive licensee has no right to sue

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Obligations of the Parties

- Reports
  - Product Development
    - Due diligence
  - Product sales and Royalty
- Records for auditing
  - Right to audit
- Best efforts to develop and commercialize Licensed Products
  - Specific milestone events
    - Date
    - May have payments associated
- Manufacture substantially in the U.S. (for sales in the U.S.)

Representations and Warranties

- Universities only represent that they have title to the Patent Rights
  - Not even complete title
    - May be additional inventors
- No other representations are made by the university, including:
  - Infringement of 3rd party patents
  - Viability of technology
- Disclaimers of liability have to be in ALL CAPS and no smaller than 12 point
  - UCC requirement

Indemnification and Insurance

- Licensee accepts all liability for their use, and any sub-licensee's use of Licensed Products
- Licensee must indemnify the University
- Product and other liability insurance is required

Confidentiality and Publication

- Reports, patent prosecution, & other information exchanged will be confidential
- University retains the right to publish its research related to the Patent Rights

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Term and Termination

- Term of the License
  - Longer of:
    - Life of the last to expire patent included within Patent Rights
    - 10 years from first commercial sale

    on a country by country basis
- Licensee is free to terminate the license at their option
  - Can't force them to continue to invest if they don't want to
- Termination fees might be required
  - Or return of the product including all the know-how they've created
  - Compensation for consumption of the patent life
- Termination by the University for breach and bankruptcy only
- Sublicenses in good standing continue, with Licensor replacing licensee
- Fully paid-up perpetual license after expiration of royalty term

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Dispute Resolution

- "Summit Meeting"
- Mediation
- Arbitration
  - Binding or non-binding
- None – straight to Court

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Miscellaneous

- Notice
- Use of Name
- Governing Law
- Assignment
  - With or without permission
  - Acquiror of the entire company
    - Of the entire business line

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Pre-Existing Rights

Pre-Existing Relationships

- Can complicate negotiations.
- Research Sponsor:
  - Generally receives an exclusive option to an exclusive license to any inventions made with their funding
    - Companies often demand a license, not an option. Why not?
      - US Non-Profit Tax Code makes it very difficult
        - If set terms in advance = commercial research
        - Limited to 10% of space funded with tax exempt bonds
  - Often demand an option to background rights
    - What if invented by a different professor?
  - Important to time limit
    - So clear to deal with others
    - 6 months after end of funding

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Pre-Existing Relationships

- Recipient of Materials
  - Often gets a license to make and use but not sell
    - i.e., a research license
- Right of First Refusal ("ROFR")
  - Right to make an offer for a technology
  - If licensor declines the proposal, licensee receives a right to match a lower bid
    - Makes it very difficult to deal in good faith with third parties
  - Important to time limit

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Pre-Existing Relationships

- Improvements
  - Licensees often demand improvements for all time
    - At no additional consideration!
  - Interests of professor and company rapidly diverge
    - Professor on to the “next big thing”
    - Company still working to make a reality of the “last big thing”
  - Limit to 2-3 years

Questions?

astevens@bu.edu

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Licensing Strategy and Valuation Case Studies

Case Study – A Gene for an Inherited Cancer

written by
Ashley Stevens, D.Phil. (Oxon)
Lecturer, School of Management
Boston University

Past President
Association of University Technology Managers

Background

Professor Richards is a geneticist who studies basic genetics in an academic model system -- he studies RNA translation errors in drosophila and the genes that control it and, much more importantly, the genes that are activated when a translation error occurs and correct it. He has done this work with a network of drosophila geneticists at other universities. His most important collaborator is one of his former post-doctoral fellows, Professor Fowel, who is now an assistant professor at a flagship state university in a neighboring state, and there are other important scientific relationships with senior professors at an Ivy League school and a state university out west. Unfortunately, Fowel's university has no OTT, though the Ivy and the western university have sophisticated OTT's

Someone brings to Richards' attention two studies published simultaneously which provide linkage evidence showing that the inherited form of human pancreatic cancer appears to be related to errors in RNA translation. Richards wonders whether mutations in the human homologues of his drosophila genes could be the genes that cause the inherited form of pancreatic cancer, by preventing correction of RNA translation errors and the consequent production of aberrant proteins. Even though the bulk of pancreatic cancer – over 90% -- is sporadic and there is no familial pattern – identifying the genes which cause the inherited form will be very important.

It is a matter of a couple of week's work for his and his collaborators' labs to clone the human homologues of the drosophila RNA translation error repair genes, using standard PCR techniques, but where does he go from here? To confirm that these genes are indeed linked to familial pancreatic cancer he'll need access to patient samples from families with familial pancreatic cancer. The problem is that a very well known professor, Professor Bertstein, who heads

This case study is based on an actual situation. The names and the science have been altered sufficiently to maintain anonymity. A number of academic institutions have provided material for these case studies.

the Department of Medical Genetics at one of the US' largest medical schools, is regarded as the father of pancreatic cancer genetics. He has already identified genes that are associated with sporadic forms of pancreatic cancer and for certain precancerous lesions. These discoveries have allowed him to raise substantial federal funding, and he also has a corporate partnership with Rabbitt Laboratories, one of the world's biggest pharmaceutical companies, which also has a major diagnostics division.

Richards' problem is that he has never done any genetic analysis of humans. He doesn't have a freezer full of well documented human patient samples, and neither do any of his collaborators. Fruit flies yes, humans no.
So Richards starts asking people who don't collaborate with Bertstein for samples, so as to not alert Bertstein to what he's doing.

The samples were arriving and Richards and his students and collaborators were doing the studies when a couple of months later Richards' Blackberry suddenly displayed the email he was dreading receiving. It was from Bertstein. He'd learned about Richards search for pancreatic cancer patient samples, had looked up Richards' publication record and had indeed worked out Richards' hypothesis.

As the race with Bertstein unfolds, Richards and Fowel, working with a researcher at yet another university discover a second and a third human gene with a role in familial pancreatic cancer that is a homologue of their drosophila RNA transcription genes.

With their papers prepared and submitted, Richards is ready to turn his attention to create IP to protect his important discovery and to work with his OTT on its commercialization. So, what should their priorities be? What should be their licensing strategy? How valuable an invention is this?

They quickly learn that about 50,000 patients develop pancreatic cancer a year in the US. There are currently no prognostic tests for pancreatic cancer. Diagnosis is via MRI/CT scans, sometimes involving use of a dye as an imaging agent, followed by biopsy. Total costs to definitively diagnose pancreatic cancer is upwards of $5,000.

Treating pancreatic cancer is very difficult. Five year survival is less than 6%. However, if pancreatic cancer can be detected before metastasis, before it has spread to other organs, five year survival is over 23%. Genetic tests for other cancers typically cost around $2,000.

This case study is based on an actual situation. The names and the science have been altered sufficiently to maintain anonymity. A number of academic institutions have provided material for these case studies.

Strategy Questions:

1. **What are the likely applications of the gene(s) that cause human pancreatic cancer?**
2. **How will each of these products be used?**
3. **Why does Rabbit Labs fund Dr. Bertstein's lab?**
4. **What should OTT's IP strategy and priorities be?**
5. **What should OTT's licensing strategy be?**
6. **How would OTT license these fields of use**

Valuation Questions:

1. **What data would you seek and what models would you build before starting the negotiations?**
2. **Suggest appropriate financial and due diligence terms for the various licenses.**

Technology Licensing, Valuation and Acquisition for The Biotechnology Sector

Lecture 5: Valuation Part 1

Biotechnology Industry Research Assistance Programme
Department of Biotechnology

February 11/12, 2013 Bangalore
and
February 14/15,2013 New Delhi

Dr. Ashley J. Stevens
Past President, Association of University Technology Managers
and
Lecturer, Health Sector Management Program
School of Management
Boston University

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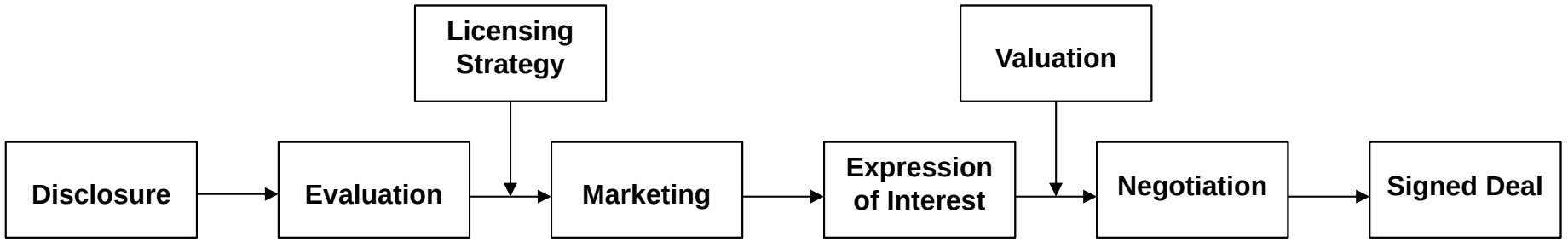
The Technology Transfer Process



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Objectives

- To provide a fundamental set of principles of technology valuation
- To describe the terms and techniques you will encounter
- To provide specific tools and resources for valuing specific technologies
- Look at some case studies

Agenda

- Valuation vs. Pricing
- Factors Affecting Value
- Valuation Methodologies
  - Cost
  - Industry Standards – Comparables
  - Rules of Thumb
  - Discounted Cash Flow
  - Equity

Valuation ➔ Pricing

- Various techniques
- Different answers
- An opinion

- A negotiation
- One outcome
- A commitment

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Valuation ➔ Pricing

- With a valuation basis
- You negotiate the basis

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Valuation ➔ Pricing

- With a valuation basis
- Without a valuation basis

- You negotiate the bases
- You negotiate from emotion

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What do we mean by a "Valuation"

- A written analysis of what we believe the value of a technology to be
- Prepared to:
  - Give it to the other side
  - Identify the sources of the data
  - Discuss the data
  - Modify based on discussions with the other side
    - Data
    - Valuation methodology used

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What do we mean by a "License Valuation"

- Constructing the various financial elements of a proposed license
  - Upfront payments
  - Ongoing pre-commercial payments
    - Patent costs
    - Milestone payments
    - Annual Minimum Royalties
    - Research support
  - Sublicense income sharing
  - Manufacturing
  - Earned royalties or sales/profit sharing
- **i.e., the Term Sheet**

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Upfront Payments

- Cash fee
  - Includes sunk patent costs
  - Reflects the initial value of the technology being transferred
  - A NewCo may only be able to pay in stock
  - For out-licensing, reflects recapture of know-how created
    - May likely be paid in stages via milestones
- Purchase of equity
  - Establishes partnership
  - Corporate partners should pay a premium to reflect strategic value of the technology
    - Separate transaction from purely investment transactions

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Ongoing Pre-Commercial Payments

- Patent costs
- Milestone payments
  - Reflects increase in value of technology to licensee as they make progress
    - Common with life sciences inventions
    - Clinical development milestones
    - Patent milestones
    - Sales milestones
  - Early ones can be paid in stock
- Annual Minimum Royalties
  - Due diligence mechanism
    - Typically escalate substantially after 3 or so years
  - More common with physical sciences inventions

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Sublicense Income Sharing

- Licenses with large companies typically have a **pass through** on sublicenses
  - Sales by sublicensees included in definition of “Net Sales”
    - Licensor gets paid the same irrespective of who sells the product
  - Philosophy is that deal was done with expectation that licensee will take to market
    - If they elect not to for strategic reasons and instead chose to sublicense, licensors return should not be diminished

Sublicense Income Sharing

- Licenses with small companies typically exclude sales by sublicensees from definition of “Net Sales”
- Separate section on sublicense income **allocation** between licensee and licensor
  - Philosophy is that deal was done with expectation that licensee will not/cannot take to market and will either sublicense or do a distribution deal with a large company which will sell to end users
    - Return from that sublicensee must be apportioned between the licensor and the licensee
  - 25% rule is a good starting point; higher (50%?) if they “flip”
    - This is often the REAL economic negotiation with a start-up, not the royalty rate
      - But, if company gets acquired, then the license will be assigned to the acquirer, who will pay the royalty rate

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Research Support

- Typically partner shares later stage, higher cost development costs
- Paid on an FTE basis
  - Fully loaded costs

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Manufacturing

- Typically done on a cost plus basis
  - +20% common in pharmaceuticals
- In physical sciences, sales price typically includes profit in lieu of royalties

Royalty Rate

- The main post-commercialization economic component of the license
- Biggest long term impact if the product is successful
- Either:
  - % of sales
  - Fixed amount per unit
- Must be easy (i.e., cheap) to audit
- Royalty base
  - Sales or units on which royalties are based
  - Normally “Net Sales”
    - Gross Sales less either
      - Standard deductions
        - Shipping
        - Insurance
        - Returns
      - Or a standard deduction – typically 5%

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Royalty Rate

- Royalty rate can be either:
  - Flat
    - Single royalty rate for all sales
  - Tiered
    - Royalty rate is different at different levels of sales

Offsets/Stacking

- Can drastically reduce the return from the licensee
  - Credits for:
    - Current year annual minimum royalties YES
    - Prior year annual minimum royalties NO
    - Sunk patent costs NO
  - Offsets for royalties paid to third parties RARELY
- Universities have probably been too generous on offsets
  - 5 protein therapeutics (3 antibodies; 2 cytokines):
    - Gross royalty burden 13.0-19.3%
    - Net royalty burden 10.0-15.2%
- Current environment:
  - Limit offsets severely
  - All patent applications now published after 18 months

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Offsets/Stacking

- Standard form:
  - Offset 50% of third party royalties but down to no less than 50% of royalty payable
- Example:
  - Royalty rate 5%; third party royalty of 2%
    - Net royalty payable: 5 – 0.5*2 = 4%
  - Royalty rate 6%; third party royalties of 4%, 2% and 1%
    - Net royalty payable: 6 – 0.5*(4+2+1) = 6 – 3.5 = 2.5%
      - This is less than 3% (6*0.5), so net payable is 3%

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Example

License issue fee	$50k
Annual minimum royalties	$10k yrs 2-4 $25k yrs 5-7 $50k thereafter
Milestone payments	$50k yr 3 $100k yr 4 $250k yr 5 $500k yr 6
Royalty rate	5%
Sunk patent costs	$75k
Annual patent costs	$10 - $25k

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Product Sales

Year	Product Sales
7	$750,000
8	$3,000,000
9	$5,000,000
10	$10,000,000
11	$15,000,000
12	$20,000,000
13	$25,000,000
14	$25,000,000
15	$25,000,000
16	$23,000,000
17	$21,000,000
18	$19,000,000
19	$17,000,000
20	$15,000,000

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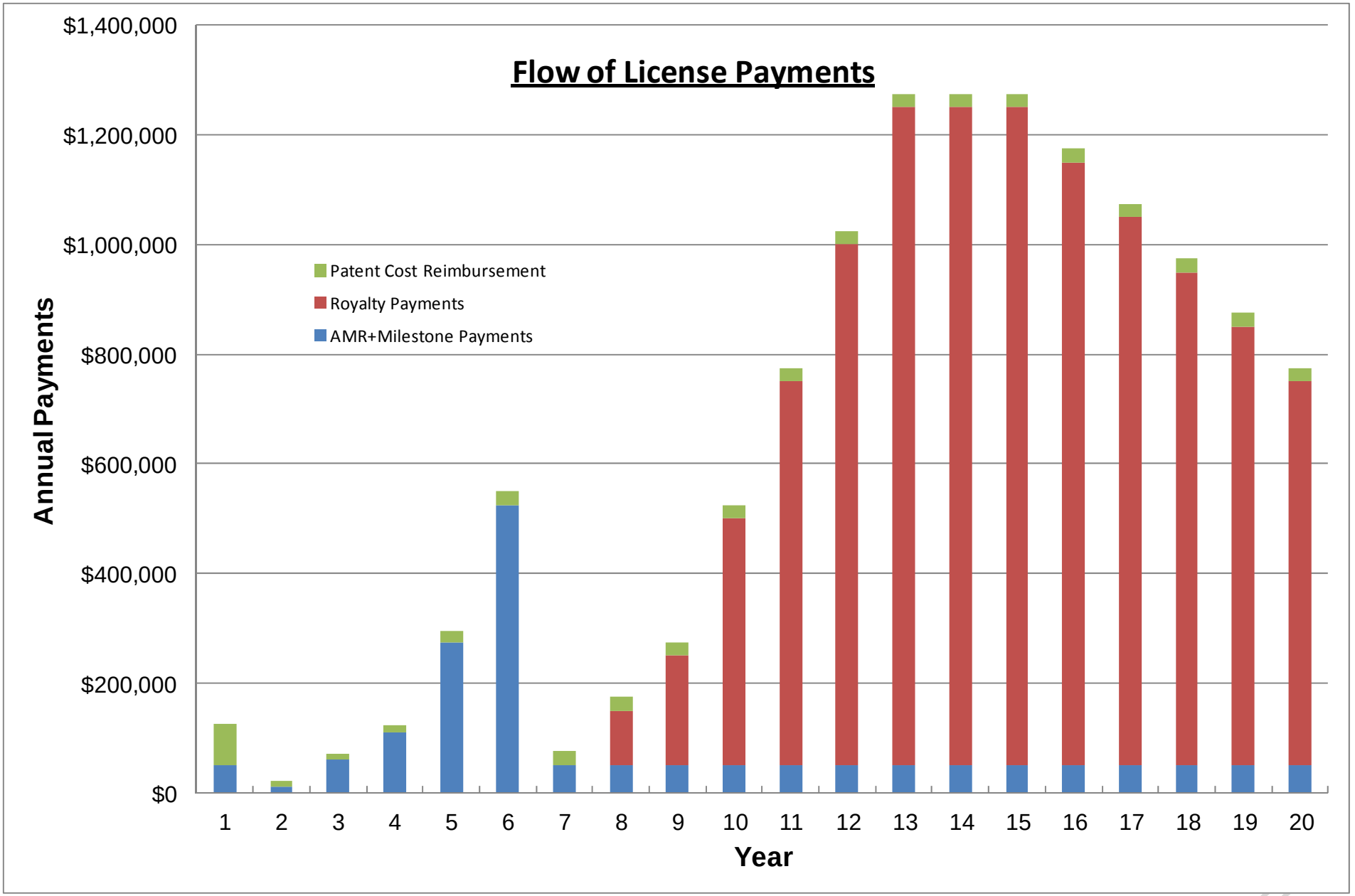
Flow of License Payments
$1,400,000
$1,200,000
$1,000,000
$800,000
$600,000
$400,000
$200,000
$0
Annual Payments
Patent Cost Reimbursement
Royalty Payments
AMR+Milestone Payments
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
Year

When Is Technology Valued?

- Retrospectively
  - By litigators
  - Value established and paid at a point in time
  - Adversarial -- outcome imposed judicially
  - Discovery – all relevant information known to both sides
- Prospectively
  - By deal makers
  - Value extracted over time
  - Must be win-win
  - Not much information and asymmetric

Who Needs to Value Technology?

Willing Sellers	Academia, Start-ups
Willing Buyers	Start-ups, BigCo
Investors	VC's, Investment Bankers, Corporate R&D Managers,
Lenders	Secured creditors
Acquirers	Investment Bankers
Monetizers	Partnerships
Unwilling Buyers or Sellers	Litigators

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The Essence of Technology Licensing

TR R A DE™

Trade Mark of Richard Razgaitis

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The Essence of Technology Licensing

TR R A DE™

Technology Rights

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The Essence of Technology Licensing

TR **R** A DE™

Technology Rights

Risk

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The Essence of Technology Licensing

TR R A DE™

Technology Rights

Risk

Art of Deal Making

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The Essence of Technology Licensing

TR R A DE™

Technology Rights

Risk

Art of Deal Making

Deal Economics

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Technology Rights

Technology Rights

- Scope of license
  - Can't value technology till licensing strategy has been decided.
    - Assignment vs. License vs. Freedom from Suit
    - Exclusive vs. Non-exclusive
    - Fields of use
    - Geographic extent
- How strong are the patents?
- What other technology rights are included?
  - Background rights
  - Improvements
  - Biological materials
  - A prototype
  - Clinical data

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Characteristics of the Patent

- What does it protect?
  - Composition of matter (pharmaceuticals)
  - Apparatus (materials)
  - Composition of matter (materials)
  - Method of treating
  - Manufacturing process
  - Formulation
- Does it protect characteristics perceived to be of value by consumers?
- How broadly does it exclude others? (i.e., how easily is it avoided?)

"The economic value of a patent depends fundamentally upon the nature and extent of non-infringing substitutes"

John Culbertson and Roy Weinstein
"Product Substitutes and the Calculation of Patent Damages"
J. Patent and Trademark Office Society, 70.11, 749-761 (1988)

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Risk

Types of Risk

- R&D risk
  - FDA risk
- Standards risk
- Manufacturability risk
- Marketing risk
- Competitive risk
- Legal risk
  - Patent risk

Overall

- I in 10,000 drug candidates makes it to FDA approval
- 1 in 3,000 raw ideas make it to market
- 1/3rd to 2/3rd of new product launches fail to recoup their investment

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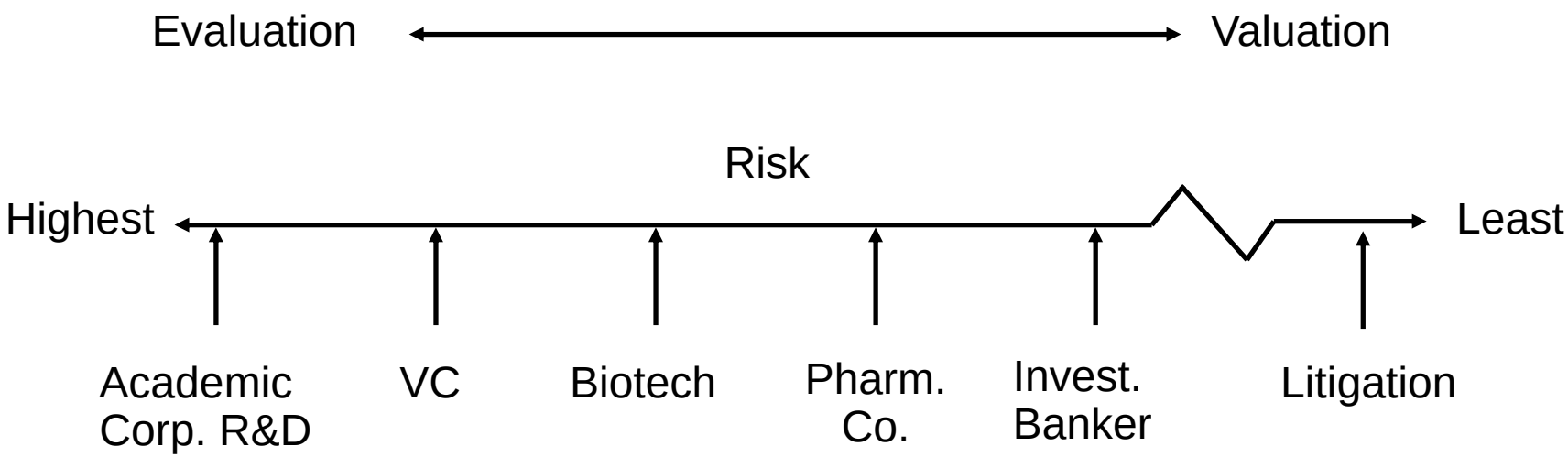
Risk vs. Time – Drug Development



Information available at time of valuation

Therapeutic target	Spec. disease	Indication	Actual sales
Competitive profile	Reg. strategy	Toxicology	Actual profits
Patent position		Man. costs	

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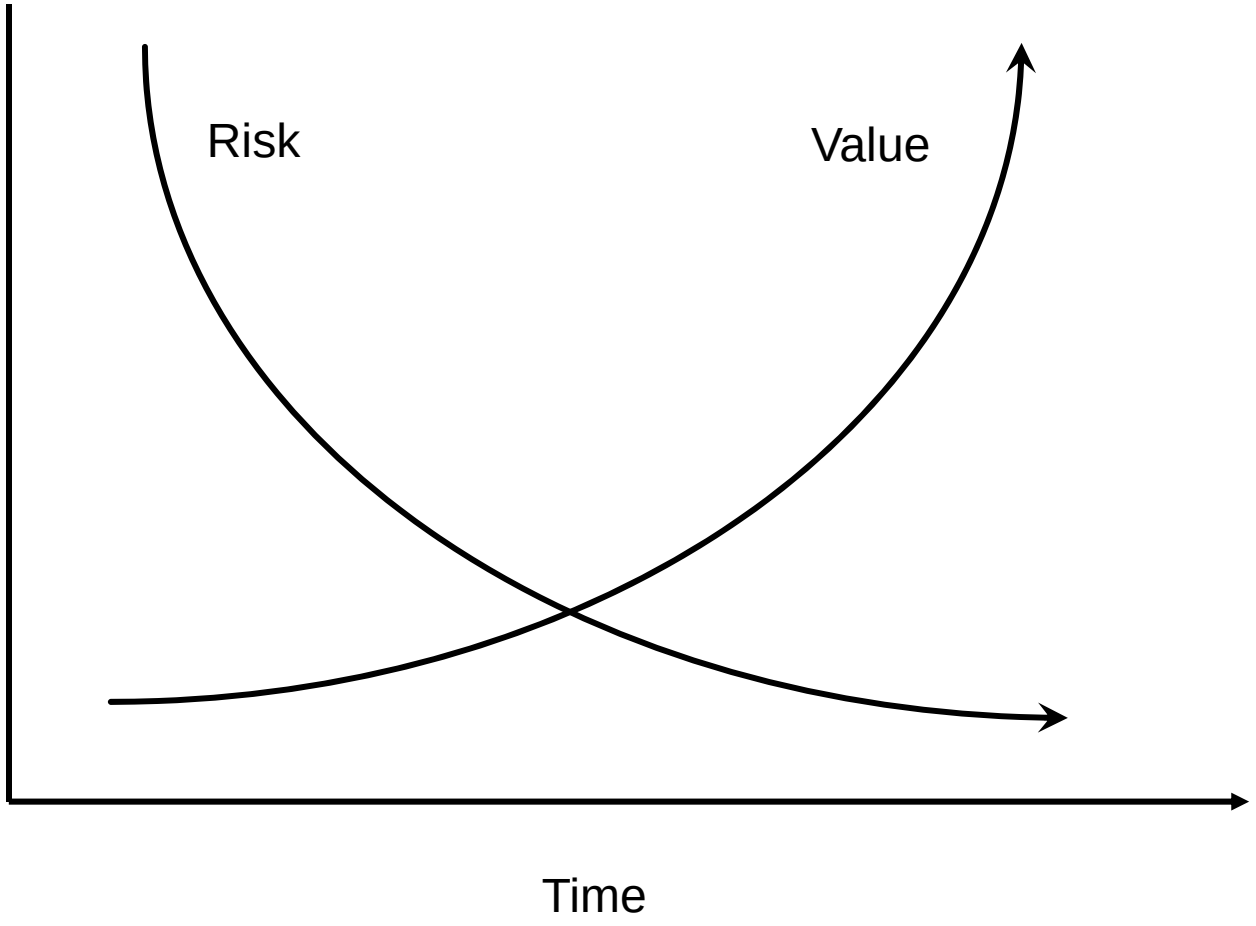
Value vs. Risk



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Technology Licensing, Valuation and Acquisition for The Biotechnology Sector

Lecture 6: Valuation Part 2

Biotechnology Industry Research Assistance Programme
Department of Biotechnology

February 11/12, 2013 Bangalore
and
February 14/15,2013 New Delhi

Dr. Ashley J. Stevens
Past President, Association of University Technology Managers
and
Lecturer, Health Sector Management Program
School of Management
Boston University

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The Basic Ways to Approach Valuation -- the Economist's Perspective

- Cost
- Market
- Income

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The Basic Ways to Approach Valuation -- the Licensing Guy's Perspective

Look back	Cost
Look around	Industry Standards – Comparables
Look at the pieces	Ranking/Rating
Look down	Rules of Thumb
Look forward	Discounted Cash Flow
Look to the dice	Monte Carlo
Look to others	Auction
Look no farther	Common sense
Look to the market	Equity

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Today

Look back	Cost
Look around	Industry Standards – Comparables
Look down	Rules of Thumb
Look forward	Discounted Cash Flow
Look to the market	Equity

With so many to choose from……..

Why limit yourself to one?

-- for a really important technology, use more than one

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Look Back -- Cost

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Look Back -- Cost

- Cost to develop plus a return
- Is cost to develop relevant?
  - Would you want to or be able to sell a used lottery ticket for what you paid for it?
  - Wasn't the technology developed with a GRANT?
- Two areas where cost enters license negotiations:
  - For academic institutions
    - Sunk patent costs
    - Relative ownership in a collaboration
    - Modified Replacement Cost method to calculate upfront
  - For corporations – transfer of know-how

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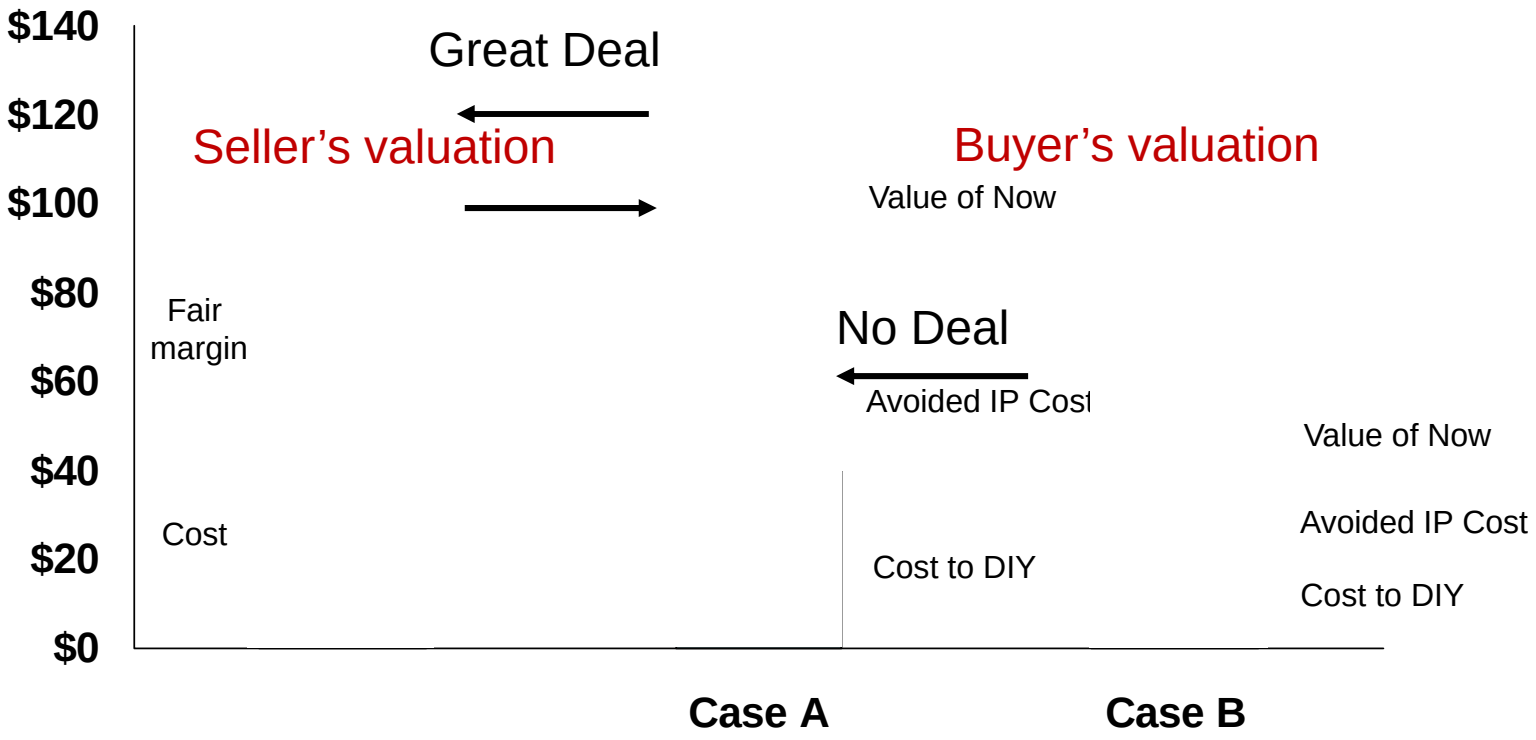
Cost Driven Negotiation



Source: Richard Razgaitis

Example of a Cost-Based Valuation

- 2006 “Venture Philanthropy” deal between CombinatoRx and Cystic Fibrosis Foundation Therapeutics
- HTS for synergistic drug combinations to treat cystic fibrosis
- Terminated May 2009

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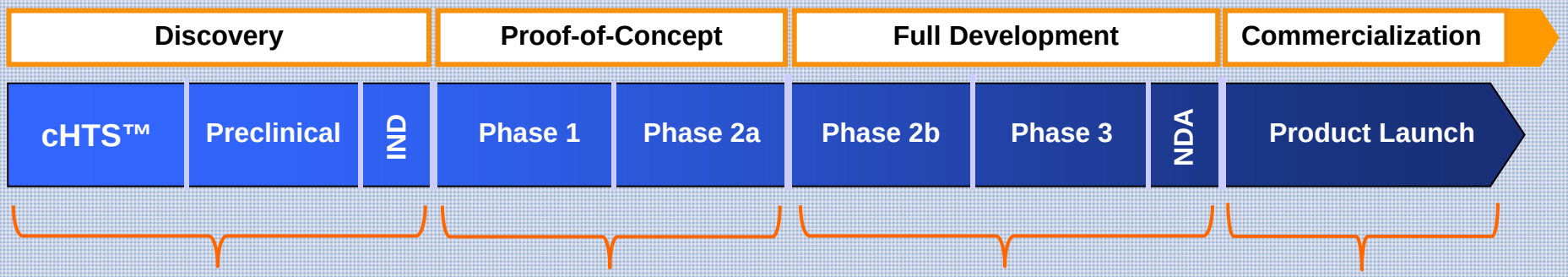
CRXX- CFFT Deal Structure



- $13.8M research funding from CFFT
- CRXX owns all new intellectual property
- CFFT pays 75% of expenses (IND-2a)
- Milestone payment from CFFT to CRXX
- CRXX pays 100% of expenses (2b-NDA)
- Milestone payments from CFFT to CRXX
- CRXX has WW commercial rights
- Royalty payments from CRXX to CFFT

- Funding from bench through patient POC plus 100% commercial rights
- New therapeutic area with focused specialty audience & high unmet need
- Multi-pathway combination sciences approach to CFTR modulation

Look Around – Industry Standards/Comparables

Sources of Comparable Transaction Data

- Probably the most important method for academic licensing.
- Sources of Comparable Transactions
  - Internal database
  - Published surveys
  - Public announcements
  - Word of mouth
  - Litigation
  - Required disclosure

Internal Database

- Licenses previously done by your company
- Trends over time

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Published Surveys

- Relatively few in number
- Most are old
- Best review:
  - Richard Razgaitis in AUTM Licensing Manual, Chapter VII-4
- Three good relatively recent surveys:
  - Degnan and Horton (1996)
  - LES BioPharmaceutical Royalty Rates and Deal Terms Survey (2006)
  - LES Chemicals, Energy, Environmental and Materials (CEEM) Survey (2010)
  - LES High Tech Survey (2011)

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Degnan and Horton

Median Royalty Rates	Pharma	Non-Pharma
Revolutionary	10-15%	5-10%
Major Improvement	5-10%	3-7%
Minor Improvement	2-5%	1-3%

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LES Royalty Rates and Deal Terms Survey

- Members only benefit of LES
- $290 membership dues in 2011
- www.lesusacanada.org/royaltydealssurveys
  - Biopharmaceuticals – 2006, 2008 and 2010
  - Chemicals, Energy, Environmental and Materials (CEEM) – 2010
  - High Tech (2011)

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LES BioPharmaceutical Royalty Rates and Deal Terms Survey – 2010

- Oncology and CNS most prevalent
- 82% were exclusive
- 60% were global
- 2/3rd had expected peak sales <$500 million
- Royalty structure
  - 105 fixed royalties
  - 48 tiered royalties
  - 31 other
    - 4 profit split
    - 27 no royalties

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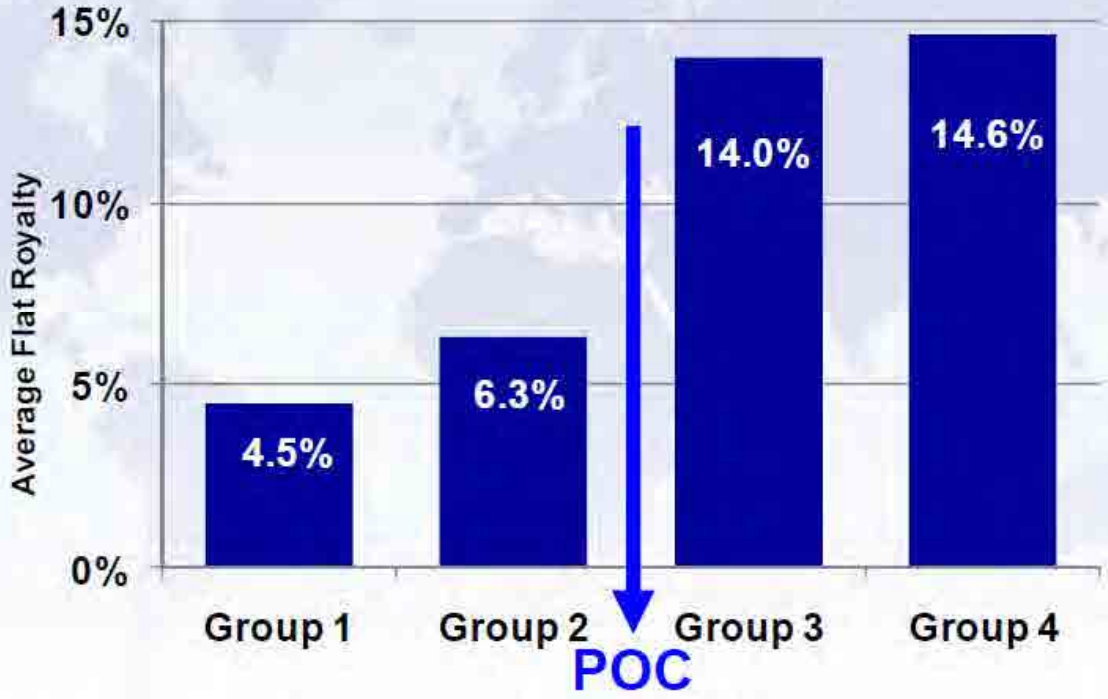
LES BioPharmaceutical Royalty Rates and Deal Terms Survey – 2010

- Deals covered NCE's, platforms, device/drug combos, diagnostics
  - Development stage
  - Divided by route of administration
  - Therapeutic modality

Flat Royalties
Average Royalty by Stage of Development

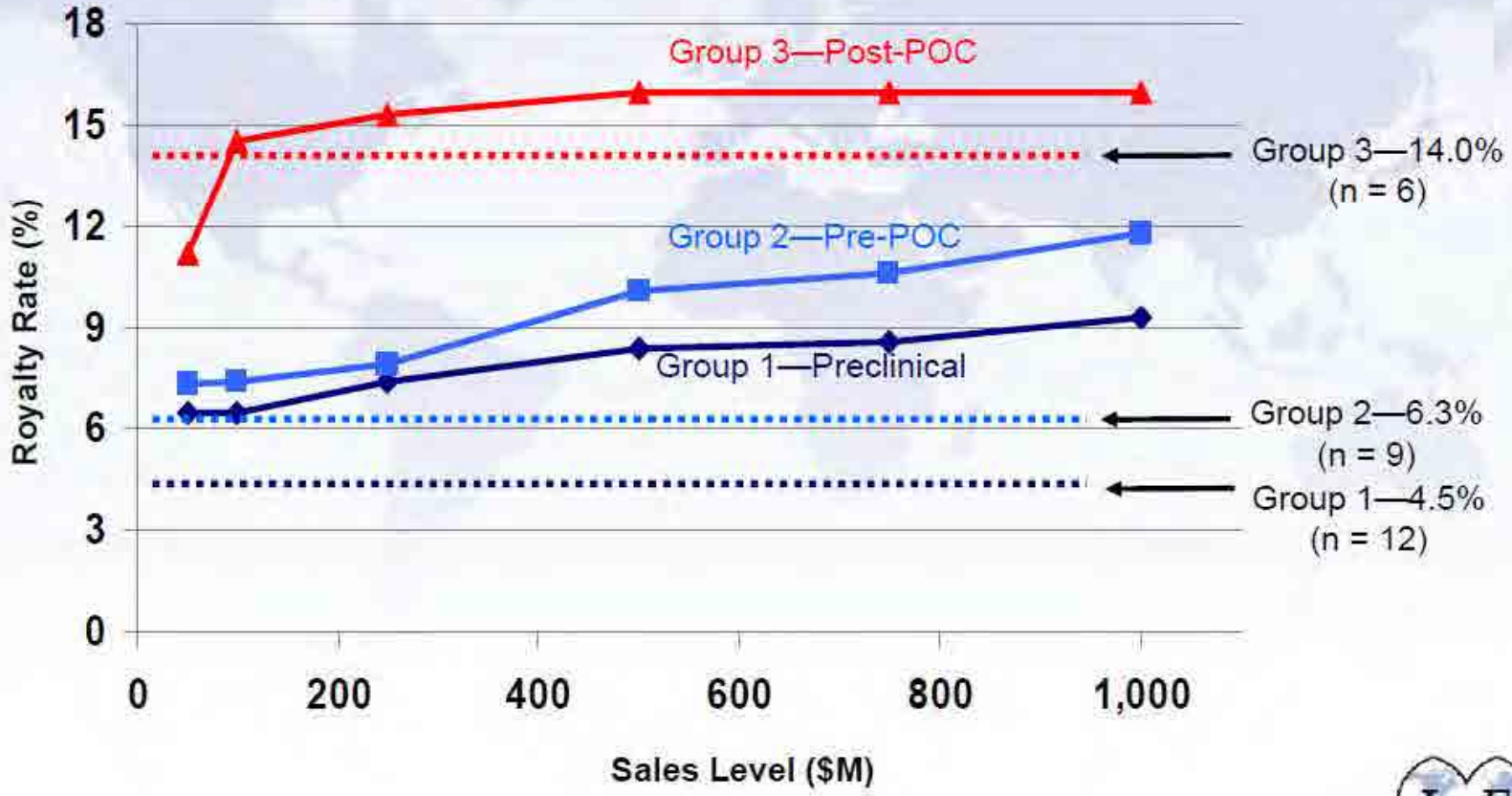
Royalty level increased with stage of development.



	Group 1	Group 2	Group 3	Group 4
No. of deals	27	6	5	7
Median	5%	5%	16%	15%
Min	1%	2%	3%	7%
Max	10%	20%	20%	30%

Flat vs. Tiered Royalties
Stage of Development

Within groups, mean flat royalty levels were below the values for tiered royalties.



LES CEEM Royalty Rates and Deal Terms Survey

- www.lesusacanada.org/royaltyratesurvey
- Technologies
  - Chemicals 52%
  - Energy 28%
  - Materials 14%
  - Environmental 6%

CEEM Key Deal Statistics

- Royalties:
  - Overall average: 5.25%
  - Chemicals 0.13 – 25%, average 5.73%
  - Energy 0.5 –15%, average 4.93%
  - Environmental & materials 0.5 – 7.5%, average 3.67%

- Royalties and stage of development:
  - Existing sales: 4.29%
  - Sales exp. within 1 year: 7.94%
  - Sales exp. within 2 years: 5.15%
  - Sales exp. within 5 years: 4.23%

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Required Disclosure

- Contained in SEC filings
- Company must be public or have filed to go public
- Contained in exhibits to the S1 (IPO), 10K (Annual Report), 10Q (Quarterly Report) or 8K (Material Event)
- Only for “Material” transactions
  - 10% of sales, or
  - 5% of assets
- Can redact commercially sensitive information from public disclosure
  - Redaction has increased since transition to electronic filing
  - Redaction only good for 5 years
    - More later

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Steps

- Identify comparable transactions that would be helpful models
- Determine if the agreement has been filed with SEC
- Find it!
- Other benefits
  - Identifying contractual terms/approaches acceptable to Licensee

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Accessing SEC Filings Yourself

- SEC EDGAR system
  - http://www.sec.gov/edgar/searchedgar/companysearch.html
  - Getting a lot more user friendly
  - Companies phased in, biggest first, January ‘94 - May ‘96
  - For older transactions, current 10K will show when or whether it was filed
- Edgar Online
  - http://pro.edgar-online.com/
  - $1,200 per year – available monthly
  - Formerly offered Free Edgar

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Accessing SEC Filings Yourself

- 10k Wizard (Now Morningstar)
  - www.tenkwizard.com/
  - $240/year for unlimited access
  - Makes finding and looking at exhibits particularly easy

Some Databases to Find Comparables

<u>Technology</u>	
RoyaltySource	royaltysource.com/
Tech Agreements	www.techagreements.com/
RoyaltyStat	www.royaltystat.com/
Business Valuation Resources	www.bvresources.com/
<u>Life Sciences</u>	
Recombinant Capital	www.recap.com/
PharmaDeals	www.pharmadeals.net/
Windhover	www.elsevierbi.com/deals

- All charge – either per agreement ($35) or an annual subscription
- Many just access SEC filings
  - ~12,000 agreements filed

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Tech-Agreements

Contact:
www.techagreements.com

TechAgreements LLC
30 Hancock Street
Lexington, MA 02420

Cost:
$35 per agreement

Comment:
Can search for frr
Preview available, may show you whether redacted
Computer, internet, telecom
Organized by company, industry
Searchable

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- Build, Operate and Transfer Agreements
- Build-to-Suit Agreements

read more...

nversion Agreements

- Debenture Conversion Agreements
- Debt to Equity Conversion Agreements
- Loan Conversion Agreements
- Note Conversion Agreements
- Omnibus Conversion Agreements

read more...

operation Agreements

- Cooperation Agreements
- Business Cooperation Agreements
- Internet Cooperation Agreements
- Technology Cooperation Agreements

rporate Formation Documents

- Articles of Incorporation
- Articles of Organization
- Corporate Bylaws
- Formation Agreements

rivative Agreements

- All Derivative Agreements
- Index Agreements
- ISDA Credit Support Annex
- ISDA Master Agreements (Local Currency - Single Jurisdiction)

read more...

velopment Agreements

- Development Agreements
- Chip Design Agreements
- Drilling Agreements
- Drug Development Agreements

- Hazardous Materials Indemnification

Insurance

- Co-Insurance Agreements
- Insurance Agreements
- Insurance Assignment Agreements
- Key Person Insurance Agreements
- Life Insurance Agreements

read more...

Intellectual Property Agreements

- Copyright Assignment Agreements
- Copyright License Agreements
- Copyright Security Agreements
- Domain Name Assignment Agreements
- Intellectual Property Agreements
- Intellectual Property Matters Agreements
- Intellectual Property Security Agreements
- Intellectual Property Transfer Agreements
- Patent Assignment Agreements
- Patent License Agreements
- Patent Purchase Agreements
- Patent Security Agreements
- Patent Transfer Agreements
- Trademark Assignment Agreements
- Trademark License Agreements
- Trademark Security Agreements

show less...

Internet Agreements

- Ecommerce and Online Services Agreements
- Internet Access Agreements
- Linking Agreements
- Website Acquisition Agreements
- Website Development Agreements

read more...

Joint Ventures

Real Estate Leases

- Cotenancy
- Farm Lease Contracts
- Geothermal Leases
- Ground Leases
- Industrial Leases

read more...

Real Estate Miscellany

- Anchor Tenant Agreements
- Attornment Agreements
- Building Management Agreements
- Easement, Use and Right of Access Agreements

read more...

Real Estate Purchase and Sale

- Building Purchase & Sale Agreements
- Real Estate Purchase and Sale Agreements

Representation Agreements

- Board Representation Agreements
- International Representation Agreements
- Investor Representation Agreements
- Manufacturer Representation Agreements
- Sales Representative Agreements

Research Agreements

- All Research Agreements by Industry
- Clinical Research Agreements
- Clinical Trial Agreements
- Collaborative Research Agreements
- Feasibility Agreements

read more...

Retainer Agreements

Refine your search

GaN | Electronics and Miscellaneous T | [All Governing Laws] | GO

Filter by company or law firm

Company: Top 300 Companies Top 3,000 Companies

Law Firm: [All Law Firms]

Top 300 Law Firms

Search Results

Search Term: GaN, Industry: Electronics and Miscellaneous Technology
Displaying results 1-20 of 21

Page 1 2 Next >>

Agreement Matches

Siemens Ag / Cree Research - Osram Purchase Agreement
... Products supplied under this Agreement will be "GaN LEDs," "InGaN LEDs" and "SiC Wafers" as described in Schedule 3. 2. PURCHASE AND SALE 2.1 Purchase ...

Cree - Purchase Agreement
... Products supplied under this Agreement will be "GaN LEDs," "InGaN LEDs" and "SiC Wafers" as described in Schedule 3. 2. PURCHASE AND SALE 2.1. ...

Cree - Letter Will Serve To Document The Following Agreement
... the parties have reviewed and discussed in good faith [***] and agree to extend the term of Distributor ?s appointment as a distributor of GaN Wafer Products ...

Cree - Amended And Restated Exclusive Supply Agreement
... inventions developed by employees of C3 or acquired by C3 during the term of this Agreement which relate to SiC or gallium nitride (GaN) material, including ...

Industry Matches

Electronics and Miscellaneous Technology
All agreements under the Electronics and Miscellaneous Technology industry sector

Osram Purchase Agreement

Exhibit 10.2

[*] - Certain information omitted and filed separately with the Commission pursuant to a confidential treatment request under Commission Rule 24b-2.

PURCHASE AGREEMENT

between

Recombinant Capital (Deloitte)

San Francisco, CA 94104
(925) 952-3870
www.recap.com/

Two Services

- Recap.com
  - $1,000 per year + $100 per extra seat; $500 set up fee
  - Half price for not-for-profits
  - Database of transactions
  - Fee can be applied to individual transaction documents
    - $200 per transaction ($300 if first to request)
- rDNA.com
  - $15,000 - $26,000 per year depending on number of users
  - Half price for not-for-profits
  - Search results downloadable
  - Access to full text of all deals
  - Limited number of “analyzed” deals

Recombinant Capital (Deloitte)

- Price has gone up substantially since acquisition
- Particular strength is going back to SEC and getting unredacted copies after expiration of confidentiality under FOIA

Search Strategies

- No cost
  - Search using TechAgreements (Physical Sciences) or Windhover (Life Sciences)
  - Find agreements using SEC
- Low Cost Life Sciences
  - Search using Recap Basic
  - Get first 5 agreements from Recap; then SEC
- High Cost Life Sciences
  - Search and get agreements using IQ Series by Deloitte

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How Useful Are Older Deals?

- A royalty rate is a royalty rate
- Cash components
  - Adjust for inflation, market size changes, etc.

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Example

- siRNA
- Tools:
  - rDNA.com/Recap.com
  - 10k Wizard

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RECAP by Deloitte

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Deloitte Recap Industry Conferences

2011 BIO International Convention

Deloitte Recap's Lisa Natanson speaks at Session 203 – De-risking the Phase II to Phase III Advancement Decision: Sound Science, Critical Thinking and Weighing Time vs. Cost

Learn More

Deloitte Recap Special Report

Therapeutic Monoclonal Antibodies - Insights, Strategies and Data

How U.S. Biotechnology Companies Pioneered the Path to Clinical, Regulatory and Market Success for Monoclonal Antibodies

Purchase the Report

Recap IQ Series by Deloitte™

Insight into Action

Suite of database modules providing comprehensive biopharma alliance information, deal values, and drug development histories.

Learn More

Webinars

Insight and analysis on topics impacting the Biopharma industry

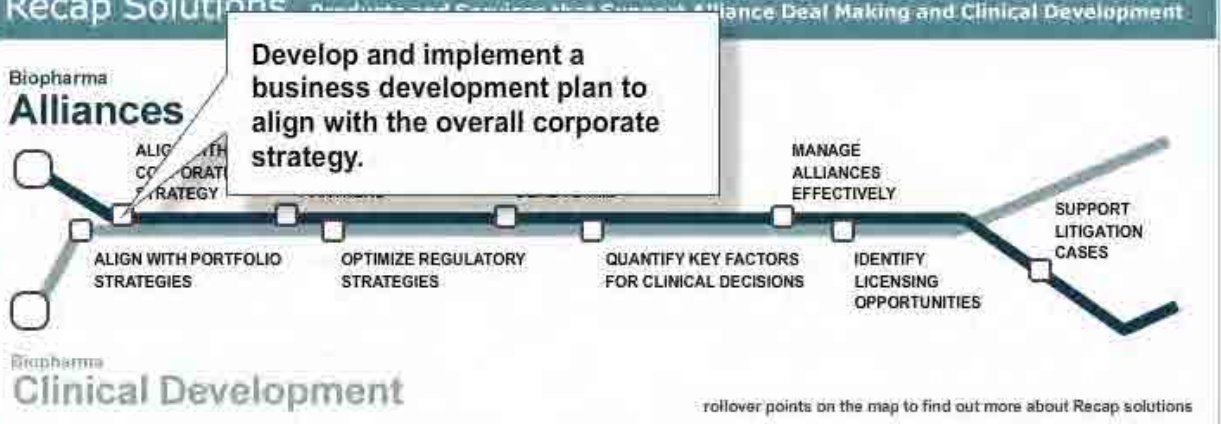
Next Webinar:
August 8, 2011

Topic:
Soon to be annnounced

Register to Attend

Recap Solutions

...iance Deal Making and Clinical Development



rollover points on the map to find out more about Recap solutions

Commentary | Daily Deal | Valuation Trends | Clinical Analytics

Allicense 2011
Deloitte Recap's annual Allicense Conference was held May 3-4 in San Francisco. This year's event brought a wealth of data, cutting-edge insight from analysts and perceptive talks by high-level industry experts in a program themed, "A New Deal for Biotech: Bringing Innovative Financing and Creative Partnering to the Table."
Read the Post-Conference Highlights and Notes

White Paper
Innovative Strategies for Oncology Drug Development
How biotech companies have won a growing share of oncology drug approvals.
Register to receive

Deloitte Recap News
New Deloitte Recap report identifies strategies to help reduce development times and increase success rates for cancer drugs.
Read it

Case Studies
Buy-Side Due Diligence – Potential Deal Encumberments
Learn how milestone payments and post-launch Effective Royalty Rates factor into a company's value.
Register to receive

A Look Back:

10 Deals that Changed Biotech
20 Compounds that Defined Biotech

Consulting:

Alliance Advisory Services

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DEAL builder | VALUATION analyzer | DEVELOPMENT optimizer | Site Search

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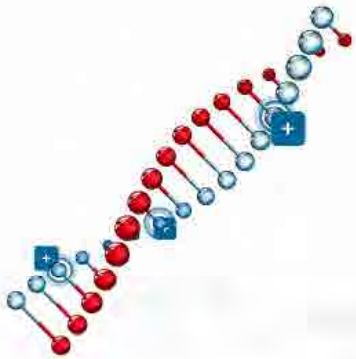
Alliances
Contracts

Intelligent toolkits for biopharmaceutical business intelligence

Introducing the new **Recap IQ Series by Deloitte.** The subscription database products within the new IQ Series provide analytical tools to help Life Sciences companies leverage comprehensive biopharma alliance data, deal values, and drug development histories to support the development of alliance and clinical development strategies.



Support

Each product within the series is designed around specific biopharmaceutical business intelligence research needs to give you the right toolkit for the job. Put the pieces together for a total solution that can help provide information on everything from alliance formation to corporate product development.

For customer support questions or to schedule a product tutorial:

Andrea Chesney
Boston, MA
+1 443 838 1227
achesney@deloitte.com

Inna Shtargot
Walnut Creek, CA
+1 415 599 6218
ishtargot@deloitte.com

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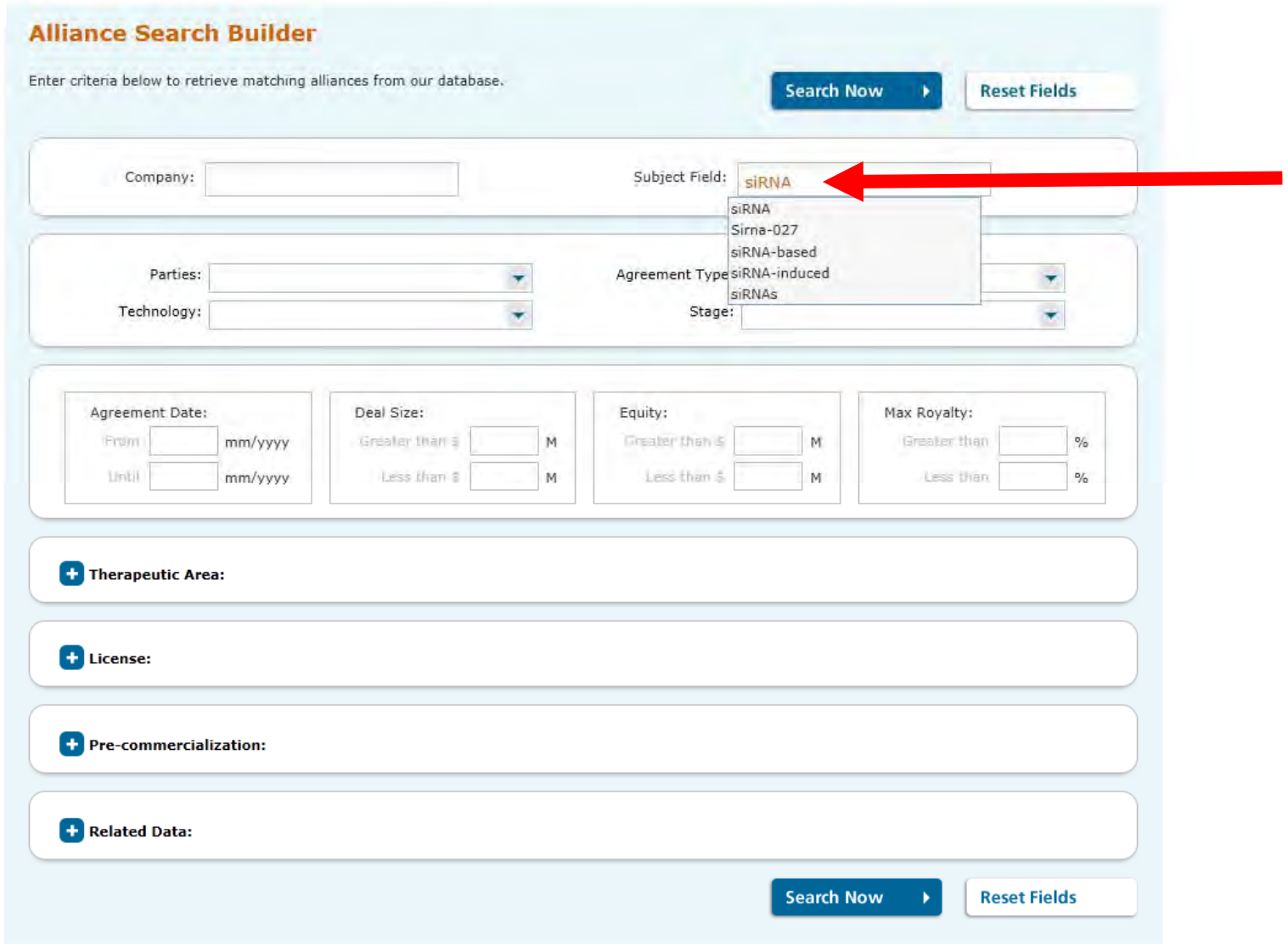
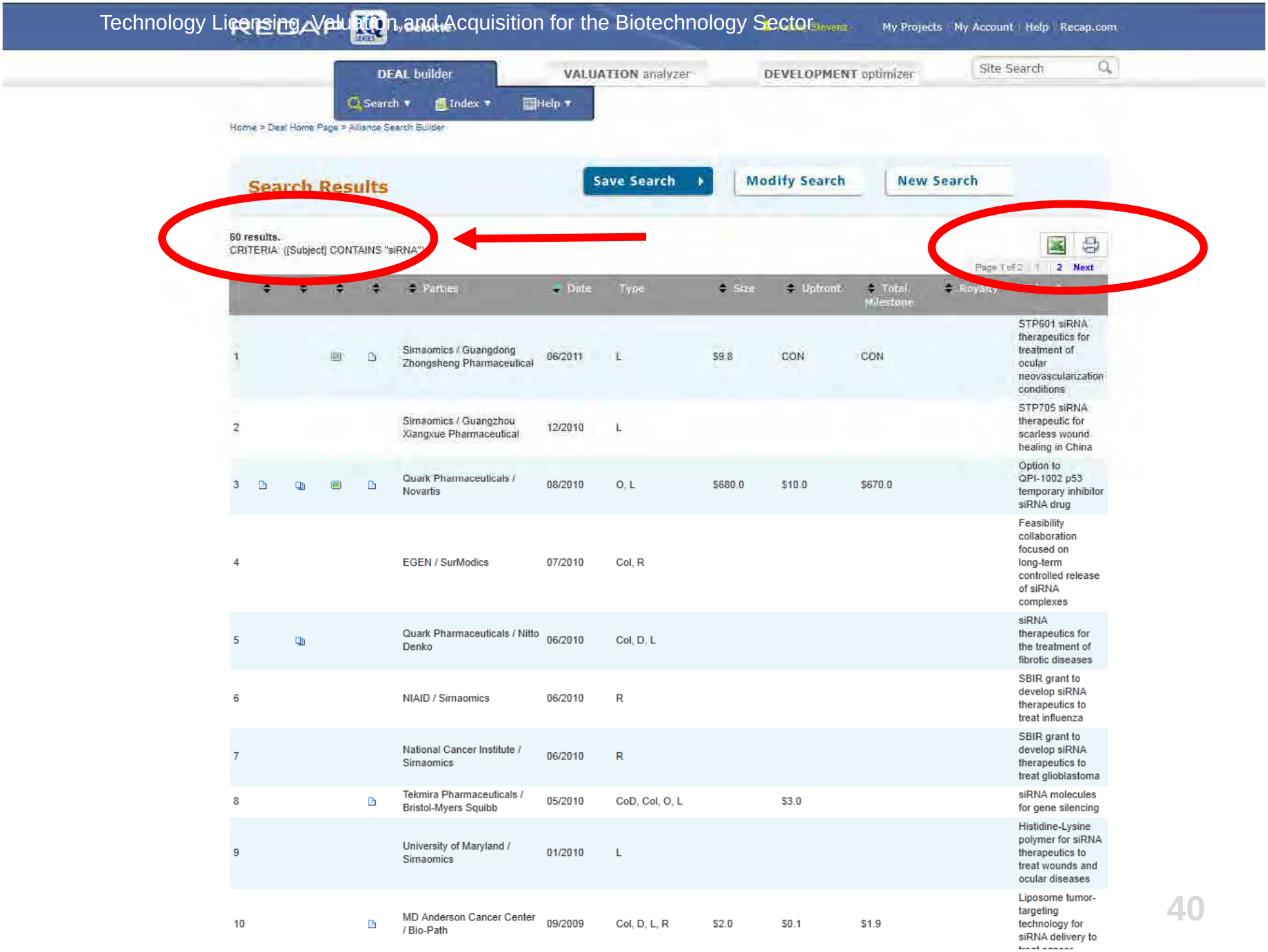


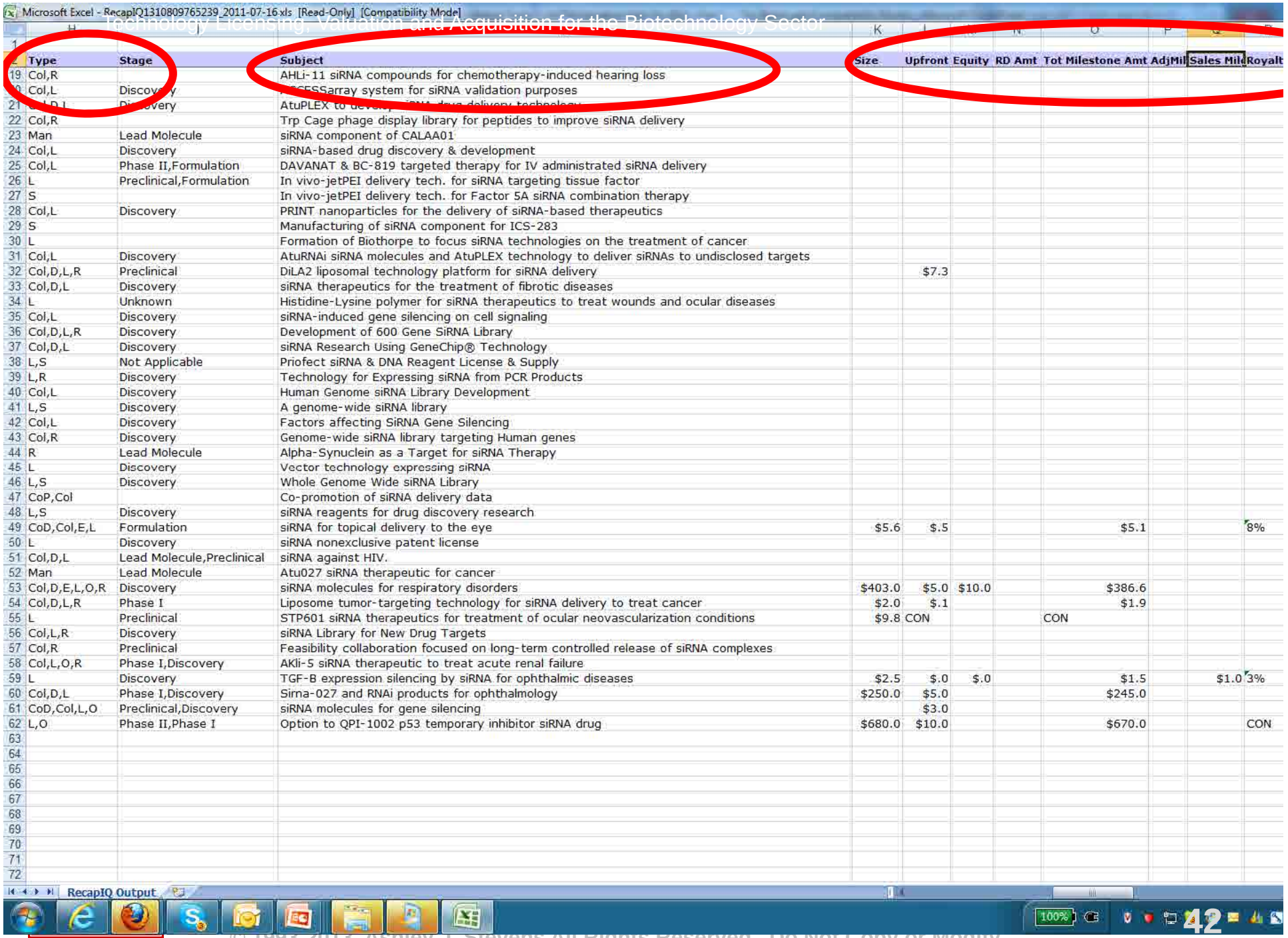


	Parties	Date	Type	Size	Upfront	Total Milestone	Royalty	
1	Sirnaomics / Guangdong Zhongsheng Pharmaceutical	06/2011	L	$9.8	CON	CON		STP601 siRNA therapeutics for treatment of ocular neovascularization conditions
2	Sirnaomics / Guangzhou Xiangxue Pharmaceutical	12/2010	L					STP705 siRNA therapeutic for scarless wound healing in China
3	Quark Pharmaceuticals / Novartis	08/2010	O, L	$680.0	$10.0	$670.0		Option to QPI-1002 p53 temporary inhibitor siRNA drug
4	EGEN / SurModics	07/2010	Col, R					Feasibility collaboration focused on long-term controlled release of siRNA complexes
5	Quark Pharmaceuticals / Nitto Denko	06/2010	Col, D, L					siRNA therapeutics for the treatment of fibrotic diseases
6	NIAID / Sirnaomics	06/2010	R					SBIR grant to develop siRNA therapeutics to treat influenza
7	National Cancer Institute / Sirnaomics	06/2010	R					SBIR grant to develop siRNA therapeutics to treat glioblastoma
8	Tekmira Pharmaceuticals / Bristol-Myers Squibb	05/2010	CoD, Col, O, L		$3.0			siRNA molecules for gene silencing
9	University of Maryland / Sirnaomics	01/2010	L					Histidine-Lysine polymer for siRNA therapeutics to treat wounds and ocular diseases
10	MD Anderson Cancer Center / Bio-Path	09/2009	Col, D, L, R	$2.0	$0.1	$1.9		Liposome tumor-targeting technology for siRNA delivery to

11-07-16.xls [Read-Only] [Compatibility Mode]

e Search Builder Subject: siRNA

act R&D Company	Client Company	Date	Amendment Date	Type	Stage	Subject
National Cancer Institute	Sirnaomics	07/2009		R	Unknown	SBIR grant to develop siRNA therapeutics to treat
National Cancer Institute	Sirnaomics	06/2010		R	Unknown	SBIR grant to develop siRNA therapeutics to treat
NIAID	Sirnaomics	06/2010		R	Unknown	SBIR grant to develop siRNA therapeutics to treat
Sirnaomics	Guangzhou Xiangxue Pharmaceutical	12/2010		L	Preclinical	STP705 siRNA therapeutic for scarless wound heali
Dharmacon	Wyeth	09/2004		S		siRNA reagents to genomic research operations
Exiqon	Applied Biosystems	11/2007		L		Locked Nucleic Acids in siRNA
Carnegie Institute	SABiosciences	11/2007		L	Discovery	siRNA nonexclusive patent license
Qiagen	AstraZeneca	07/2004		S		siRNA Molecules Supply
City of Hope	Dicerna Pharmaceuticals	11/2007		L		dsDNA processed in situ into siRNA by means of hu
Ambion	Applied Biosystems	01/2004		CoM		siRNA and Real-Time PCR Products
TNO Pharma	Mitsubishi Pharma	09/2005		Col,L	Discovery	siRNA-based Knock Down Technology
University of Michigan	Quark Pharmaceuticals	09/2007		Col,D,L	Preclinical	SiRNA Compounds for Noise-Induced Hearing Loss
ZaBeCor	Acuity Pharmaceuticals	04/2006		L,O	Lead Molecule	Excellair anti-Inflammatory siRNA for Ophthamalic u
BioFocus	Upstate, Serologicals, Millipore	05/2006		Di,L	Lead Molecule	siRNA based adenoviral reagents ex Japan
Integrated DNA Technologies	Bio-Rad	07/2006		Col,D,L		Dicer-Substrate siRNA duplexes
Atugen	Aventis	09/2004		Col,L	Discovery	siRNA Compounds
State University of New York	Quark Pharmaceuticals	08/2007		Col,R		AHLi-11 siRNA compounds for chemotherapy-induc
ExpressOn BioSystems	AstraZeneca	08/2004		Col,L	Discovery	ACCESSarray system for siRNA validation purposes
Silence Therapeutics	AstraZeneca	03/2008		Col,D,L	Discovery	AtuPLEX to develop siRNA drug delivery technology
University of Helsinki	Marina Biotech	11/2008		Col,R		Trp Cage phage display library for peptides to impr
Agilent Technologies	Calando Pharmaceuticals	07/2006		Man	Lead Molecule	siRNA component of CALAA01
Thermo Fisher Scientific	Genentech	11/2008		Col,L	Discovery	siRNA-based drug discovery & development
Galectin Therapeutics	BioCancell Therapeutics	05/2008		Col,L	Phase II,Formulation	DAVANAT & BC-819 targeted therapy for IV admini
Polyplus-transfection	SiRNAsense	06/2008		L	Preclinical,Formulation	In vivo-jetPEI delivery tech. for siRNA targeting tis
Polyplus-transfection	Senesco Technologies	07/2008		S		In vivo-jetPEI delivery tech. for Factor 5A siRNA c
Liquidia Technologies	Abbott	01/2009		Col,L	Discovery	PRINT nanoparticles for the delivery of siRNA-base
Agilent Technologies	Intradigm	06/2007		S		Manufacturing of siRNA component for ICS-283
ZaBeCor	Biothorpe Pharmaceuticals	09/2008		L		Formation of Biothorpe to focus siRNA technologies
Silence Therapeutics	Dainippon Sumitomo Pharma	08/2009		Col,L	Discovery	AtuRNAi siRNA molecules and AtuPLEX technology t
Marina Biotech	Novartis	03/2009		Col,D,L,R	Preclinical	DiLA2 liposomal technology platform for siRNA deliv
Quark Pharmaceuticals	Nitto Denko	06/2010		Col,D,L	Discovery	siRNA therapeutics for the treatment of fibrotic dis
University of Maryland	Sirnaomics	01/2010		L	Unknown	Histidine-Lysine polymer for siRNA therapeutics to
Dharmacon	Odyssey Thera	09/2003		Col,L	Discovery	siRNA-induced gene silencing on cell signaling
Dharmacon	Exelixis	06/2003		Col,D,L,R	Discovery	Development of 600 Gene SiRNA Library
Affymetrix	Qiagen	10/2003		Col,D,L	Discovery	siRNA Research Using GeneChip® Technology
Dendritic Nanotechnologies	EMD Biosciences	02/2007		L,S	Not Applicable	Priofect siRNA & DNA Reagent License & Supply
City of Hope	Ambion	07/2003		L,R	Discovery	Technology for Expressing siRNA from PCR Products
Cenix BioScience	Ambion	03/2003	08/2003	Col,L	Discovery	Human Genome siRNA Library Development
Qiagen	Novartis	08/2003		L,S	Discovery	A genome-wide siRNA library
Rosetta Inpharmatics	Dharmacon	10/2003		Col,L	Discovery	Factors affecting SiRNA Gene Silencing
MitoCheck Consortium	Ambion	07/2005		Col,R	Discovery	Genome-wide siRNA library targeting Human genes
Mayo Foundation	Alnylam Pharmaceuticals	10/2003		R	Lead Molecule	Alpha-Synuclein as a Target for siRNA Therapy
University of Massachusetts	Ambion	11/2002		L	Discovery	Vector technology expressing siRNA
Dharmacon	Millennium	05/2005		L,S	Discovery	Whole Genome Wide siRNA Library
Amaxa	Dharmacon	06/2006		CoP,Col		Co-promotion of siRNA delivery data
Dharmacon	Genentech	01/2005		L,S	Discovery	siRNA reagents for drug discovery research
Intradigm	Acuity Pharmaceuticals	06/2005		CoD,Col,E,L	Formulation	siRNA for topical delivery to the eye
Carnegie Institute	Marina Biotech	02/2004		L	Discovery	siRNA nonexclusive patent license
irsiCaixa Foundation	CombiMatrix	07/2004		Col,D,L	Lead Molecule,Preclinical	siRNA against HIV.
Genzyme, BioSpring, OctoPlus	Atugen	06/2006		Man	Lead Molecule	Atu027 siRNA therapeutic for cancer
Silence Therapeutics	AstraZeneca	07/2007		Col,D,E,L,O,R	Discovery	siRNA molecules for respiratory disorders
MD Anderson Cancer Center	Bio-Path	09/2009		Col,D,L,R	Phase I	Liposome tumor-targeting technology for siRNA deli
Sirnaomics	Guangdong Zhongsheng Pharmaceutical	06/2011		L	Preclinical	STP601 siRNA therapeutics for treatment of ocular
Dharmacon	Abbott	07/2003		Col,L,R	Discovery	siRNA Library for New Drug Targets



	Type	Stage	Subject	Size	Upfront	Equity	RD Amt	Tot Milestone Amt	AdjMil	Sales Mil	Royalt
19	Col,R		AHLi-11 siRNA compounds for chemotherapy-induced hearing loss								
20	Col,L	Discovery	ACCESSarray system for siRNA validation purposes								
21	Col,D,L	Discovery	AtuPLEX to develop siRNA drug delivery technology								
22	Col,R		Trp Cage phage display library for peptides to improve siRNA delivery								
23	Man	Lead Molecule	siRNA component of CALAA01								
24	Col,L	Discovery	siRNA-based drug discovery & development								
25	Col,L	Phase II,Formulation	DAVANAT & BC-819 targeted therapy for IV administrated siRNA delivery								
26	L	Preclinical,Formulation	In vivo-jetPEI delivery tech. for siRNA targeting tissue factor								
27	S		In vivo-jetPEI delivery tech. for Factor 5A siRNA combination therapy								
28	Col,L	Discovery	PRINT nanoparticles for the delivery of siRNA-based therapeutics								
29	S		Manufacturing of siRNA component for ICS-283								
30	L		Formation of Biothorpe to focus siRNA technologies on the treatment of cancer								
31	Col,L	Discovery	AtuRNAi siRNA molecules and AtuPLEX technology to deliver siRNAs to undisclosed targets								
32	Col,D,L,R	Preclinical	DiLA2 liposomal technology platform for siRNA delivery		$7.3						
33	Col,D,L	Discovery	siRNA therapeutics for the treatment of fibrotic diseases								
34	L	Unknown	Histidine-Lysine polymer for siRNA therapeutics to treat wounds and ocular diseases								
35	Col,L	Discovery	siRNA-induced gene silencing on cell signaling								
36	Col,D,L,R	Discovery	Development of 600 Gene SiRNA Library								
37	Col,D,L	Discovery	siRNA Research Using GeneChip® Technology								
38	L,S	Not Applicable	Priofect siRNA & DNA Reagent License & Supply								
39	L,R	Discovery	Technology for Expressing siRNA from PCR Products								
40	Col,L	Discovery	Human Genome siRNA Library Development								
41	L,S	Discovery	A genome-wide siRNA library								
42	Col,L	Discovery	Factors affecting SiRNA Gene Silencing								
43	Col,R	Discovery	Genome-wide siRNA library targeting Human genes								
44	R	Lead Molecule	Alpha-Synuclein as a Target for siRNA Therapy								
45	L	Discovery	Vector technology expressing siRNA								
46	L,S	Discovery	Whole Genome Wide siRNA Library								
47	CoP,Col		Co-promotion of siRNA delivery data								
48	L,S	Discovery	siRNA reagents for drug discovery research								
49	CoD,Col,E,L	Formulation	siRNA for topical delivery to the eye	$5.6	$.5			$5.1			8%
50	L	Discovery	siRNA nonexclusive patent license								
51	Col,D,L	Lead Molecule,Preclinical	siRNA against HIV.								
52	Man	Lead Molecule	Atu027 siRNA therapeutic for cancer								
53	Col,D,E,L,O,R	Discovery	siRNA molecules for respiratory disorders	$403.0	$5.0	$10.0		$386.6			
54	Col,D,L,R	Phase I	Liposome tumor-targeting technology for siRNA delivery to treat cancer	$2.0	$.1			$1.9			
55	L	Preclinical	STP601 siRNA therapeutics for treatment of ocular neovascularization conditions	$9.8	CON			CON			
56	Col,L,R	Discovery	siRNA Library for New Drug Targets								
57	Col,R	Preclinical	Feasibility collaboration focused on long-term controlled release of siRNA complexes								
58	Col,L,O,R	Phase I,Discovery	AKli-5 siRNA therapeutic to treat acute renal failure								
59	L	Discovery	TGF-B expression silencing by siRNA for ophthalmic diseases	$2.5	$.0	$.0		$1.5		$1.0	3%
60	Col,D,L	Phase I,Discovery	Sirna-027 and RNAi products for ophthalmology	$250.0	$5.0			$245.0			
61	CoD,Col,L,O	Preclinical,Discovery	siRNA molecules for gene silencing		$3.0						
62	L,O	Phase II,Phase I	Option to QPI-1002 p53 temporary inhibitor siRNA drug	$680.0	$10.0			$670.0			CON

									cancer
18		Polyplus-transfection / Senesco Technologies	07/2008	S					In vivo-jetPEI delivery tech. for Factor 5A siRNA combination therapy
19		Polyplus-transfection / SiRNAsense	06/2008	L					In vivo-jetPEI delivery tech. for siRNA targeting tissue factor
20		Galectin Therapeutics / BioCancell Therapeutics	05/2008	Col, L					DAVANAT & BC-819 targeted therapy for IV administrated siRNA delivery
21		Silence Therapeutics / AstraZeneca	03/2008	Col, D, L					AtuPLEX to develop siRNA drug delivery technology
22		Exiqon / Applied Biosystems	11/2007	L					Locked Nucleic Acids in siRNA
23		Carnegie Institute / SABiosciences	11/2007	L					siRNA nonexclusive patent license
24		City of Hope / Dicerna Pharmaceuticals	11/2007	L					dsDNA processed in situ into siRNA by means of human Dicer enzyme
25		University of Michigan / Quark Pharmaceuticals	09/2007	Col, D, L					SiRNA Compounds for Noise-Induced Hearing Loss
26		State University of New York / Quark Pharmaceuticals	08/2007	Col, R					AHLi-11 siRNA compounds for chemotherapy-induced hearing loss
27		Silence Therapeutics / AstraZeneca	07/2007	Col, D, E, L, O, R	$403.0	$5.0	$386.6		siRNA molecules for respiratory disorders
28		Agilent Technologies / Intradigm	06/2007	S					Manufacturing of siRNA component for ICS-283
29		Dendritic Nanotechnologies / EMD Biosciences	02/2007	L, S					Priofect siRNA & DNA Reagent License & Supply
30		University of Illinois / Acuity Pharmaceuticals	08/2006	L	$2.5	$0.0	$1.5	3.0%	TGF-B expression silencing by siRNA for ophthalmic diseases
31		Integrated DNA Technologies / Bio-Rad	07/2006	Col, D, L					Dicer-Substrate siRNA duplexes
32		Agilent Technologies / Calando Pharmaceuticals	07/2006	Man					siRNA component of CALAA01
33		Amaxa / Dharmacon	06/2006	CoP, Col					Co-promotion of siRNA delivery data
34		Genzyme, BioSpring, OctoPlus / Atugen	06/2006	Man					Atu027 siRNA therapeutic for cancer
35		BioFocus / Upstate, Serologicals, Millipore	05/2006	Di, L					siRNA based adenoviral reagents ex Japan
									Excellair

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Home > Deal Home Page > Alliance Search Builder > Alliance Summary

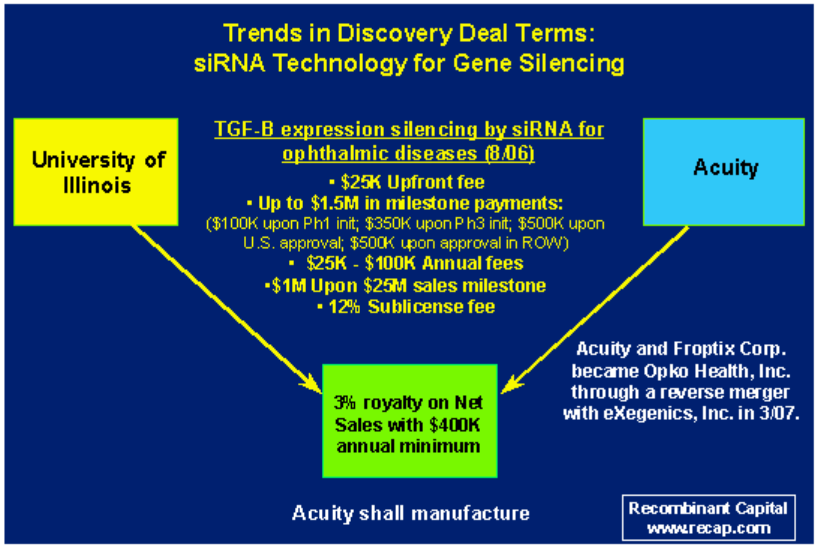
Alliance Summary

R&D Company:	University of Illinois	**R&D Parent:**	
Client Company:	Acuity Pharmaceuticals	**Client Parent:**	Opko Health

Date: 08/2006
Parties: University / Biotech
Type: License
Subject:
TGF-B expression silencing by siRNA for ophthalmic diseases

Size:	$ 2.5 M	**Therapeutic Area:**	Ophthalmic Broad Focus Ophthalmic
Equity:	$ 0 M	**Technology:**	Gene Expression, Oligonucleotides - Ribozymes
Max. Royalty:	3 %	**Stage (at signing):**	Discovery

SNAPSHOT:



LICENSE

Exclusivity:	Exclusive	**Licensed Territory:**	Worldwide

Contract Analysis

R&D Company:	University of Illinois	**R&D Parent:**	
Client Company:	Acuity Pharmaceuticals	**Client Parent:**	Opko Health
Agreement Date:	08/2006		
Alliance Summary:	Open parent Alliance Summary		

Related Contracts:

Agreement	Contract type	Contract date	pdf	Refile
University of Illinois / Acuity Pharmaceuticals (08/2006)	License	08/2006		

I. Research & Development

A. Scope of the Agreement
On 8/3/2006 ("Effective Date"), the University of Illinois (the "University") and Acuity Pharmaceuticals, Inc. ("Acuity") entered into a license agreement ("Agreement") to develop treatments for ophthalmic diseases based on TGF-beta receptor expression silencing by siRNA. [On 3/27/2007, Acuity and Froptix Corporation ("Froptix"), both privately owned, became Opko Health, Inc. ("Opko") through a reverse merger with publicly-traded eXegenics, Inc. (see Separate Deal Background -- Opko / Acuity, Froptix 3/07).]

B. Research Period
N/A

C. Cost Sharing & Reimbursement Basis
N/A

D. Upfront Payment
Acuity shall pay the University a $25K license fee within 3 business days of the Effective Date.

E. Benchmark Amounts
Acuity shall pay the University the following one-time milestone payments upon the first achievement of the following development milestone events: (1) $100K upon the initiation of phase I; (2) $350K upon the initiation of phase III; (3) $500K upon approval in the U.S.; and (4) $500K upon approval outside the U.S. Acuity shall pay the University a sales milestone of $1M upon reaching the first $25M in commercial sales of the Licensed Product (see Section II.A.).

F. Technology Acquisition Fees
N/A

G. Payment Schedule
N/A

H. Budgets
No

I. Reimbursement Start Date:
N/A

J. Regulatory Filings
All by Acuity.

K. Special Capital Requirements
None

L. Patent Ownership
The University shall not be obliged to provide Acuity or its sublicensees with any updates to the Technical Information. "Technology" shall mean the Inventions, Licensed Patents, and Technical Information, collectively. "Inventions" shall mean all devices, machines, methods, processes, manufactures, compositions of matter and uses, and Technical Information, contained in the disclosure entitled "CW081 Silencing of TGF-beta Receptor Expression by siRNA." "Licensed Patents" shall mean the following patents and applications owned by the University including any continuations, reissues, or foreign

Contract

R&D:	University of Illinois	**R&D Parent:**	
Client:	Acuity Pharmaceuticals	**Client Parent:**	Opko Health
Parties:	University / Biotech	**Subject:**	TGF-B expression silencing by siRNA for ophthalmic diseases
Alliance Summary:	Open parent Alliance Summary		

Alliance Type:	License	**Date:**	08/2006
		Revision:	

Contract Type:	License	**Filing Date:**	08/2006

CONTENT: EX-10.8 8 g06337exv10w8.htm EX-10.8 TECHNOLOGY LICENSE AGREEMENT

EXHIBIT 10.8

TECHNOLOGY LICENSE AGREEMENT

License Agreement ("**Agreement**"), effective as of August 3, 2006 between THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, (the "**University**"), and ACUITY PHARMACEUTICALS, INC., a Delaware corporation, having its principle place of business at 3701 Market Street, Philadelphia, PA, 19104 ("**Licensee**" or "**Acuity**").

Preliminary Statement

University holds certain rights to the Technology described below and desires to have the Technology commercialized. Licensee wishes to obtain the right to use the Technology for commercial purposes. Therefore, in consideration of the mutual obligations set forth below and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, University and Licensee agree as follows.

ARTICLE I
DEFINITIONS

The following capitalized terms are used in this Agreement with the following meanings:

1.1. "**Effective Date**" means August 3, 2006.

1.2. **"FDA"** means the United States Food and Drug Administration, or any successor thereto.

1.3. "**IND**" means an "investigational new drug application" as defined by the United States Food, Drug, and Cosmetic Act, as amended (the "Act"), and applicable FDA rules and regulations or a foreign equivalent.

1.4. **"Inventions"** means all devices, machines, methods, processes, manufactures, compositions of matter and uses, and Technical Information, contained in the disclosure entitled "CW081 Silencing of TGF ß Receptor Expression by SiRNA."

1.5. "**Licensed Field**" means the inhibition of and treatment of ophthalmic disease.

1.6. "**Licensed Patents**" means (a) the patents and patent applications listed on Schedule 1 and any continuations, divisionals, reissues, renewals, re-examinations, foreign counterparts, or substitutions of or to the above.

1.7. "**Licensed Product**" means any product or process or license for information, in the Field of Use, that is distributed by Licensee that is covered by any of the University's rights in the Technology.

1.8. **"NDA"** means a "new drug application," as defined in the Act and applicable FDA rules and regulations, including an application of the type described in section 505(b)(2) of the Act.

obligation to provide Licensee or any Sublicensee with any updates of or additional Technical Information owned, controlled or in the possession of any of them.

ARTICLE III
PAYMENTS

3.1. **Royalties and Reimbursements**. For the licenses granted in Section 2.1 of this Agreement, Licensee shall:

(a) within three (3) business days of the execution of this Agreement, pay University a non-refundable licensing fee in the amount of $25,000;

(b) within thirty (30) days of the first and second anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $25,000;

(c) within thirty (30) days of the third anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $50,000;

(d) within thirty (30) days of the fourth anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $50,000;

(e) within thirty (30) days of the fifth anniversary of the Effective Date and each subsequent anniversary thereafter until the Licensee receives NDA approval on its first Licensed Product, pay University an annual non-refundable licensing fee in the amount of $100,000;

(f) pay University a Royalty equal to three percent (3%) of Net Sales of Licensed Products sold, leased, rented, licensed or otherwise distributed by Licensee during the term of this Agreement, if any. If no valid claim of any issued patent among the Licensed Patents covers the Licensed Products in a country of the Territory, then the royalties shall be reduced to one and one-half percent (1.5%) of Net Sales of Licensed Products sold, leased, rented, licensed or otherwise distributed by Licensee in such country of the Territory.

3.2. **Milestones and Milestone Payments**. Licensee agrees to make the milestone payments to University as set forth below (the "**Milestone Payments**") within forty-five (45) days after the occurrence of each event set forth on such Schedule.

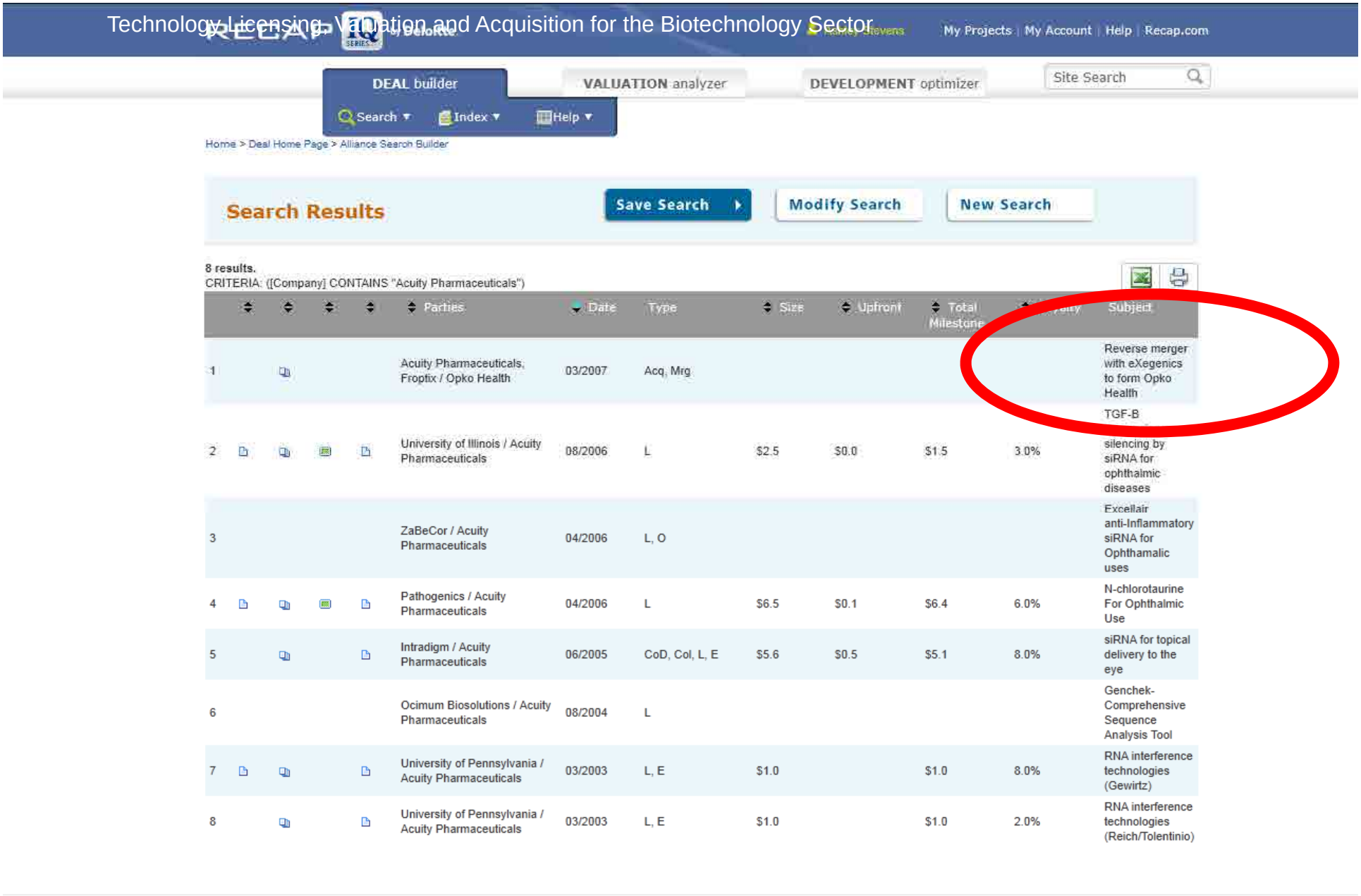
Milestone		**Payment**
First Phase I Clinical Trial initiated	$	100,000
First Phase III Clinical Trial initiated	$	350,000
First NDA Approval in the U.S	$	500,000
First NDA Equivalent Approval outside of US	$	500,000
Upon first $25,000,000 of commercial sales of any Licensed Products	$	1,000,000

Each of the foregoing payments shall be made only once. Thereafter, no additional Milestone Payments shall be due or payable by Licensee for License Products.

3.3. **Calculations and Payment of Royalties.**

(a) Royalties shall be paid in quarterly increments (the "Royalty Period"). Royalties shall be calculated for each Royalty Period as of the last day of each such Royalty Period. Payment of Royalties with respect to each Royalty Period shall be due within sixty (60) days after the end of Royalty Period, beginning with the earlier of (i) the Royalty Period in which the first sale of a Licensed Product occurs, or (ii) the Royalty Period for which Annual Minimum Royalties are due.

(b) Within sixty (60) days of the end of each Royalty Period (whether or not Royalties are due), Licensee shall deliver to University a true and complete accounting of sales or distributions of any Licensed Product and revenues from those sales by Licensee and its Sublicensees for each country of sales origin during such Royalty Period and deductions taken, with a separate accounting for each Licensed Product of sales and receipts by country, and a detailed calculation of the Royalty payment due University for such Royalty Period, in each case in form and



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8 results.
CRITERIA: ([Company] CONTAINS "Acuity Pharmaceuticals")

	Parties	Date	Type	Size	Upfront	Total Milestone	Royalty	Subject
1	Acuity Pharmaceuticals, Froptix / Opko Health	03/2007	Acq, Mrg					Reverse merger with eXegenics to form Opko Health
2	University of Illinois / Acuity Pharmaceuticals	08/2006	L	$2.5	$0.0	$1.5	3.0%	TGF-B silencing by siRNA for ophthalmic diseases
3	ZaBeCor / Acuity Pharmaceuticals	04/2006	L, O					Excellair anti-Inflammatory siRNA for Ophthamalic uses
4	Pathogenics / Acuity Pharmaceuticals	04/2006	L	$6.5	$0.1	$6.4	6.0%	N-chlorotaurine For Ophthalmic Use
5	Intradigm / Acuity Pharmaceuticals	06/2005	CoD, Col, L, E	$5.6	$0.5	$5.1	8.0%	siRNA for topical delivery to the eye
6	Ocimum Biosolutions / Acuity Pharmaceuticals	08/2004	L					Genchek-Comprehensive Sequence Analysis Tool
7	University of Pennsylvania / Acuity Pharmaceuticals	03/2003	L, E	$1.0		$1.0	8.0%	RNA interference technologies (Gewirtz)
8	University of Pennsylvania / Acuity Pharmaceuticals	03/2003	L, E	$1.0		$1.0	2.0%	RNA interference technologies (Reich/Tolentinio)

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Filings Search

SEARCH RESET PREFERENCES

Identifier Company Name: OPKO HEALTH, INC. — Begins with / Contains

Keywords 0/255 characters

Focus Search

Date From: Jan 1 200 — To: Oct 17 201 — Period Ending: Mont Day Year

All Dates

Geography

Filer Location: City

State of Incorporation: [State], Alabama, Alaska

Filing Agent: City

Categories

Exchange: Select All, Nasdaq Capital Market, Nasdaq Global Market

Index: Select All, Morningstar US Market, Morningstar US Core TR

Accelerated Status: Select All

Peer Groups

Financial All Items >= ADD CRITERIA

Industry Industries Industry Lookup — Standard Industrial Code SIC Lookup

All Industries
Basic Materials
Chemicals
Chemicals - Major Diversified
Synthetics

Forms Enter Form Form Lookup — Form Sections: 10K Items

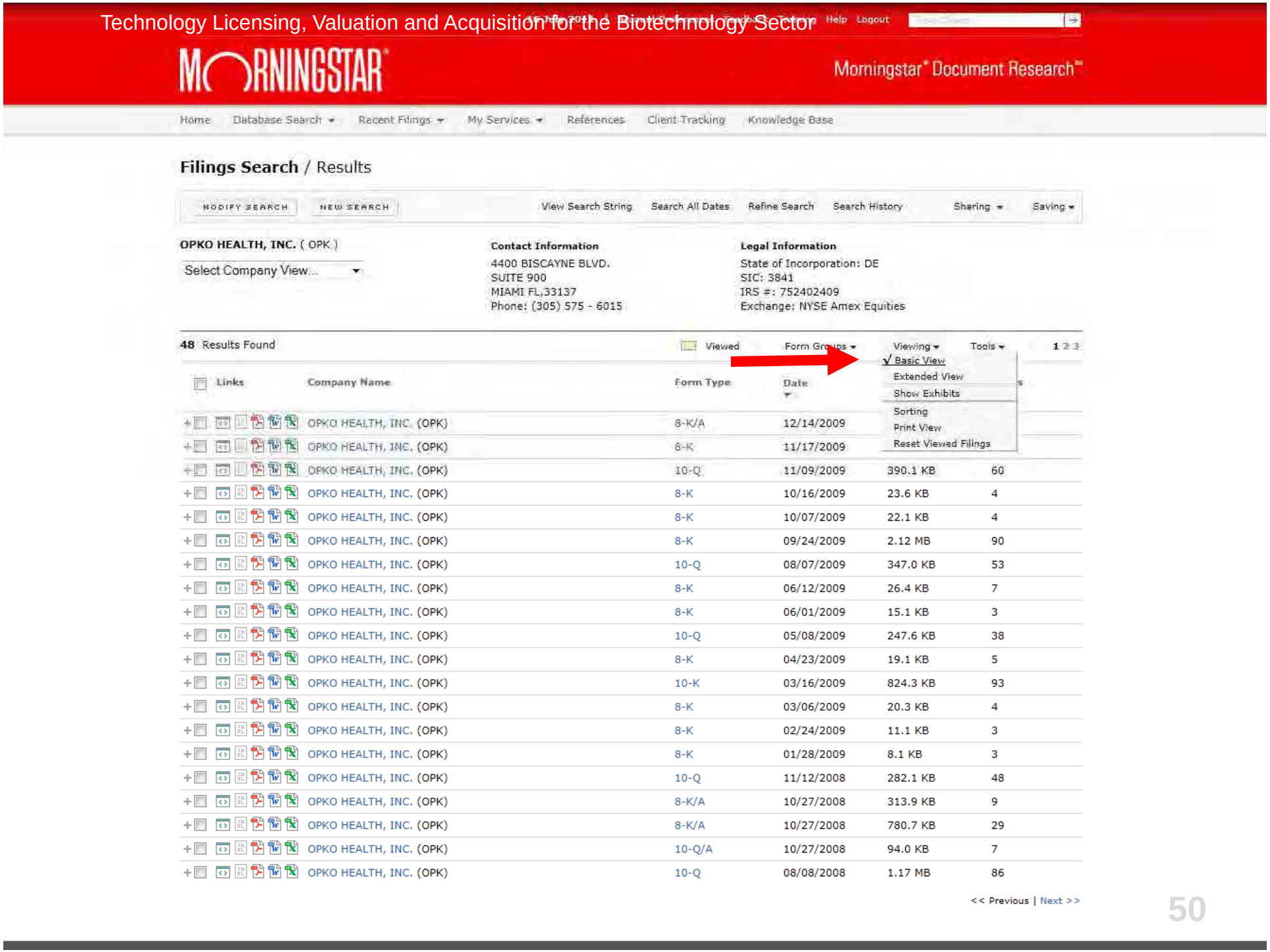
Form Groups Group Lookup

10-K & 10-Q Related
10-K Related
10-K,10-Q,8-K,144
10-K,10-Q,8-K,6-K,DE
10-Q Related

10K Part I
10K Part II
10K Part III

Do not include

SEARCH RESET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Select Company View...
Contact Information
4400 BISCAYNE BLVD.
SUITE 900
MIAMI FL,33137
Phone: (305) 575 - 6015
Legal Information
State of Incorporation: DE
SIC: 3841
IRS #: 752402409
Exchange: NYSE Amex Equities
48 Results Found
Viewed
Form Groups
Viewing
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Basic View
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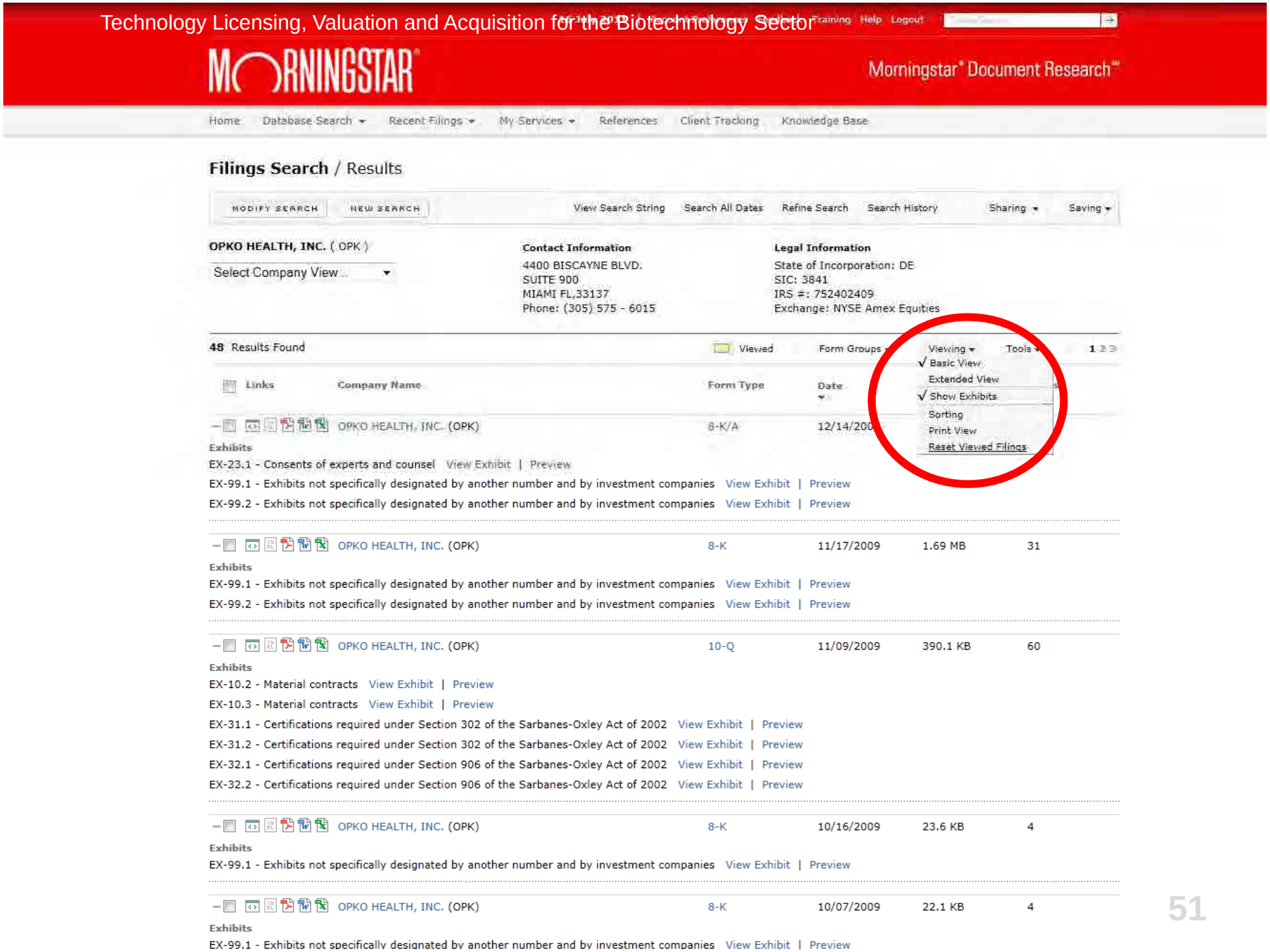
OPKO HEALTH, INC. (OPK) 8-K 10/16/2009 23.6 KB 4
OPKO HEALTH, INC. (OPK) 8-K 10/07/2009 22.1 KB 4
OPKO HEALTH, INC. (OPK) 8-K 09/24/2009 2.12 MB 90
OPKO HEALTH, INC. (OPK) 10-Q 08/07/2009 347.0 KB 53
OPKO HEALTH, INC. (OPK) 8-K 06/12/2009 26.4 KB 7
OPKO HEALTH, INC. (OPK) 8-K 06/01/2009 15.1 KB 3
OPKO HEALTH, INC. (OPK) 10-Q 05/08/2009 247.6 KB 38
OPKO HEALTH, INC. (OPK) 8-K 04/23/2009 19.1 KB 5
OPKO HEALTH, INC. (OPK) 10-K 03/16/2009 824.3 KB 93
OPKO HEALTH, INC. (OPK) 8-K 03/06/2009 20.3 KB 4
OPKO HEALTH, INC. (OPK) 8-K 02/24/2009 11.1 KB 3
OPKO HEALTH, INC. (OPK) 8-K 01/28/2009 8.1 KB 3
OPKO HEALTH, INC. (OPK) 10-Q 11/12/2008 282.1 KB 48
OPKO HEALTH, INC. (OPK) 8-K/A 10/27/2008 313.9 KB 9
OPKO HEALTH, INC. (OPK) 8-K/A 10/27/2008 780.7 KB 29
OPKO HEALTH, INC. (OPK) 10-Q/A 10/27/2008 94.0 KB 7
OPKO HEALTH, INC. (OPK) 10-Q 08/08/2008 1.17 MB 86
<< Previous | Next >>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OPKO HEALTH, INC. (OPK)
Select Company View...
Contact Information
4400 BISCAYNE BLVD.
SUITE 900
MIAMI FL,33137
Phone: (305) 575 - 6015
Legal Information
State of Incorporation: DE
SIC: 3841
IRS #: 752402409
Exchange: NYSE Amex Equities
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Date
OPKO HEALTH, INC. (OPK) 8-K/A 12/14/200
Exhibits
EX-23.1 - Consents of experts and counsel View Exhibit | Preview
EX-99.1 - Exhibits not specifically designated by another number and by investment companies View Exhibit | Preview
EX-99.2 - Exhibits not specifically designated by another number and by investment companies View Exhibit | Preview
OPKO HEALTH, INC. (OPK) 8-K 11/17/2009 1.69 MB 31
Exhibits
EX-99.1 - Exhibits not specifically designated by another number and by investment companies View Exhibit | Preview
EX-99.2 - Exhibits not specifically designated by another number and by investment companies View Exhibit | Preview
OPKO HEALTH, INC. (OPK) 10-Q 11/09/2009 390.1 KB 60
Exhibits
EX-10.2 - Material contracts View Exhibit | Preview
EX-10.3 - Material contracts View Exhibit | Preview
EX-31.1 - Certifications required under Section 302 of the Sarbanes-Oxley Act of 2002 View Exhibit | Preview
EX-31.2 - Certifications required under Section 302 of the Sarbanes-Oxley Act of 2002 View Exhibit | Preview
EX-32.1 - Certifications required under Section 906 of the Sarbanes-Oxley Act of 2002 View Exhibit | Preview
EX-32.2 - Certifications required under Section 906 of the Sarbanes-Oxley Act of 2002 View Exhibit | Preview
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Exhibits
EX-99.1 - Exhibits not specifically designated by another number and by investment companies View Exhibit | Preview

EX-32.1 - Ex-32.1 section 906 cao certification View Exhibit | Preview

EX-32.2 - Ex-32.2 section 906 cao certification View Exhibit | Preview

OPKO HEALTH, INC. (OPK)	8-K	04/18/2007	9.2 KB	5
OPKO HEALTH, INC. (OPK)	8-K	04/13/2007	44.9 KB	15

Exhibits

EX-10.1 - Exhibit 10.1 View Exhibit | Preview

EX-16.1 - Exhibit 16.1 View Exhibit | Preview

OPKO HEALTH, INC. (OPK)	8-K	04/02/2007	2.16 MB	393

Exhibits

EX-2.1 - Ex-2.1 merger agreement & plan of reorganization View Exhibit | Preview

EX-4.1 - Ex-4.1 form of common stock warrant View Exhibit | Preview

EX-4.2 - Ex-4.2 form of series c preferred stock warrant View Exhibit | Preview

EX-10.1 - Ex-10.1 form of lock-up agreement View Exhibit | Preview

EX-10.2 - Ex-10.2 credit agreement View Exhibit | Preview

EX-10.3 - Ex-10.3 amended & restated venture loan agreement View Exhibit | Preview

EX-10.8 - Ex-10.8 technology license agreement View Exhibit | Preview

EX-10.9 - Ex-10.9 license agreement View Exhibit | Preview

EX-10.10 - Ex-10.10 amendment no. 1 to license agreement View Exhibit

EX-10.11 - Ex-10.11 amendment no. 2 to license agreement View Exhibit

EX-10.12 - Ex-10.12 license and collaboration agreement View Exhibit |

EX-10.13 - Ex-10.13 univ. of penn. license agreement View Exhibit | Pre

EX-10.14 - Ex-10.14 univ. of penn license agreement View Exhibit | Pre

EX-10.15 - Ex-10.15 1st amendment to upenn license agreement View E

EX-10.16 - Ex-10.16 1st amendment to upenn license agreement View E

EX-10.17 - Ex-10.17 amended restated subordination agreement View Ex

EX-10.18 - Ex-10.18 reich employment letter View Exhibit | Preview

EX-10.19 - Ex-10.19 pfost employment agreement View Exhibit | Previe

EX-99.1 - Ex-99.1 press release View Exhibit | Preview

EX-10.8 Technology License Agreement EXHIBIT 10.8 TECHNOLOGY LICENSE AGREEMENT License Agreement ("Agreement"), effective as of August 3, 2006 between THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, (the "University"), and ACUITY PHARMACEUTICALS, INC., a Delaware corporation, having its principle place of business at 3701 Market Street, Philadelphia, PA, 19104 ("Licensee" or "Acuity"). Preliminary Statement University holds certain rights to the Technology described below and desires to have the Technology commercialized. Licensee wishes to obtain the right to use the Technology for commercial purposes. Therefore, in consideration of the mutual obligations set forth below and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, University and Licensee agree as follows. ARTICLE I DEFINITIONS The following capitalized terms are used in this Agreement with the following meanings: 1.1. "Effective Date" means August 3, 2006. 1.2. "FDA" means the United States Food and Drug Administration, or any successor thereto. 1.3. "IND" means an "investigational new drug application" as defined by the United States Food, Drug, and Cosmetic Act, as amended (the "Act"), and applicable FDA rules and regulations or a foreign equivalent. 1.4. "Inventions" means all devices, machines, methods, processes, manufactures, compositions of matter and uses, and Technical Information, contained ...

[Close]

OPKO HEALTH, INC. (OPK)		07	43.1 KB	5
OPKO HEALTH, INC. (OPK)		07	1.37 MB	50

Exhibits

EX-3.1(I).(i) - Articles of Incorporation View Exhibit | Preview

EX-23.1 - Consents of experts and counsel View Exhibit | Preview

EX-23.2 - Consents of experts and counsel View Exhibit | Preview

EX-31.1 - Certifications required under Section 302 of the Sarbanes-Oxley

EX-31.2 - Certifications required under Section 302 of the Sarbanes-Oxley Act of 2002 View Exhibit | Preview

EX-32.1 - Certifications required under Section 906 of the Sarbanes-Oxley Act of 2002 View Exhibit | Preview

EX-32.2 - Certifications required under Section 906 of the Sarbanes-Oxley Act of 2002 View Exhibit | Preview

ARTICLE III
PAYMENTS

3.1. **Royalties and Reimbursements**. For the licenses granted in Section 2.1 of this Agreement, Licensee shall:

(a) within three (3) business days of the execution of this Agreement, pay University a non-refundable licensing fee in the amount of $25,000;

(b) within thirty (30) days of the first and second anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $25,000;

(c) within thirty (30) days of the third anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $50,000;

(d) within thirty (30) days of the fourth anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $50,000;

(e) within thirty (30) days of the fifth anniversary of the Effective Date and each subsequent anniversary thereafter until the Licensee receives NDA approval on its first Licensed Product, pay University an annual non-refundable licensing fee in the amount of $100,000;

(f) pay University a Royalty equal to three percent (3%) of Net Sales of Licensed Products sold, leased, rented, licensed or otherwise distributed by Licensee during the term of this Agreement, if any. If no valid claim of any issued patent among the Licensed Patents covers the Licensed Products in a country of the Territory, then the royalties shall be reduced to one and one-half percent (1.5%) of Net Sales of Licensed Products sold, leased, rented, licensed or otherwise distributed by Licensee in such country of the Territory.

3.2. **Milestones and Milestone Payments**. Licensee agrees to make the milestone payments to University as set forth below (the "**Milestone Payments**") within forty-five (45) days after the occurrence of each event set forth on such Schedule.

Milestone	Payment
First Phase I Clinical Trial initiated	$ 100,000
First Phase III Clinical Trial initiated	$ 350,000
First NDA Approval in the U.S	$ 500,000
First NDA Equivalent Approval outside of US	$ 500,000
Upon first $25,000,000 of commercial sales of any Licensed Products	$1,000,000

Each of the foregoing payments shall be made only once. Thereafter, no additional Milestone Payments shall be due or payable by Licensee for License Products.

3.3. **Calculations and Payment of Royalties.**

(a) Royalties shall be paid in quarterly increments (the "Royalty Period"). Royalties shall be calculated for each Royalty Period as of the last day of each such Royalty Period. Payment of Royalties with respect to each Royalty Period shall be due within sixty (60) days after the end of Royalty Period, beginning with the earlier of (i) the Royalty Period in which the first sale of a Licensed Product occurs, or (ii) the Royalty Period for which Annual Minimum Royalties are due.

(b) Within sixty (60) days of the end of each Royalty Period (whether or not Royalties are due), Licensee shall deliver to University a true and complete accounting of sales or distributions of any Licensed Product and revenues from those sales by Licensee and its Sublicensees for each country of sales origin during such Royalty Period and deductions taken, with a separate accounting for each Licensed Product of sales and receipts by country, and a detailed calculation of the Royalty payment due University for such Royalty Period, in each case in form and substance as set forth on Exhibit A attached to this Agreement. If no sales of Licensed Products were made or other payments due in such Royalty Period, then Licensee's statement shall so state.

(c) Each Annual Minimum Royalty payment shall be accompanied by a calculation of the Annual Minimum Royalty such that University can verify the amount of the payment.

3.4. **Royalty stacking and combination products**: The royalty rate will not diminish for combination products or stacking royalties.

3.5. **Annual Minimum Payments**. Beginning one year after the Licensee or any Sublicensee receives NDA approval on its first Licensed Product, it the total payments actually paid to University payments (including any payments required pursuant to this Article III) for any annual period are less than $400,000, Licensee shall pay University an amount (the "**Annual Minimum Royalty**") for that annual period equal to the difference between the payments actually paid for such annual period and the Annual Minimum Royalty owing for that annual period. Such payment shall be made within forty five days of the end of each year of this Agreement beginning one year after the Licensee receives NDA approval on its first Licensed Product. If this Agreement is terminated by Licensee for any reason during any year, a pro-rata Annual Minimum Royalty shall be paid.

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Agreement	Date	Type	Size	Equity	Roy.	Subject
Targeted Genetics / Sirna Therapeutics	4/08	L				Preclinical Huntington's disease program
Merck / Sirna Therapeutics	10/06-12/06	Acq	$1,100.0			Acquisition for cash
Rockefeller University / Sirna Therapeutics	8/06	L				miRNA tech. for gene expression modulation
University of Massachusetts / Sirna Therapeutics	5/06	L				miRNA tech. for the modulation of gene expression
GlaxoSmithKline / Sirna Therapeutics	3/06	Col,D,E,L	$712.0	$6.0		RNAi-Based therapeutics for respiratory disease
Allergan / Sirna Therapeutics	9/05	Col,D,L	$250.0			Sirna-027 and RNAi products for ophthalmology
Mass General Hospital / Sirna Therapeutics	6/05	Col,L,R				siRNAs in Hearing Restoration
Targeted Genetics / Sirna Therapeutics	1/05	CoD,Col,L				Huntington's Disease Collaboration
Sirna Therapeutics / Skinetics Biosciences	12/04	Acq	$2.5			Acquisition of Skinetics for shares
Archemix / Sirna Therapeutics	7/04	Col,Man				Aptamer Manufacturing Alliance
Lilly / Sirna Therapeutics	1/04	Col,L,R				RNAi oncology collaboration
Archemix / Sirna Therapeutics	10/03	Man				ACR183 Antithrombin Aptamer
University of Massachusetts / Sirna Therapeutics	9/03	L				RNA Interference Technology
Geron / Sirna Therapeutics	7/02	S				Geron's lead anticancer drug GRN163
Fujirebio / Sirna Therapeutics	3/02	D,L,R				Ribozyme-based clinical diagnostic products
Sirna Therapeutics / Geron	12/01	Col,L				GRN163 Telomerase Inhibitor
Sirna Therapeutics / Archemix	5/01	E,L,Sub				Proteomics & molecular diagnostics
Medizyme / Sirna Therapeutics	1/00	JV,L				Angiozyme VEGF-R ribozyme
Avecia / Sirna Therapeutics	1/00	Col				Angiozyme(TM) and Heptazyme (anti-HCV ribozyme)
Elan / Sirna Therapeutics	12/99-2/03	E,JV,LoI,Lo,Ter,W	$40.0	$20.0		Herzyme (HER-2 ribozyme)& Medipad for breast cancer

Company Valuation

- Most recent 10Q to get number of shares outstanding
- Share prices:
  - http://www.nasdaq.com/
    - direct links to SEC filings
    - can get underlying price data
    - charting, news items, analyst reports

OPKO Health, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	75-2402409
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

4400 Biscayne Blvd.
Miami, FL 33137
(Address of Principal Executive Offices) (ZIP Code)

(305) 575-4100
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 mont for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☑ YES ☐ NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and pos pursuant to Rule 405 of Regulation S-T (§232.405 of this Chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post suc files). YES ☐ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☑	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): YES ☐ NO ☑

As of November 3, 2009, the registrant had 253,744,539 shares of common stock outstanding.


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Feb 12, 2010
US Market Closed
NASDAQ 2183.53 6.12 0.28% | DJIA 10099.14 -45.05 -0.44% | S&P 1075.51 -2.96 -0.27%
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S. Stock Quotes, Charts, and Research
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OPK
2 Click a link below to use your selected symbols.
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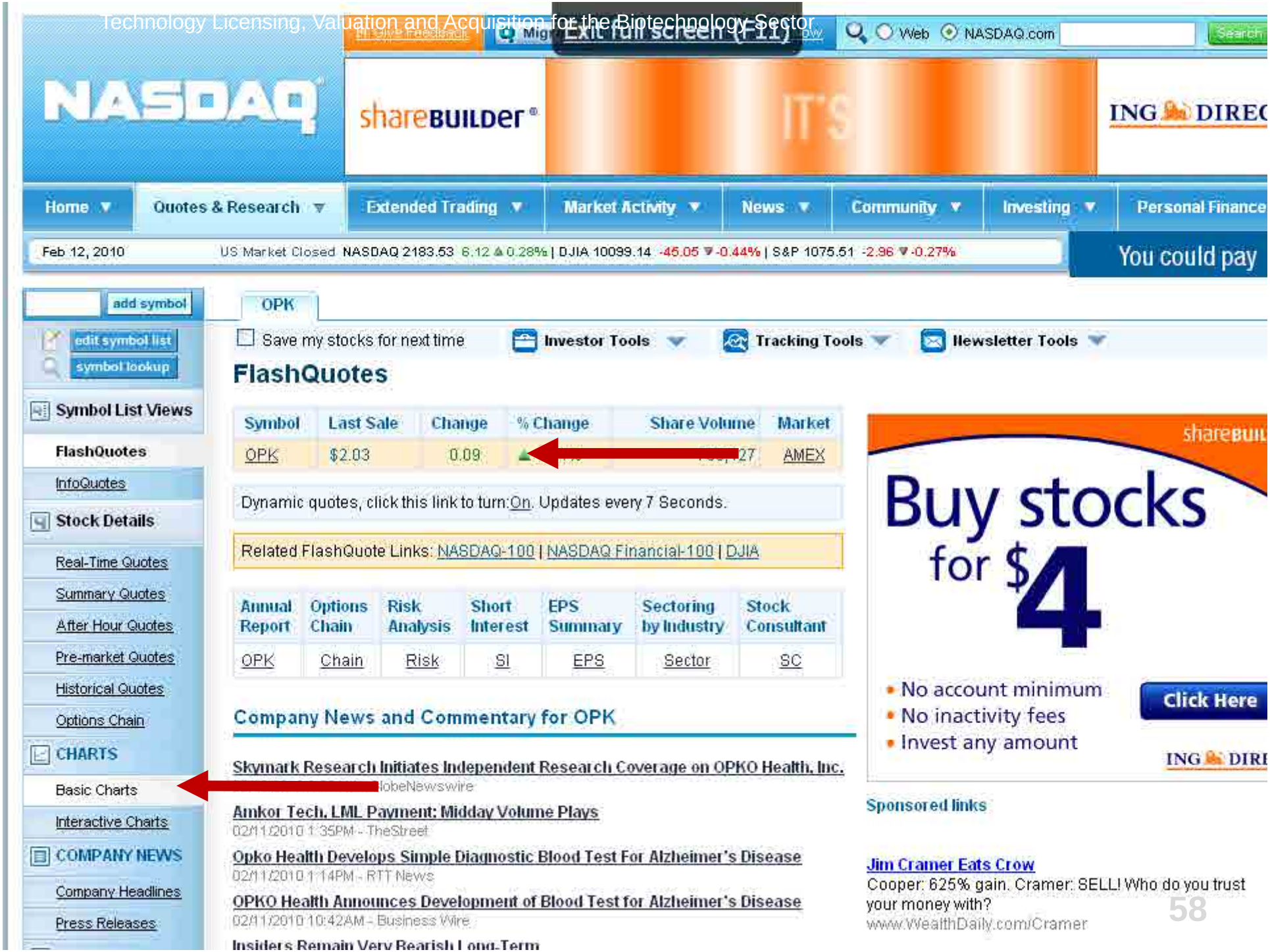
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Feb 12, 2010
US Market Closed NASDAQ 2183.53 6.12 0.28% | DJIA 10099.14 -45.05 -0.44% | S&P 1075.51 -2.96 -0.27%
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Share Volume
Market
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Short Interest
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Amkor Tech, LML Payment: Midday Volume Plays
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Opko Health Develops Simple Diagnostic Blood Test For Alzheimer's Disease
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OPKO Health Announces Development of Blood Test for Alzheimer's Disease
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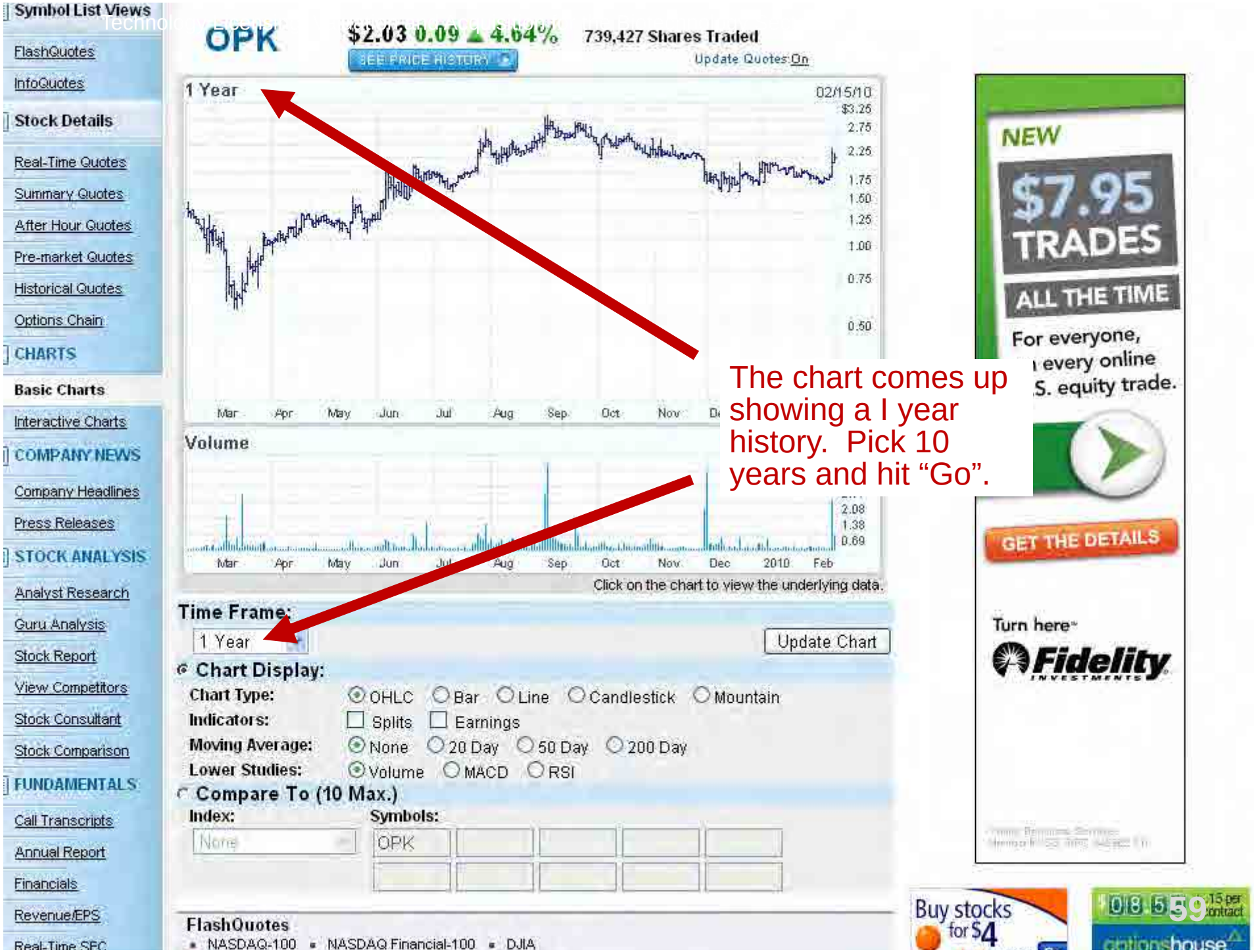
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OPK
$2.03 0.09 ▲ 4.64%
739,427 Shares Traded
SEE PRICE HISTORY
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1 Year
02/15/10
$3.25
2.75
2.25
1.75
1.50
1.25
1.00
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Mar Apr May Jun Jul Aug Sep Oct Nov
Volume
2.08
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Mar Apr May Jun Jul Aug Sep Oct Nov Dec 2010 Feb
Click on the chart to view the underlying data.
The chart comes up showing a I year history. Pick 10 years and hit "Go".
Time Frame:
1 Year
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Chart Display:
Chart Type: OHLC Bar Line Candlestick Mountain
Indicators: Splits Earnings
Moving Average: None 20 Day 50 Day 200 Day
Lower Studies: Volume MACD RSI
Compare To (10 Max.)
Index:
None
Symbols:
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Opko Health Inc (OPK) Stock Charts

OPK $2.03 0.09 ▲ 4.64% 739,427 Shares Traded

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Time Frame:

10 Years | Update Chart

Chart Display:

Chart Type: OHLC | Bar | Line | Candlestick | Mountain

Indicators: Splits | Earnings

Moving Average: None | 20 Day | 50 Day | 200 Day

Lower Studies: Volume | MACD | RSI

Compare To (10 Max.)

Index: Symbols:

$2.09 x 253,744,539 shares = $530,326,087

Example

- Beverages
- Tools:
  - 10k Wizard

BOSTON UNIVERSITY

N/A	STOKELY VAN CAMP INC	10-K405	03/26/1997 (12/31/1996)	exhibit(s) mda xls	86.5 KB	5
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N/A	STOKELY VAN CAMP INC	10-QT	11/14/1995 (09/30/1995)	FILING mda xls	23.2 KB	2
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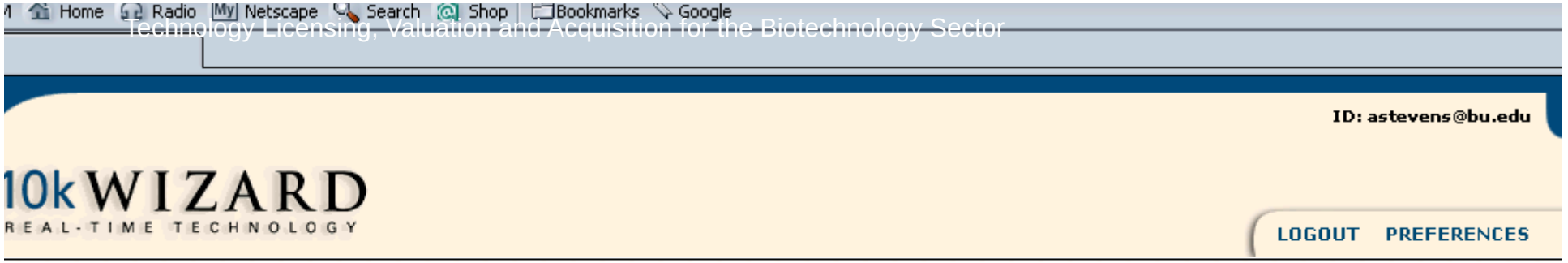

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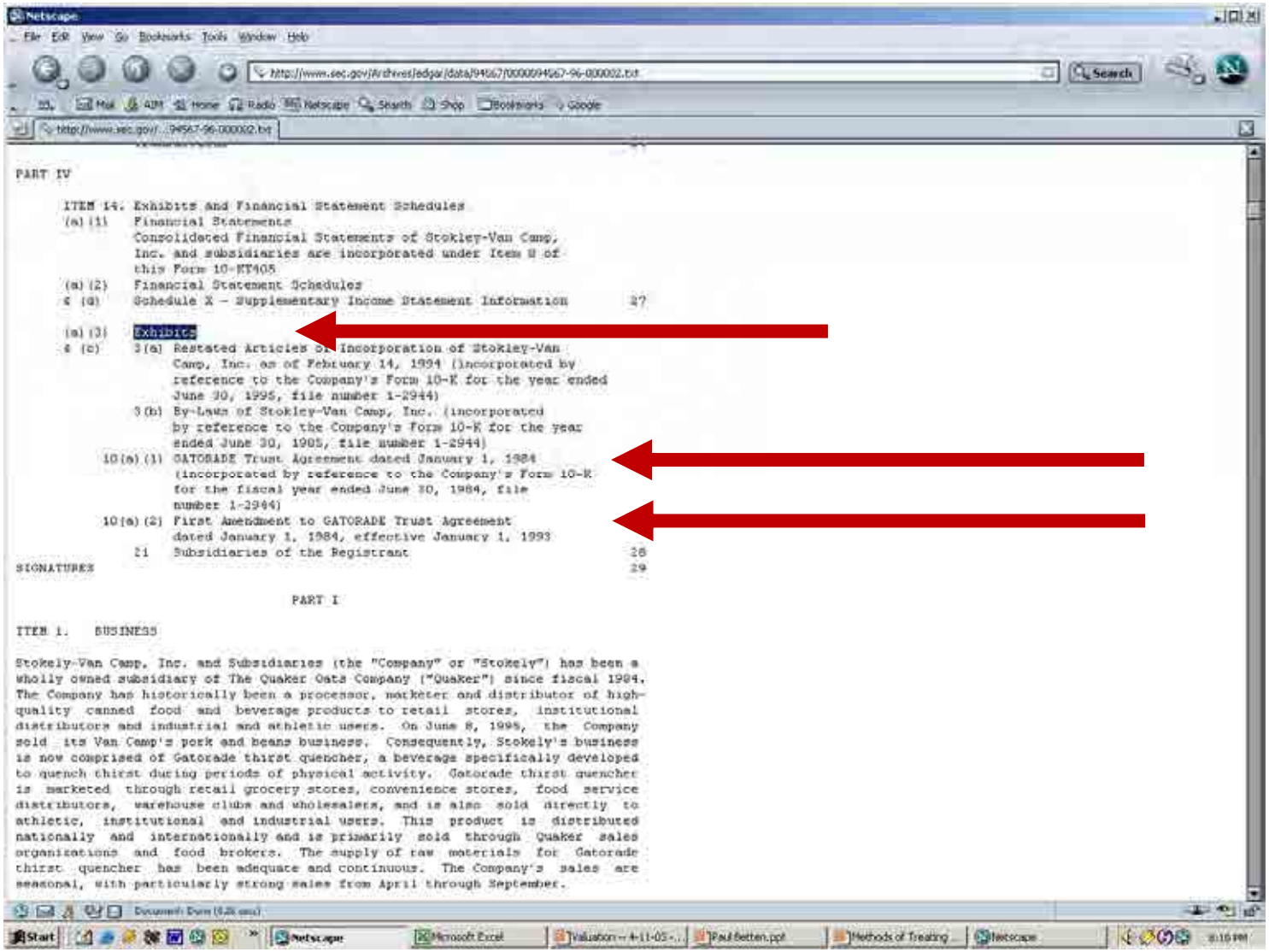
Symbol	Company Name	Form Type	Date Filed (Period Ending)	Exhibit	More Info
			△▽		
N/A	STOKELY VAN CAMP INC	10KT405	04/01/1996 (12/31/1995)	EX-21. Subsidiaries of the registrant	EXHIBIT filing
N/A	STOKELY VAN CAMP INC	10KT405	04/01/1996 (12/31/1995)	EX-10. Exhibit 10 (a) (2) AMENDMENT TO AGREEMENT	EXHIBIT filing



PART IV

ITEM 14. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements

Consolidated Financial Statements of Stokley-Van Camp, Inc. and subsidiaries are incorporated under Item 8 of this Form 10-KT405

(a)(2) Financial Statement Schedules

S (d) Schedule X - Supplementary Income Statement Information 27

(a)(3) Exhibits

S (c) 3(a) Restated Articles of Incorporation of Stokley-Van Camp, Inc. as of February 14, 1994 (incorporated by reference to the Company's Form 10-K for the year ended June 30, 1995, file number 1-2944)

3(b) By-Laws of Stokley-Van Camp, Inc. (incorporated by reference to the Company's Form 10-K for the year ended June 30, 1985, file number 1-2944)

10(a)(1) GATORADE Trust Agreement dated January 1, 1984 (incorporated by reference to the Company's Form 10-K for the fiscal year ended June 30, 1984, file number 1-2944)

10(a)(2) First Amendment to GATORADE Trust Agreement dated January 1, 1984, effective January 1, 1993

21 Subsidiaries of the Registrant 28

SIGNATURES 29

PART I

ITEM 1. BUSINESS

Stokely-Van Camp, Inc. and Subsidiaries (the "Company" or "Stokely") has been a wholly owned subsidiary of The Quaker Oats Company ("Quaker") since fiscal 1994. The Company has historically been a processor, marketer and distributor of high-quality canned food and beverage products to retail stores, institutional distributors and industrial and athletic users. On June 8, 1995, the Company sold its Van Camp's pork and beans business. Consequently, Stokely's business is now comprised of Gatorade thirst quencher, a beverage specifically developed to quench thirst during periods of physical activity. Gatorade thirst quencher is marketed through retail grocery stores, convenience stores, food service distributors, warehouse clubs and wholesalers, and is also sold directly to athletic, institutional and industrial users. This product is distributed nationally and internationally and is primarily sold through Quaker sales organizations and food brokers. The supply of raw materials for Gatorade thirst quencher has been adequate and continuous. The Company's sales are seasonal, with particularly strong sales from April through September.

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Exhibit 10 (a) (2)

AMENDMENT TO AGREEMENT

THIS AMENDMENT, made effective and entered into as of this 1st day of January, 1993, to that certain Agreement dated January 1, 1984 (hereinafter the "1984 Agreement"), by and between STOKELY-VAN CAMP, INC. (hereinafter "Stokely"), a wholly owned subsidiary of The Quaker Oats Company, and BANK ONE, INDIANAPOLIS, N.A., as successor trustee to American Fletcher National Bank and Trust Company, solely in its capacity as the Trustee (hereinafter the "Trustee") of The Gatorade Trust (hereinafter the "Trust") created under the laws of the State of Indiana by virtue of a Trust Agreement dated May 16, 1967, as amended on May 23, 1967.

WHEREAS, Stokely and the Trustee mutually desire to amend the 1984 Agreement to provide certain alternatives for Stokely to market and distribute Gatorade and to clarify certain aspects of the 1984 Agreement.

NOW THEREFORE, in consideration of the foregoing and the mutual covenants of the parties hereinafter set forth, the existence and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Subparagraph 4.03 of the 1984 Agreement is modified to read: "On Contract Product sold after June 30, 1984 (except as provided in subparagraph 4.06), Stokely shall make Payment equal to:"

2. New subparagraph 4.06 is added to the 1984 Agreement to read: 4.06 On Contract Product sold on or after January 1, 1993,

(a) For sales of Contract Product by Stokely, The Quaker Oats Company, their Affiliates and their Hybrid Licensees, the Payment Basis (as defined in subparagraph 2.08) shall be multiplied by the Payment Rate, wherein the respective Payment Rate for the respective levels of Payment Basis are set forth in the following tables:

(i)

For Payment Basis on Domestic Sales (including the first $30,000,000 in Can and Fountain Domestic and Foreign Sales) in Each Respective Full or Partial Fiscal Year Beginning January 1, 1993	Payment Rate is:
On the First $ 50,000,000	3.6%
On the Second $ 50,000,000	3.4%
On the Third $ 50,000,000	3.0%
On the Fourth $ 50,000,000	2.4%
In Excess of $200,000,000	1.9%

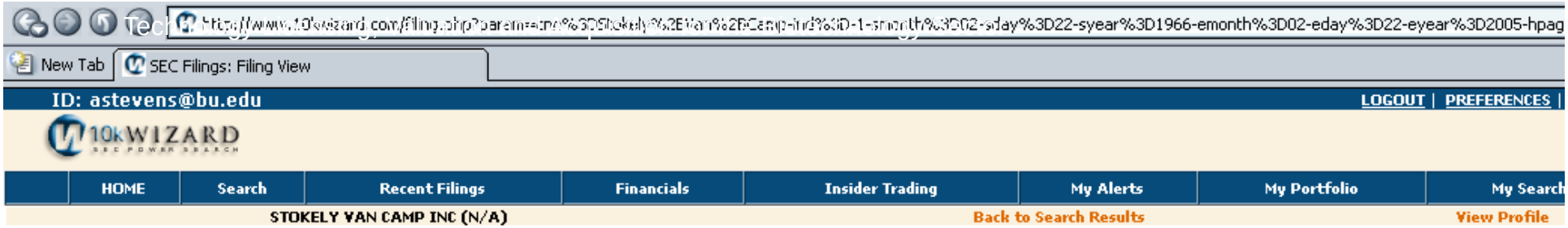
For Payment Basis on Can and Fountain Domestic and Foreign Sales in Each Respective Full or Partial Fiscal Year Beginning January 1, 1993	Payment Rate is:
On all sales in excess of $30,000,000	1.4%

For Payment Basis on Foreign Sales in Each Respective Full or Partial Fiscal Year Beginning January 1, 1993	Payment Rate is:
On the First $160,000,000 (1)	1.9%
In Excess of $160,000,000	1.4%

(1) This assumes that domestic sales (excluding can and fountain sales) exceed $200,000,000 in each fiscal year; otherwise, the Payment Basis on the first $160,000,000 of foreign sales would be treated as if such sales were domestic sales (excluding can and fountain sales).

plus

(ii) Twenty-five percent (25%) of the royalty paid to



Ordering a copy of the Filing:
This paper SEC filing is available from CCH Washington Service Bureau for a fee.
Be sure to provide the following information in your request:

Company Name : STOKELY VAN CAMP INC
Film No : -103916073
Form : 10-K
Date : 08/28/1984
client code : **WIZ**

Please call 800-289-1057, Monday through Friday, 8:30 a.m. to 8 p.m. (Eastern).

Look to your Hand – Rules of Thumb

-- the 25% Rule

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A Fundamental Principle of Technology Valuation

The Goldscheider Principle

(aka the 25% Rule)

" The Licensor should receive 25% and the Licensee should receive 75% of the pre-tax profits from a licensed product "

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The 25% Rule

- Based on empirical observations
  - 18 worldwide licenses by Swiss subsidiary of US TV company PhilCo starting in 1959
  - Complete IP portfolio - patents, ongoing know-how, trademarks, copyrighted product materials
  - 3 year term, so readily replaceable if terms inappropriate
  - Licensors made ~20% pre-tax profit, paid 5% royalty; were either #1 or #2 in their market despite strong competition
  - Concluded that the licenses resulted in successful, long term win-win relationships
- Applied to fully-loaded pre-tax profits, not gross margin

Application

- Expressed as a % of net sales in license

  royalty rate = 25% x expected profit margin
- Starting point for negotiation; tune up or down for
  - significance of IP portfolio
  - who bears principle burden of risk
- Limited value in academic licensing negotiations because of uncertainty of ultimate profitability
- Of most relevance when you're licensing to a new industry
- Major importance in infringement -- reasonable royalties theory

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So, what profitability do I use?

- Academic technologies are generally very early stage
  - Can't do realistic cost of goods or selling price projections at time of licensing
- Could look at company's overall profit margin
  - Only works for established companies
- Could look at a benchmark group
  - *Business Week* surveys
  - *Almanac of Business and Industrial Financial Ratios*
  - *Mergent Industry Review*
  - *Robert Morris Associates Annual Statement Studies*
- Could look at a "pure play" in that industry

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The Future of the 25% Rule

- Uniloc USA, Inc. and Uniloc Singapore Pvt, Ltd, vs Microsoft Corporation
- 5,490,216 “System for software registration”
  - Prevent multiple installations of the same software on different computers
- US District Court, RI, stated:

  > the concept of a ‘rule of thumb’ is perplexing in an area of the law where reliability and precision are deemed paramount

  but allowed use of the rule
- CAFC decision January 4, 2011

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The Future of the 25% Rule?

"This court now holds as a matter of Federal Circuit law that the 25 percent rule of thumb is a fundamentally flawed tool for determining a baseline royalty rate in a hypothetical negotiation. Evidence relying on the 25 percent rule of thumb is thus *inadmissible under Daubert and the Federal Rules of Evidence, because it fails to tie a reasonable royalty base to the facts of the case at issue*."

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The Future of the 25% Rule?

- Another example of the “living, breathing patent system”
- Dead for litigation
- Probably still useful in

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Look forward –

Discounted Cash Flow/Net Present Value

Time Value of Money

- Getting $1,000 next year isn't worth as much as getting $1,000 tomorrow
- What would we pay today to receive $1,000 in a year?
- Need to be compensated for:
  - Inflation
  - Risk the payment won't be made
  - A return on the investment

Risk-Free

- Inflation currently is around 3%
- Assume we're happy with a 7% return
  - 3% for inflation
  - 4% as a return on investment
  - No risk
- If we invested $1,000 today, we would expect $1,070 in a year
- What about the second year? Another $70?
- More:
  - For the second year, we have $1,070 invested, not $1,000
  - Expect a return of $1,070 x 0.07, i.e., $75 for the second year

Going the other way

- We want back $1,070 in a year if we invest $1,000 today
- So, we would be willing to invest $1,000 / $1,070 or $934.57 today to get $1,000 back in a year
  - 7% of $934.57 is $65.42
  - $934.57 + $65.42 = $999.99
- So the value today of $1,000 in a year's time is $934.57
- i.e., $934.57 is the Net Present Value of $1,000 one year out with a 7% discount rate
- 7% is the interest rate going forward, or the discount rate going backwards

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Discount Rate Formula

- So, value (FV) 2 years in the future is:

  $1,000 + $1,000 x 0.07 + ($1,000 + $1,000 x 0.07) x 0.07

  ↑ Starting ↑ Interest year 1 ↑ Interest year 2

  $FV = PV + PV * k + (PV + PV \times k) \times k$

  $FV = PV * (1 + k)^2$

- and the Net Present Value (the value today, PV) of an amount FV two years in the future is

  $FV / (1 + k)^2$

- We would pay today $873.44 to get back $1,000 in two years
- i.e., $873.44 is the Net Present Value of $1,000 in two years with a 7% discount rate

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Multiple Payments

- If we wanted to get back $1,000 in each of the next two years, we would be willing to pay

$$\$934.57 + \$873.44 = \$1,808.01$$

- i.e., $1,808.01 is the Net Present Value of two $1,000 payments one and two years out with a 7% discount rate

Net Present Value Calculations

- Take into account the facts that:
  - Expenses are certain and early
  - Return is later and uncertain
    - Product may not succeed
    - Market may not be there

Discount Rates

Inflation Rate	3%
Long Term T Bill Rate	7%
Corporate Bond Rate	12% (Blue Chip) - 18% (Junk)
Average Corporate Cost of Capital	15%
Corporate Investment Hurdle Rate	30%
VC Investment Hurdle Rate	50%

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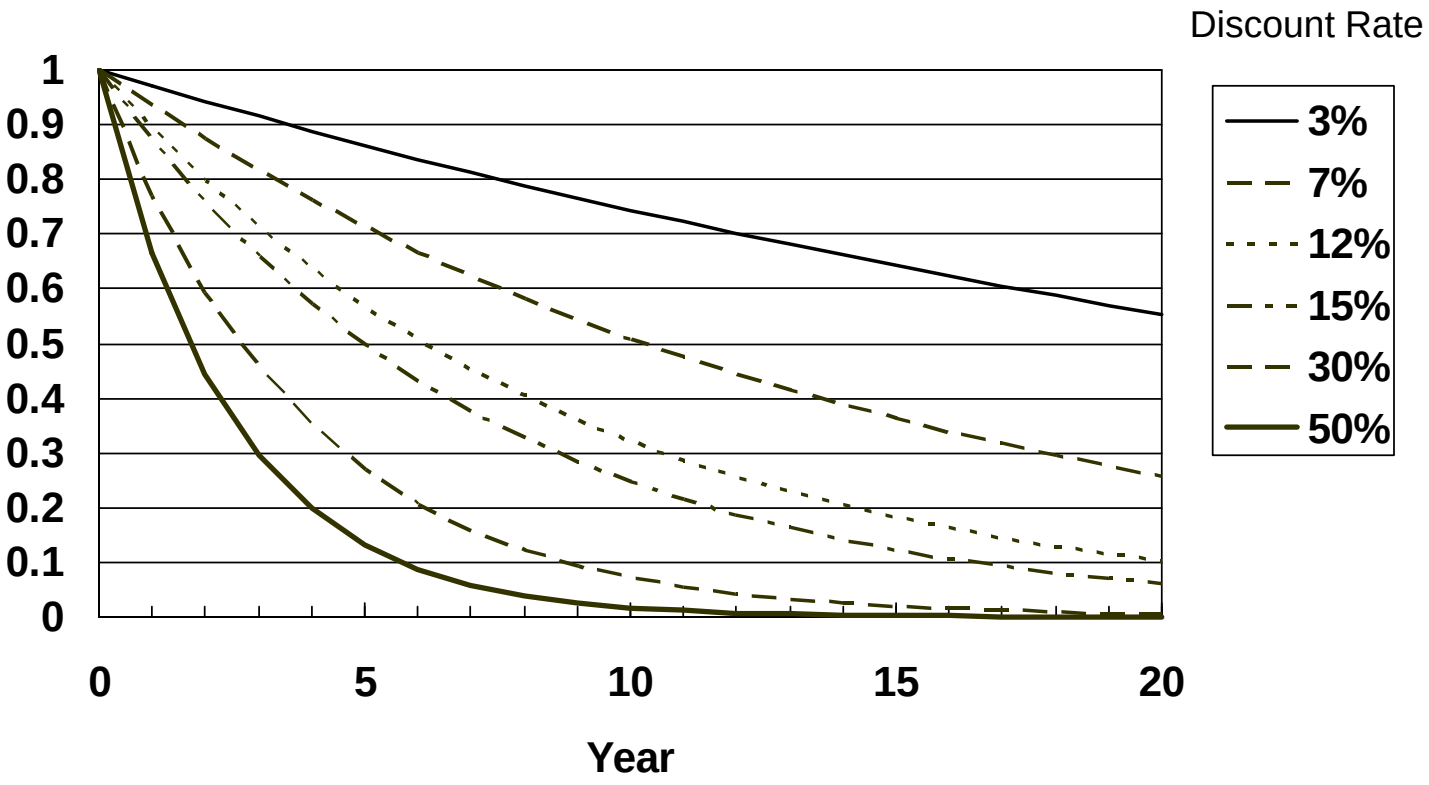
Effect of Discount Rate Over Long Periods



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Net Present Value of $1,000 in Five Years

Formula is $\$1,000/(1+k)^5$

k	Value	Payback
3%	$862.61	1.15x
7%	$712.99	1.40x
15%	$497.18	2.01x
30%	$269.33	3.71x
50%	$131.69	7.59x

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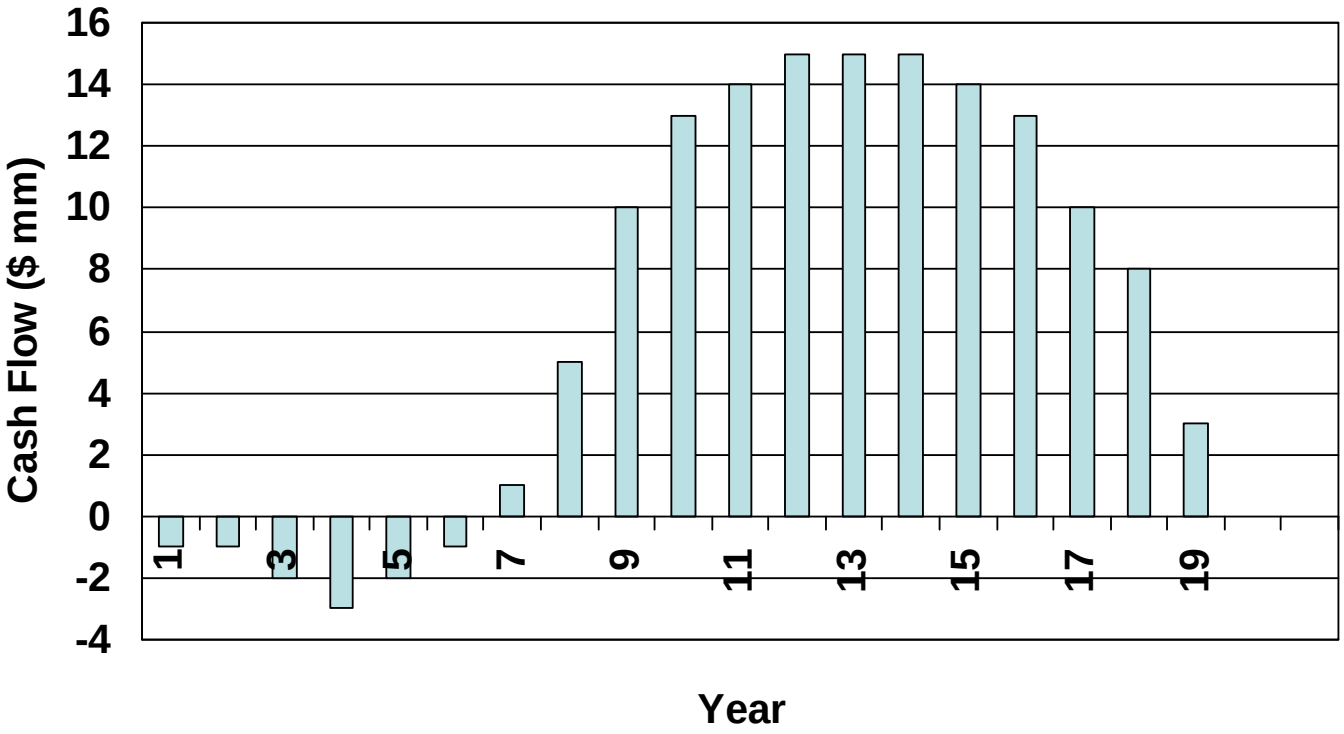
A Typical R&D Project

- $10 mm invested over 6 years
- Sales start in year 7
- Peak profits of $15 mm in years 12-14
- Over by year 19
- Total Net Income of $136 mm
- Net Profits exceed expenses by $126 mm

Looks like a great investment

A Typical R&D Project



Source: Richard Razgaitis

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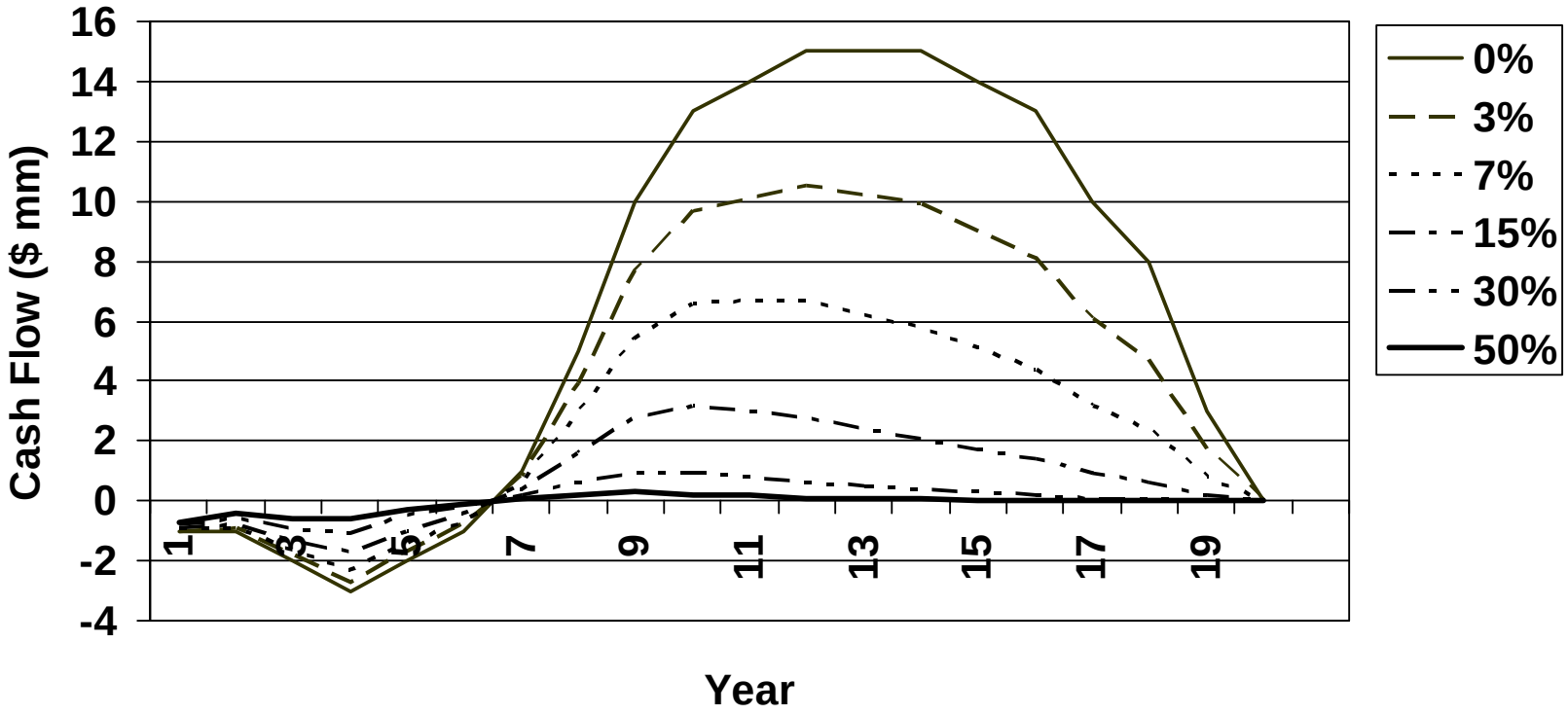
How it looks at various discount rates



Source: Richard Razgaitis

Is it still a good deal?

- The answer depends on the discount rate

k	Net Present Value	Payback
0%	$126.0 mm	12.6x
3%	$83.4mm	8.3x
7%	$49.0 mm	4.9x
15%	$17.3 mm	1.7x
30%	$1.6 mm	0.2x
50%	$(1.4 mm)	nm

Source: Richard Razgaitis

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Let's look at the 30% Case

- Licensee achieved their 30% return
- Project is still worth $1.6 mm today
- This amount is available to pay the licensor
- Could ask for $1.6 mm upfront -- unlikely -- puts all risk on licensee
- Some combination of upfront, milestone payments and royalty with an NPV, with a 30% discount rate, of $1.6 mm
- Assume license terms are:
- $100k upfront
- Milestone payments of $50k, $200k, $500k and $2 mm in years 3, 4, 5, 6
- Royalty rate of 5% (product has a pre-tax margin of 40%)
- NPV now ($280k)

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Mechanics

- Easy to do in spreadsheets
- Excel has an NPV function
  - Handles up to 29 years
- Do your own
  - Calculate a Discount Factor for each year
  - First year is 1
  - Second year is 1/(1+k)
  - Third year is second year/(1+k)
  - Etc
  - Multiply each year's cash flow by that year's Discount Factor
  - Sum

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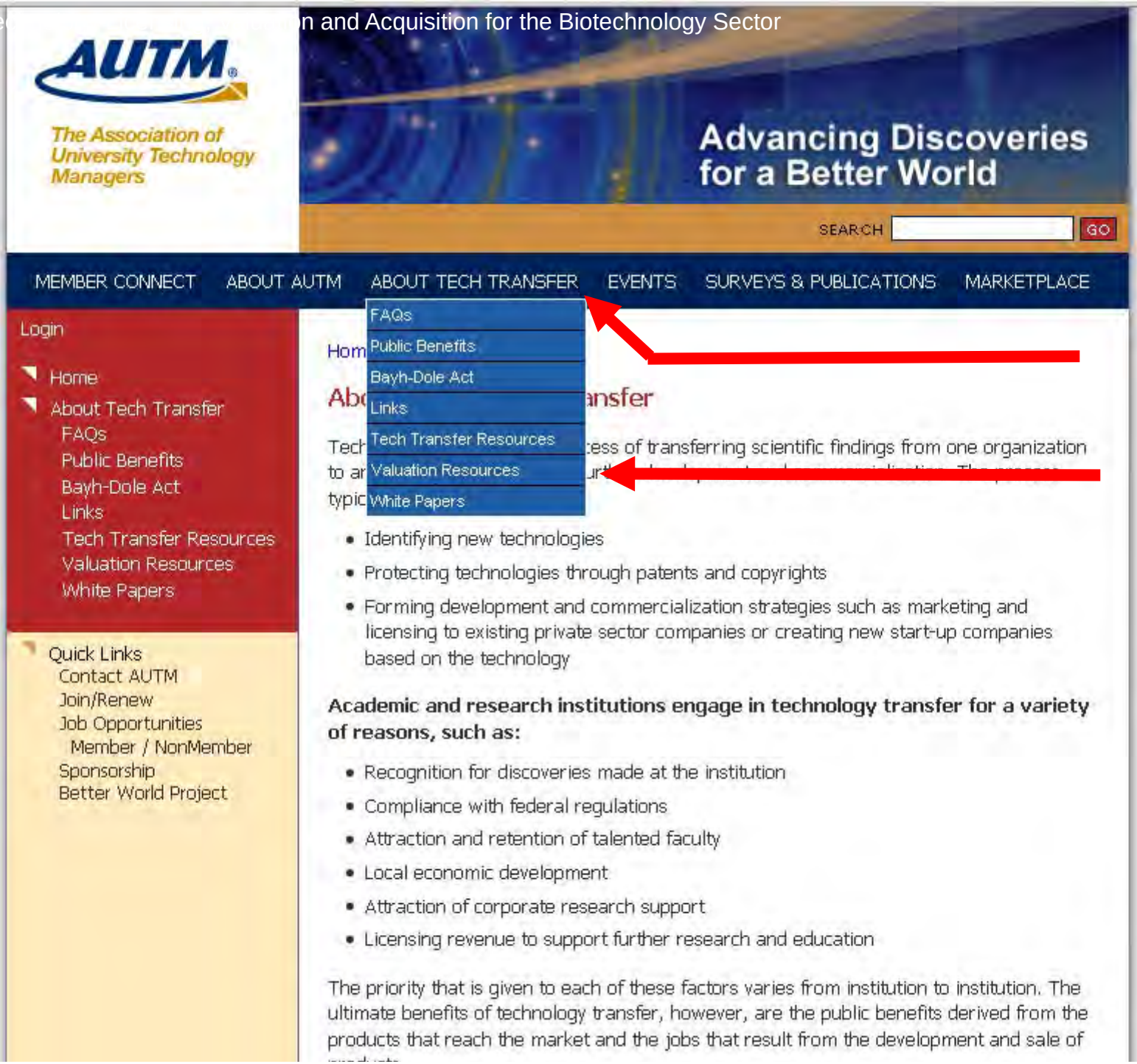
AUTM
The Association of University Technology Managers
Advancing Discoveries for a Better World
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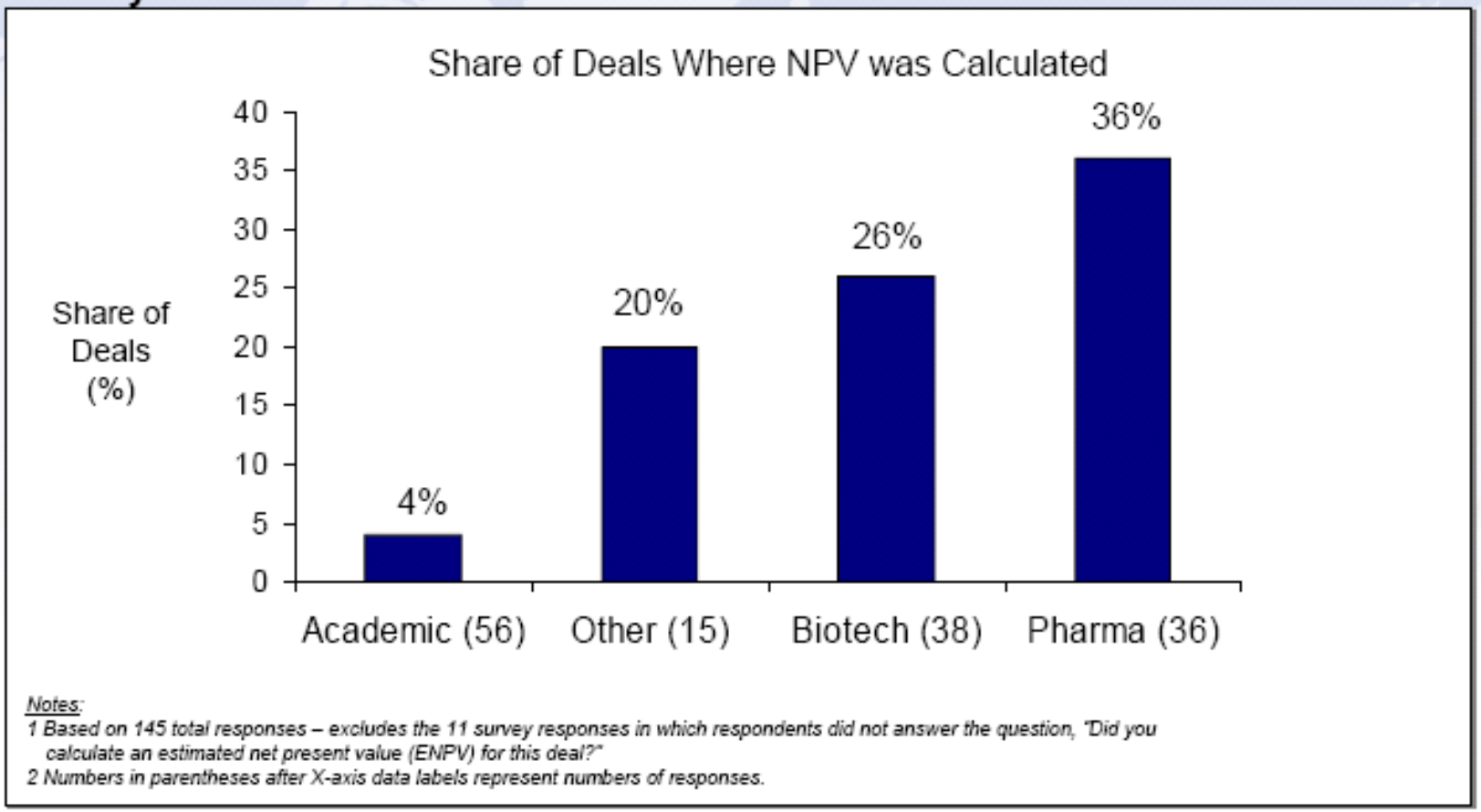
Links
Tech Transfer Resources
Valuation Resources
White Papers
Quick Links
Contact AUTM
Join/Renew
Job Opportunities
Member / NonMember
Sponsorship
Better World Project
Hom
Abo nsfer
Tech cess of transferring scientific findings from one organization
to ar
typic
Identifying new technologies
Protecting technologies through patents and copyrights
Forming development and commercialization strategies such as marketing and licensing to existing private sector companies or creating new start-up companies based on the technology
Academic and research institutions engage in technology transfer for a variety of reasons, such as:
Recognition for discoveries made at the institution
Compliance with federal regulations
Attraction and retention of talented faculty
Local economic development
Attraction of corporate research support
Licensing revenue to support further research and education
The priority that is given to each of these factors varies from institution to institution. The ultimate benefits of technology transfer, however, are the public benefits derived from the products that reach the market and the jobs that result from the development and sale of

Where Do You Get The Data?

- Ask the licensee for their projections
- Trust, but Verify!

Use of NPV Calculations

NPVs were computed by biotech and pharma companies more frequently than by academic institutions



Notes:
1 Based on 145 total responses – excludes the 11 survey responses in which respondents did not answer the question, "Did you calculate an estimated net present value (ENPV) for this deal?"
2 Numbers in parentheses after X-axis data labels represent numbers of responses.

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Look to the Market – Equity

“Equity is just cash that hasn’t turned green yet”

Joyce Brinton
Harvard University
1998

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How do you get equity in a license?

- Let them make one or more payments in stock instead of cash
  - Remember -- “Equity is just cash that hasn’t turned green yet”
- Generally the upfront fee
  - For the technology
  - For other value contributed if a start-up you’re helping create the company
- Can allow to pay early milestone payments in stock
  - Convert cash value into shares at current share price
- All other normal license terms
  - Patent costs
  - Milestones
  - AMR
  - Sublicense income sharing
  - Running royalties

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Issues with Equity

- Value of equity in a start-up can escalate rapidly
  - $1/share typical in Seed Round/Series A
  - $10/share typical in IPO
  - Could go higher later (but 6 month lock-up risk)
- Gives considerable upside
- Hedges the risk to licensor
  - Gives a return if licensed technology fails but company succeeds with something else
- Illiquid till IPO or acquisition
- Lock-up typically till 6 months after IPO – lot of insider stock wants to sell then
- One time event

And if all else fails……..

5%

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THIS AGREEMENT made this 30th day of May, A.D.

1922

BETWEEN

The Governors of the University of Toronto,

of the First Part;

-and-

The Eli Lilly Company, incorporated under the laws of the State of Indiana, of Indianapolis, in Marion County and State of Indiana,

of the Second Part.

WHEREAS the Party of the First Part is the owner of a pancreatic extract or product for the treatment of diabetes mellitus and a process for preparing the same for which application for Letters Patent was filed in the United States Patent Office on or about the 22nd day of May, A. D. 1922 under Serial Number [illegible].

AND WHEREAS the party of the First Part is not in a

Patent granted for the said process and product and any improvements thereto, on the same favourable terms as other firms similarly licensed by the said party of the first part and the said party of the second part in consideration of the said license shall pay to the party of the first part a royalty of 6% of the net selling prices which the said party of the second part receives for the product, during the life of such patent.

(10) In the event of the said party of the second part, during the said experimental period or subsequently during the period of the license referred to in paragraph 9, shall develop, improve, or simplify methods of producing the said pancreatic extract, full and complete information regarding such methods shall be communicated by the party of the second part to the said party of the first part for use in the preparation of the said extract.

Technology Licensing, Valuation and Acquisition for The Biotechnology Sector

Lecture 7: Medical Devices- Regulatory and Technology Transfer

Biotechnology Industry Research Assistance Programme
Department of Biotechnology

February 11/12, 2013 Bangalore
and
February 14/15,2013 New Delhi

Dr. Ashley J. Stevens
Past President, Association of University Technology Managers
and
Lecturer, Health Sector Management Program
School of Management
Boston University

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The Medical Device Industry

- Dominated by a few big players
  - "Pure Play" medical device companies
    - Abbott Labs
    - Becton Dickinson
    - Boston Scientific
    - Covidien
    - C.R. Bard
    - Medtronic
    - St. Jude
    - Stryker Corporation

The Medical Device Industry

- Dominated by a few big players
  - Part of Diversified Companies
    - Healthcare Conglomerates
      - Alcon
      - Baxter
      - Johnson & Johnson
    - Industrial Conglomerates
      - GE Healthcare Technologies
      - Beckman Coulter
      - Siemens
      - Toshiba

The Market

- $350 billion global market
  - US 40% of the total
  - 30 of 46 companies with sales >$1 billion in US
- Major segments
  - Cardiovascular
  - Orthopedics
  - Diagnostic imaging
  - Minimally invasive
  - Diabetes
  - Anesthesia and respiratory care
  - Dialysis products
  - Ophthalmology
  - Patient monitoring
  - Point-of-care diagnostic

Combination Products are hot

- Cardiology
  - Drug-eluting stents (DES), introduced in 2003, represent about 90% of combination product market
- Orthopedics
  - Spinal fusion devices use biologics and implants in bone regeneration devices
  - Fracture fixation devices and bone scaffolds
- Ophthalmology
  - Ocular implants and drugs to treat various eye conditions
- Other Combination Products
  - “Theranostics” combine therapeutics and diagnostics to predict, regulate and monitor pathological responses
  - Personalized medicine
  - Antibacterial / Nano coatings on medical devices

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The Medical Device Innovation Ecosystem

- Fertile start-up arena
  - Development costs substantially lower than pharma and biotech
- Exit is primarily by acquisition
  - No substantial IPO market for many years
    - 2010 8
    - 2011 3
    - 2012 4
- Large companies are happy to pay substantial premium after technology and market validated
  - Sales improve due to global distribution and service

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Medical Device Acquisitions 2009-2010

Acquirer	Target	Deal Size ($Mill)	Filing Date
Abbott Laboratories	Advanced Medical Optics	$2,770	2/24/09
	Evalve, Inc.	$410	10/30/09
	Visiogen, Inc.	$400	10/20/09
Beckman Coulter Inc.	Olympus Corp. (Diagn. Bus.)	$776	8/2/09
Becton, Dickinson	HandyLab, Inc.	$278	11/19/09
CareFusion Corporation	Medegen Holdings, LLC	$225	5/17/10
Covidien plc	ev3, Inc.	$2,709	1/9/10
	VNUS Medical Technologies, Inc.	$470	6/17/09
	Somanetics Corp.	$335	7/27/10
	Aspect Medical Systems, Inc.	$267	11/5/09
CR Bard, Inc.	SenoRx, Inc.	$210	7/6/10
Johnson & Johnson	Mentor Corporation	$1,211	1/16/09
	Acclarent, Inc.	$785	1/20/10
Medtronic, Inc.	Ablation Frontiers, Inc.	$235	2/6/09
	CoreValve, Inc.	$850	4/9/09
	Invatec s.r.l.	$500	4/21/10
	ATS Medical, Inc.	$368	8/12/10
Merck KGaA	Millipore Corp.	$7,016	7/15/10
Novartis AG	Alcon, Inc.	$28,442	8/26/10
Sonova Holding AG	Advanced Bionics Corporation	$494	12/30/09
Stryker Corp.	Ascent Healthcare Solutions, Inc.	$535	12/31/09
	Total	**$49,286**	

What Can Be Patented

- Can medical devices be patented? YES
- Can a method of manufacturing a medical device be patented? YES
- Can a method of medical treatment be patented?
  - US – YES, but doctors are not liable for direct infringement
  - Canada – NO
  - Europe – NO, unless purely non-therapeutic (i.e., cosmetic)
  - China - NO
  - Japan – NO, if method of medical treatment is for human
  - Mexico - NO

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What Can Be Patented

- Can a diagnostic method be patented?
  - US – YES
  - Canada – YES, but no steps of surgery or therapy
  - Europe – NO, if practiced on human or animal body
  - China – NO, if (1) examined subject is live human or animal body; (2) direct object of invention is to obtain diagnosis of disease; and (3) entire diagnostic process is included
  - Japan – NO, if method is for human
  - Mexico – NO, if applicable to human or animal body

Technology Transfer and Medical Devices

- Academic institutions are a fruitful source of device innovation
  - Biomedical engineering departments
- Relatively cheap to prototype and develop proof-of-principle
  - Translational Research Centers have been highly successful
    - Deshpande Center – MIT
    - Von Liebig Center – UCSD
    - Wallace H Coulter Foundation's Translational Research Partnerships in Biomedical Engineering

The Challenge

- Funding
  - US Government's primary investment in PoC funding is the SBIR and STTR programs
  - $2.5 billion annually; **BUT**
    - SBIR must be led by a company; can involve a university
    - STTR must involve a company and a university; either can lead
      - i.e., The technology must already have been transferred
  - Some faculty start a company just to apply for SBIR or STTR grants

Proof-of-Concept ("PoC") Funding

- Aka "Translational Research"

"Translational research is what we call product development in academia. We can't call it "Product Development", so we call it "Translational Research" and everyone's happy"

Paul Zavracky
Dean, School of Technological Entrepreneurship
Northeastern University
2008

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Purpose of PoC Funding

- Reduce technical risk
- Reduce market risk
- Help Technology Push find its Market Pull

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Typical Uses of Funds

- Proof of Concept
  - Hiring of additional staff/grad students for specific experiments
  - Buying of specific testing equipment
  - Pivotal translational proof of concept experiments
- Prototype development
  - Testing in an industrial setting or by 3rd Parties
  - Clinical Development
- Marketing and Customer Development
  - Developing user friendly interfaces
  - Engaging end users to evaluate the technology

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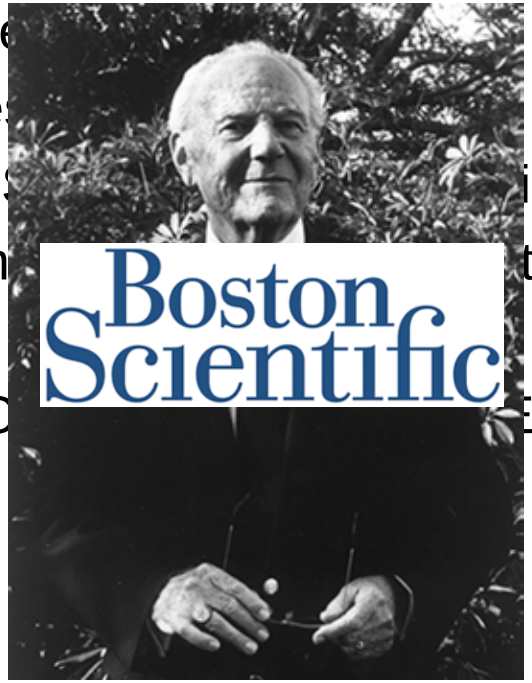
Proof of Concept Funding

- Majority of PoC funding to date has come from institutional, philanthropic or state sources
- Philanthropic
  - Individual institution
    - MIT/Deshpande, UCSD/von Liebig, USC/Stevens
  - National
    - Coulter, Kauffman Entrepreneurial postdoctoral fellowships
- State
  - Massachusetts Technology Transfer Center
  - Ben Franklin (Pennsylvania)
  - Edison (Ohio)

William J. von Liebig

- Founded Meadox Me
- Manufactured textile
- Acquired by Boston ion in 1995
- Founded the William tion in 1975
- Died 1999
- $10 million gift to UC Engineering in 2001



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VON LIEBIG CENTER

ABOUT

FUNDED PROJECTS

SERVICES

EDUCATION

GIVING

CONTACT

(858) 822-1435

email »

Wireless Health Innovation Challenge

apply »
for advisory services

Accelerating Innovation

Advisory services and seed funding to advance commercialization of Jacobs School discoveries

« PREVIOUS NEXT »

Help us select winning projects »

Mentor a project team »

Invest: your gift supports inventions to transform our world »

Support
the von Liebig Center

EVENTS

There are not any von Liebig events listed at this time. View other Jacobs School events »

ANNOUNCEMENTS

- Innovation Day Expo and Symposia
- Call for Entries - LES Foundation Graduation Student Business Plan Competition
- San Diego's Leading Ventures Takes on Commercialization of Bioengineering Breakthroughs | Xconomy
- von Liebig Center startup Ortiva Raises $8M from Intel Capital

Von Liebig Center

- Advisory services:
  - Stimulate University/Industry exchange
  - Develop new alliances
  - Explore appropriate commercialization strategies for new technologies
- Analyze Commercial Potential
  - Protect Intellectual Property
  - Identify Potential Licensees
  - Market to Companies
  - Write Business Plan
  - Market to Investors

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Von Liebig Center

- Seed grants
  - $75,000 for proof of concept

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Desh Deshpande

- Serial entrepreneur
  - Coral Networks, rou 5 million in 1989
  - Cascade Communi Ascend Communications for $3.7 billion in 19
  - Sycamore Netwo ved market cap of $18 billion (briefly!)
  - Tejas Networks,
  - ASG-Omni, 200(CA
- Gave $20 million to est de Center in 2002

Great ideas abound at MIT, and The Deshpande Center strives to make them a reality. By funding novel early stage research and connecting MIT's innovators to the business community, the center helps emerging technologies to emerge.

KEEP ME INFORMED

BRIDGING THE GAP BETWEEN IDEA AND IMPLEMENTATION

ABOUT THE CENTER
RESEARCH PORTFOLIO
ACTIVITIES
CALENDAR
GRANT PROGRAM
NEWS
SPINOUTS
SUPPORT THE CENTER
RESOURCES FOR INNOVATORS

ACTIVITIES
Grant Program
Catalyst Program
i-Teams
IdeaStream

INNOVATION AT MIT:
In 2006, 23 MIT technology-based startups were funded.

NEWS

October 19, 2010
Press Release
MIT Deshpande Center Announces Fall 2010 Research Grants

September 17 , 2010
In The News
Digital ear canal scanner project spins out into Lantos Technologies.

June 28, 2010
In The News
A recent NY Times article, "The Idea Incubator Goes to Campus", discusses how visionaries, researchers, engineers, and entrepreneurs, are all working together to mo
Deshpande Center for Technological Innovation.

May 28, 2010
In The News
Can a 'tattoo' help diabetics track their blood sugar? In the Department of Chemical Engineering, Prof. Michael Strano and postdoctoral researcher, Paul Barone, are expe
under the skin to reveal blood glucose levels. This research is being funded by the Deshpande Center. Read the full article on the MIT News Office site.

May 21, 2010
In The News
Prof. Chris Love, of the Department of Chemical Engineering, believes that there is a better way to diagnose food allergies. One of his projects, funded in part by the De
analyze individual immune cells taken from patients, allowing for precise measurement of the cells' response to allergens such as milk and peanuts. To learn about this p

May 20, 2010
In The News
Hear ye, hear ye! Prof. Doug Hart, of the Department of Mechanical Engineering, and his research team are developing 3-D imaging technology, funded by the Deshpand
function — better than current models. To learn about this project read the MIT News Office article.

Deshpande Center

- Grant Program
  - Ignition Grants – upto $50,000
  - Innovation Grants – upto $250,000
- Catalyst Program
  - Mentors
- i-Teams
  - For-credit courses
    - Fall and Spring semesters
  - Offered through MIT Entrepreneurship Center
- IdeaStream
  - Early stage investors' forum for Deshpande funded spin-outs

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Proof of Concept Centers: Accelerating the Commercialization of University Innovation

January 2008

Ewing Marion
KAUFFMAN
Foundation

Results

	Von Liebig		Deshpande	
Annual Investment	$1.2 mm		$1.7 mm	
Projects Funded	66		64	
Average Investment	$42k		$109k	
Licenses	4	(6%)	1	(2%)
Start-Ups	16	(24%)	10	(16%)
Total Capital Raised	$71 mm		$88.7 mm	
Average per Start-Up	$4.4mm		$8.9mm	
Leverage	105x		81x	

Source: Kauffman Foundation, 2008

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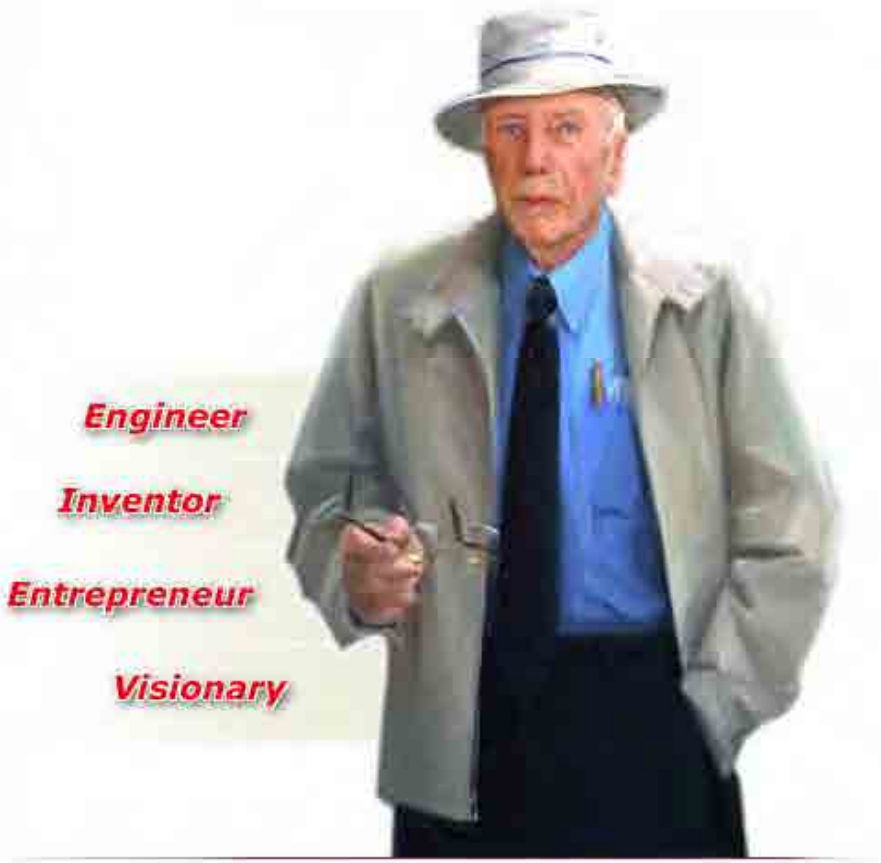
Wallace H. Coulter

- Electrical engineer (Ge… plied his skills to biomedical problems
  - Regarded himself as … dical engineers
  - Worked in his garage
  - Created the Coulter C…
  - Patent issued 1953; s… e NIH
- Founded the Coulter El… his brother Joe in 1958
- Acquired by Beckman I… for $1.1 billion
  - Beckman-Coulter acquir… Corporation for $6.8 billion February 2011
- Founded Wallace H. Cou… on in 1997
- Died 1998

DANAHER

WALLACE H. COULTER Foundation

- Wallace H. Coulter
- The Coulter Foundation
- Coulter Translational Partnership Award
- Coulter Translational Research Award
- Contact Us
- Home



790 NW 107th Avenue, Suite 215
Miami, Florida 33172-3158
Phone (305) 559-2991
Fax (305) 559-5490
www.whcf.org

Wallace H. Coulter Foundation

- Established Coulter Translational Research Programs in Biomedical Engineering in 2005
- National solicitation:
  - 83 universities with BME attended kick-off meeting
  - 20 invited to submit full applications
  - 14 site visited
  - 10 selected
    - Boston University
    - Case Western Reserve University
    - Drexel University
    - Duke University
    - Georgia Tech / Emory University
    - Stanford University
    - University of Michigan
    - University of Virginia
    - University of Washington
    - University of Wisconsin

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Wallace H. Coulter Foundation

- Launched in 2006
- 5 year program;
- $1 million per year
- Program Director
  - Senior level medical device industry
- Key elements
  - Co-PI's
  - Committee to select projects
    - University
    - Coulter Foundation
    - Local community
      - VC's
      - Entrepreneurs
      - Industry

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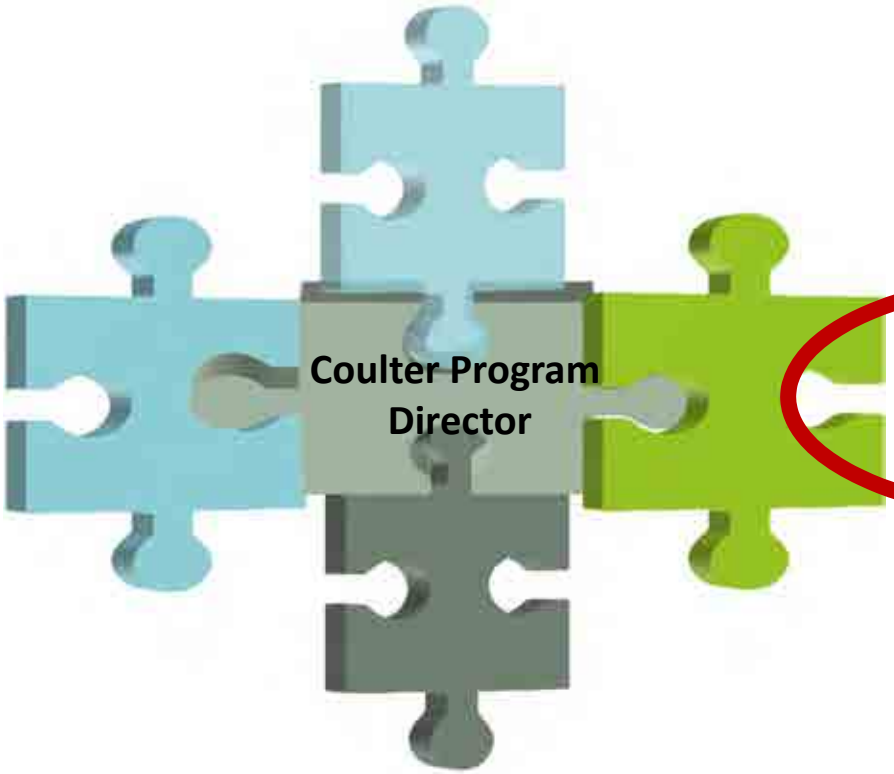
Coulter Process Elements

IP/Commercial
Risk Analysis

Oversight
Committee (OC)



Partnership
Co-PI's
Engineer & Clinician

Office of
Technology Transfer
(OTT)

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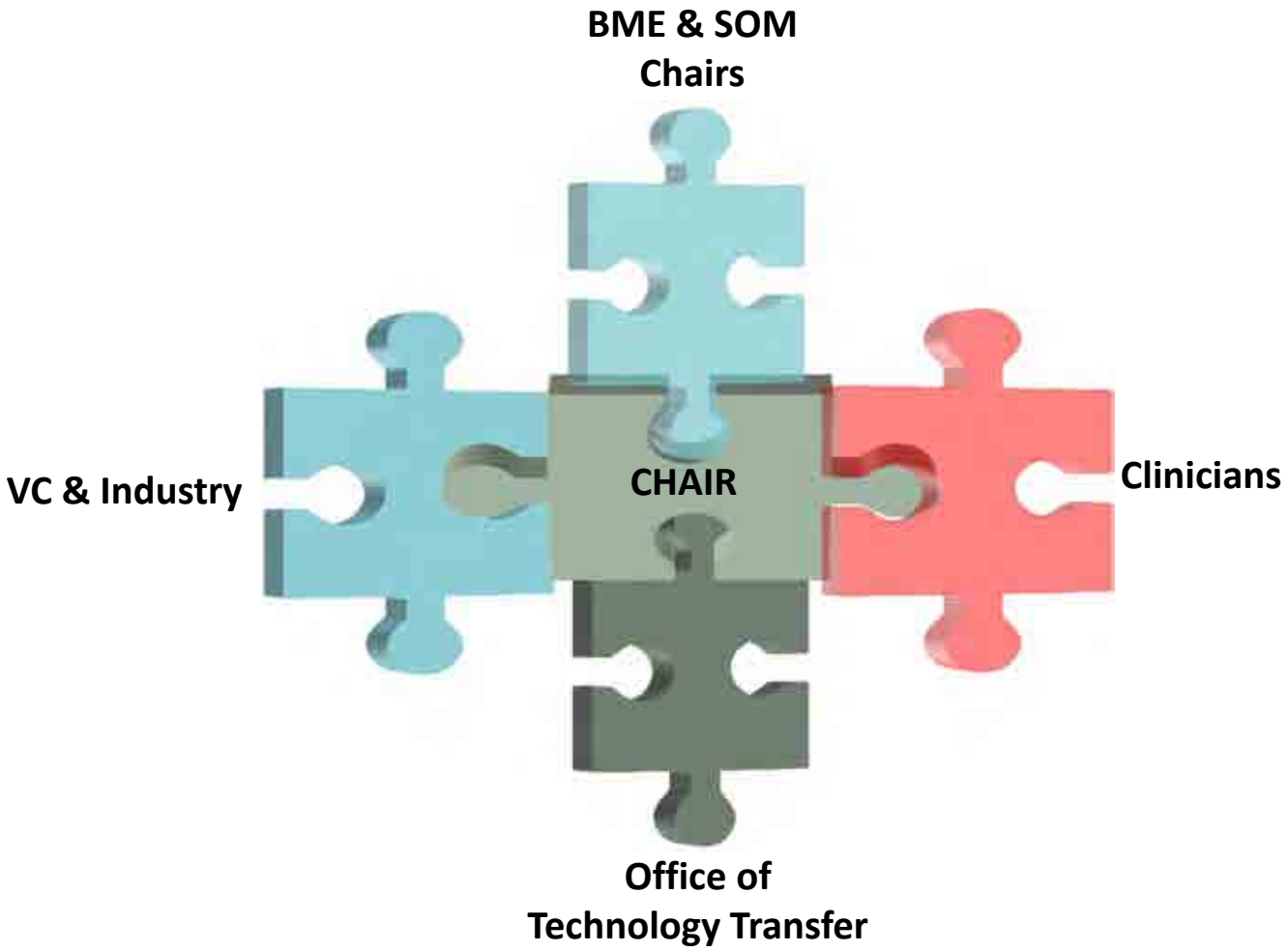
Oversight Committee



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Coulter Process

DE-RISKING

PROGRAM MANAGEMENT

Proposal Evaluation

- Opportunity for impact
  - Unmet clinical need
- Technology
  - Development stage
    - If any discovery remains to be done, it's too early
  - IP
- Team
  - Competency, commitment)
- Plan
  - Commercial risk mitigated
  - Appropriate endpoint and years of funding
  - Milestones
  - Follow-on-funding sources identified

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Project Management

- Coordination of all commercial activities related to the project
  - Risk reduction
  - Follow-on sources of funding
- Shield research team from unnecessary burden
  - Focus on achieving critical milestones

Results – Coulter

(2006-2011)

	Number	Amount ($ mm)	Average ($ mm)	Leverage
Projects Funded	200	$46	$0.23	
Start-Ups				
VC Funded	38	$294	$7.74	34.4x
Seed Stage	28	$5	$0.18	0.8x
Total Start-Ups	66	$299	$4.53	20.1x
Licensed to Industry	28			
Gov't Follow-on Funding		$150		
Total	94	$305	$3.24	14.4x
LSR	47.0%			

Source: Caro Elias, Wallace H. Coulter Foundation, Personal Communication, February 2012

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Needs a rich ecosystem

- Internal resources:
  - Tech Transfer Office
  - Research Administration - COI
  - Prototype/Machine Shop
  - Business School
  - Animal Facilities
  - Clinical Research Services
  - SBIR/STTR Funding Office

Regulatory and Reimbursement

Regulatory and Reimbursement

- When you're developing a product for healthcare, there are two fundamental challenges:
  - Obtain regulatory approval to sell the product
  - Get payors to pay for it

Regulatory Approval

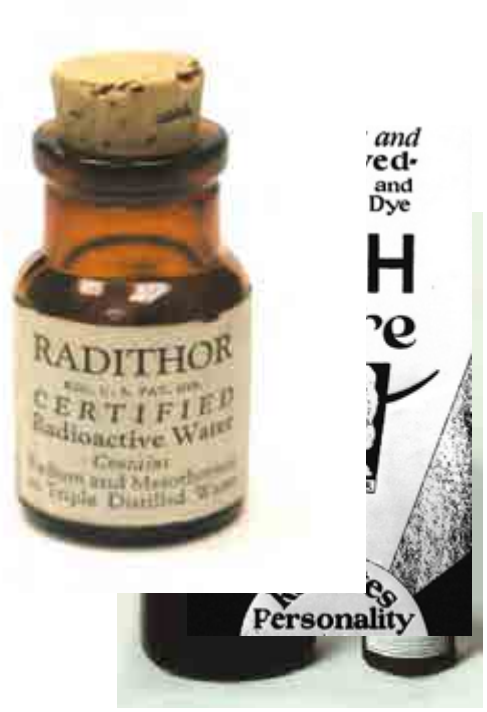
- Need to show that the product is:
  - Safe
  - Efficacious

Regulatory Approval

- Efficacious
  - "Patent Medicines"
- 1906 Food and Drug Act ("Wiley Act")
  - Adulteration of food and drugs
  - Driven by USDA Bureau of Chemistry
  - Department of Food, Drugs and Insecticides created in 1927

Regulatory Approval

- 1930's: Concerns over unsafe products legal under 1906 law
  - Radioactive beverages
    - Several deaths from radium poisoning
  - Mascara that caused blindness
    - Several deaths from inflammation and *S. aure*
  - Improperly formulated sulfanilamide
    - Over 100 people died from diethylene glycol p
- 1938 Food, Drug and Cosmetic Act ("FD&C Act"
  - Required safety testing
  - Banned fraudulent efficacy claims



Regulatory Approval

- Gruenthal denied ity
- Finally apologized **r 2012**

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Special Guide to Midsummer Vacation Spots—Pages 16-25

The Washington Post

480,000

'Heroine' of FDA Keeps Bad Drug Off of Market

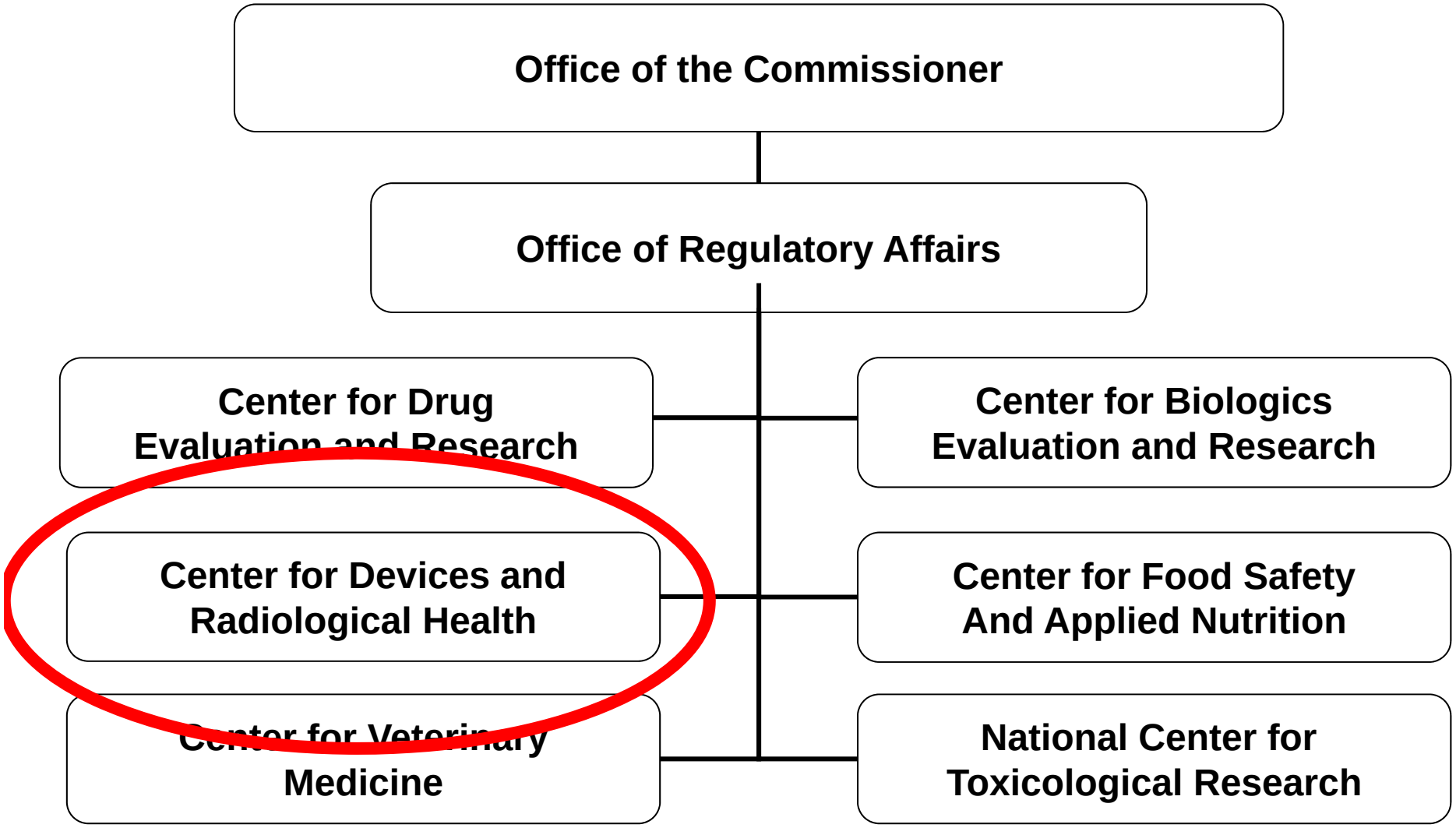
U.S. Captain Killed in ...ited Attack

President Designates Mayor of Cleveland As Secretary of HEW

(c) 1962, The Washington Post. Reprinted with permission

Frances Kelsey makes headlines on july 15, 1962 after winning her two year battle to keep thalidomide out of the American market

FDA Organization



Medical Device Approval

- Class I
  - Not intended to help support or sustain life or be substantially important in preventing impairment to human health
  - May not present an unreasonable risk of illness or injury
    - e.g., Elastic bandages
    - Examination gloves
    - Hand-held surgical instruments.
- Class II
  - General controls alone cannot assure safety and effectiveness, and existing methods are available that provide such assurances.
  - Held to a higher level of assurance than Class I devices
  - Designed to perform as indicated without causing injury or harm to patient or user
    - E.g., Powered wheelchairs
    - Infusion pumps
    - Surgical drapes

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Medical Device Approval

- Class III
  - Insufficient information exists to assure safety and effectiveness solely through the general or special controls sufficient for Class I or Class II devices
  - 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
    - E.g., Implantable pacemakers
    - Pulse generators
    - HIV diagnostic tests
    - Automated external defibrillators
    - Endosseous implants

Medical Device Approval

- Class I
  - General controls
  - Most products are exempt from 510(k) notification
- Class II
  - General controls and special controls
  - Most products require 510(k) notification
- Class III
  - Most products require Premarket Approval (“PMA”)

Classification

- Devices are assigned to a panel, which assigns a classification:
  - Anesthesiology
  - Cardiovascular
  - Clinical Chemistry and Clinical Toxicology
  - Dental
  - Ear, Nose, and Throat
  - Gastroenterology and Urology
  - General and Plastic Surgery
  - General Hospital and Personal Use
  - Hematology and Pathology
  - Immunology and Microbiology
  - Neurology
  - Obstetrical and Gynecological
  - Ophthalmic
  - Orthopedic
  - Physical Medicine
  - Radiology

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Classification

- On FDA website.
  - e.g., **Blood pressure cuff**
    - Regulation Description: Blood pressure cuff
    - Definition: A blood pressure cuff is a device that has an inflatable bladder in an elastic sleeve (cuff) with a mechanism for inflating the bladder. The cuff is used to determine a subject's blood pressure.
    - Regulation Medical Specialty: Cardiovascular
    - Review Panel: Cardiovascular
    - Product Code: DXQ
    - Submission Type: 510(k)
    - Regulation Number: 870.1120
    - Device Class: 2
    - GMP Exempt? No
    - Recognized Consensus Standards
      - – AAMI SP10:2002 Manual, electronic or automated sphygmomanometers
    - Guidance Document
      - – Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance
    - Version 1; Final
    - Third Party Review: Eligible for Accredited Persons Program

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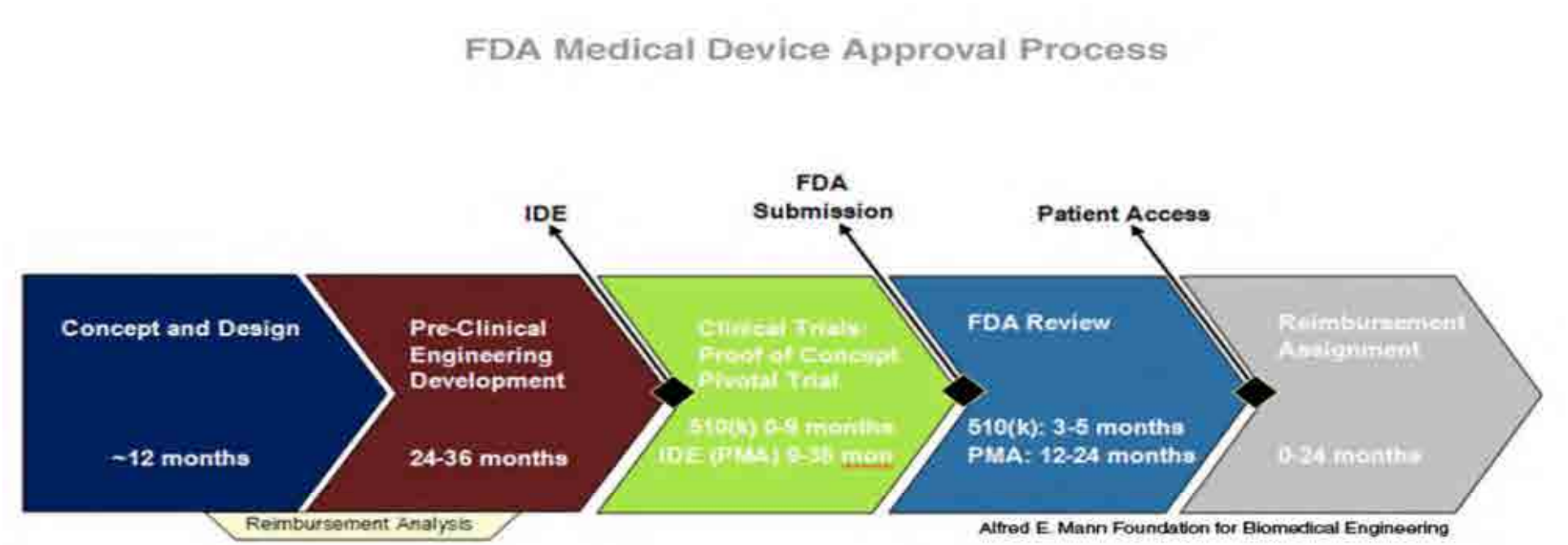
Substantial Equivalence

- One approach in the premarket notification submission (510(k)) demonstrates the device is "substantially equivalent“ to a legally marketed device
  - The “Predicate Device”
- Substantially equivalent means:
  - Same intended use as the predicate device
  - Same technological characteristics as the predicate device, or
  - Different technological characteristics but is as safe and effective as a legally marketed device, and
  - Does not raise different questions of safety and effectiveness than the predicate device
- ~44% of medical devices go through 510(k)
  - 15% of these will require clinical data to demonstrate substantial equivalence
  - Takes three to five months after submission to the FDA.

Device FDA Approval

- ~40 PMA devices approved each year
- ~3,000 510 (k) clearances.
- Concept to product launch typically takes between 4-10 years
  - $5 and $300 million dollars depending on the complexity of the device and required regulatory process.
  - FDA User fees:
  - ~$200K for a PMA submission
  - ~$3,500 for a new 510 (k) submission
    - Reduced for initial submission from a small business



- Need to show efficacy (clinical trials), safety, and design. Showing efficacy can delay a launch 1 – 3 years and costs between an additional $10-12M to show these efficacy studies.

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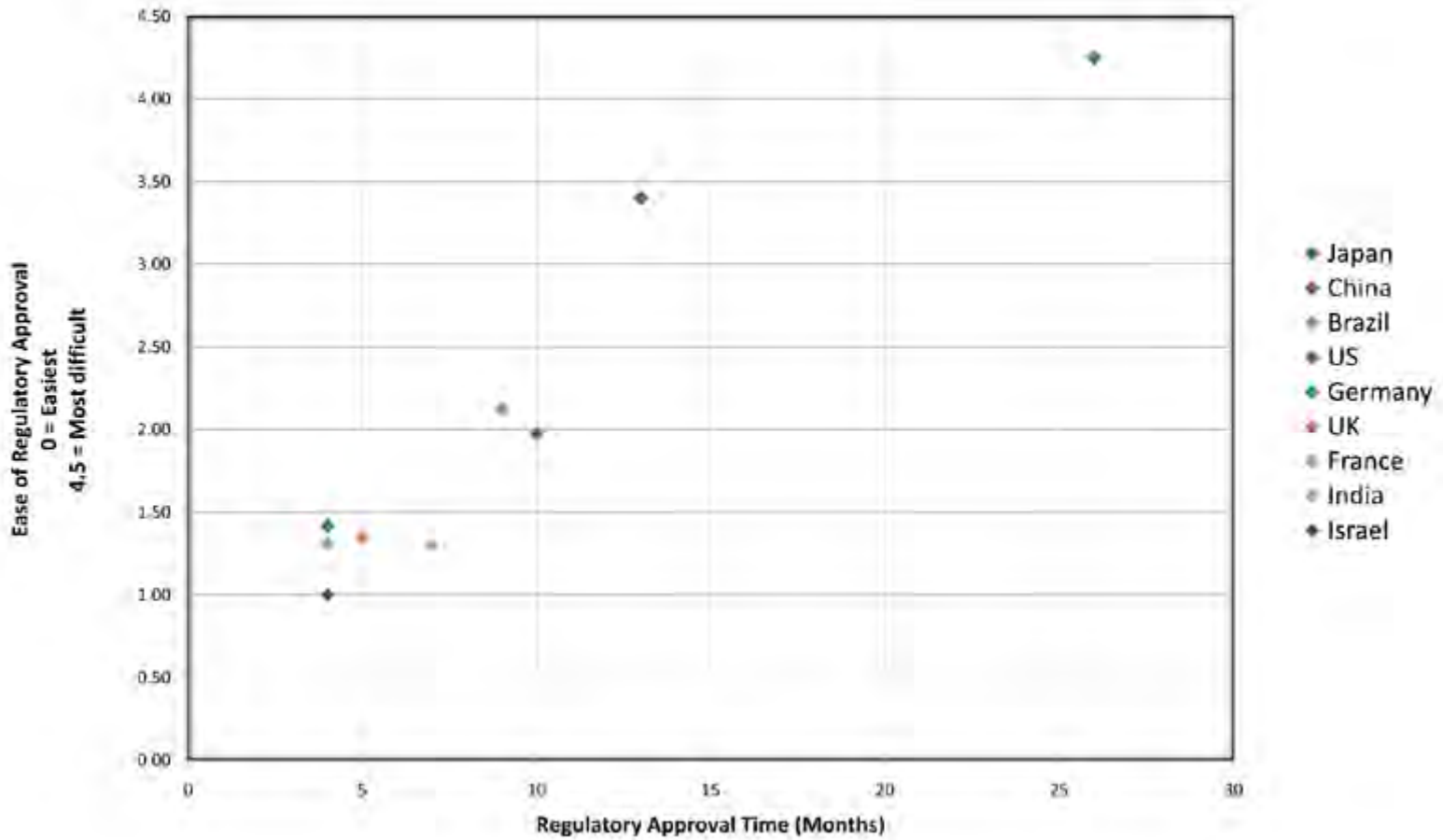
Humanitarian Use Device Exemptions (HDE)

- A Humanitarian Use Device (HUD) is any device intended help patients who suffer from rare conditions.
  - Treating or diagnosing condition that affects fewer than 4,000 people in the United States each year.
  - Similar to a Pre-Market Approval (PMA) application, but clinical trials may not be needed.
    - HDE approvals in 2011:
      - Berlin Heart – an small artificial heart designed to keep children alive in hospital for months or years until a suitable donor heart can be found
      - Microwave based treatment for cervical cancer patients who are ineligible for chemotherapy.

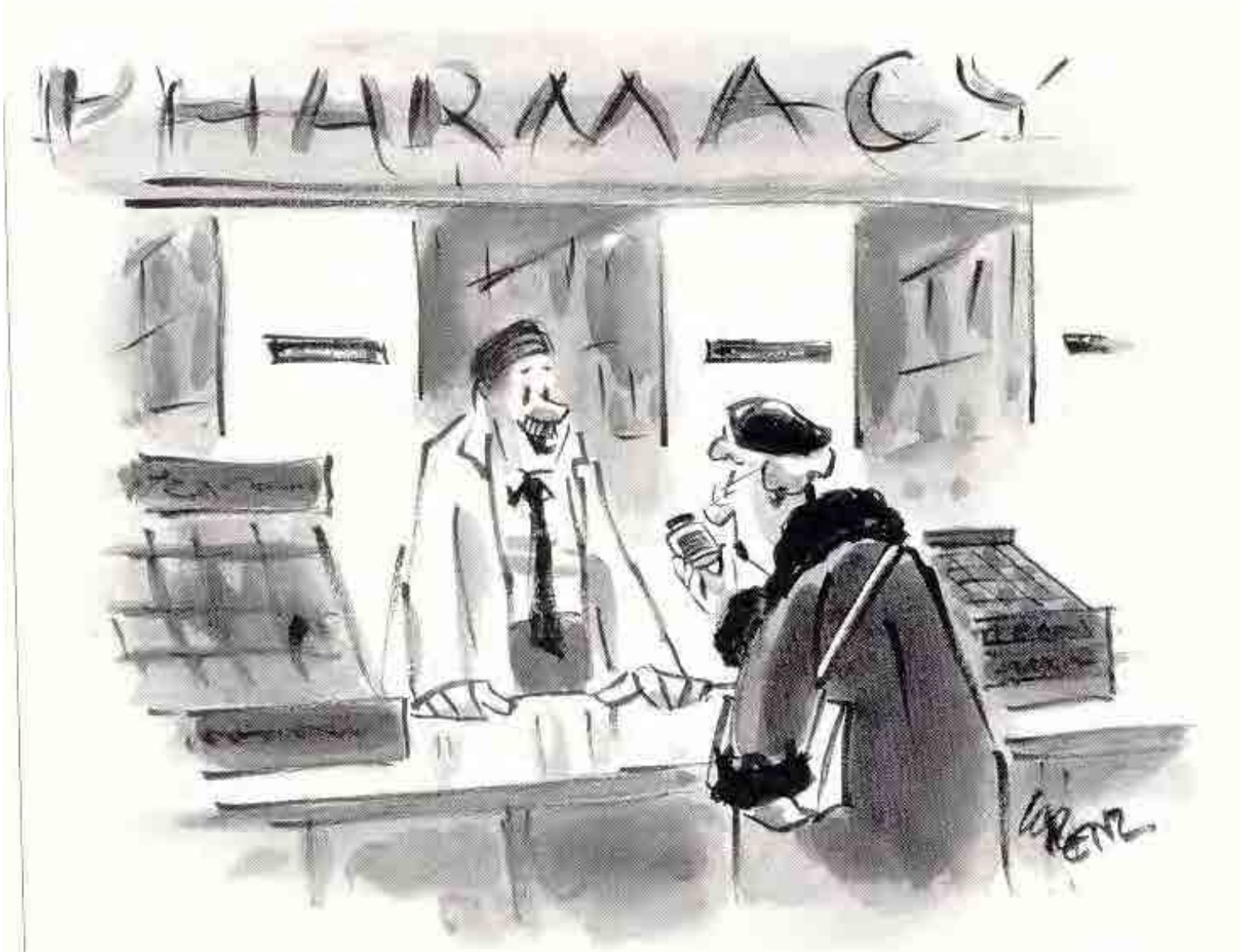
Development Phases

- **Pre-Clinical Development**: bench testing, biocompatibility and other laboratory testing, and animal studies.
- **IDE:** Investigational device exemption is the regulatory authorization for the device to be used in a clinical study to collect safety and efficacy data. This data is required to support a Pre-market Approval (PMA) application or in some instances a Pre-market Notification [510(k)] submission to FDA.
- **Proof of Concept in Man**: 10-30 healthy subjects, safety studies.
- **Pivotal Trials:** 75-400 subjects, study safety and preliminary evidence of efficacy in target indication.

Regulatory Approvals Worldwide

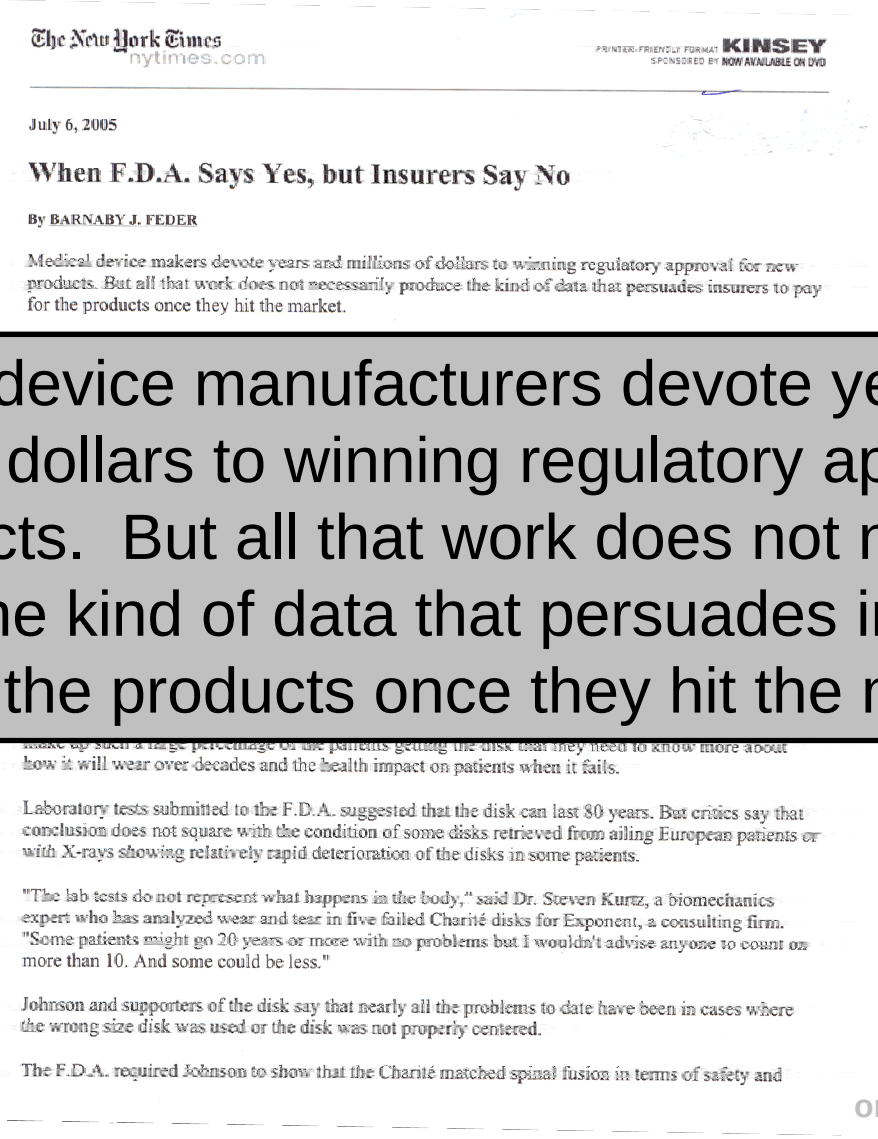


Reimbursement



"The F.D.A. is nuts about it."

In Practice, Things Can Be Different



The New York Times
nytimes.com

July 6, 2005

When F.D.A. Says Yes, but Insurers Say No

By BARNABY J. FEDER

Medical device makers devote years and millions of dollars to winning regulatory approval for new products. But all that work does not necessarily produce the kind of data that persuades insurers to pay for the products once they hit the market.

Medical device manufacturers devote years and millions of dollars to winning regulatory approval for new products. But all that work does not necessarily produce the kind of data that persuades insurers to pay for the products once they hit the market.

make up such a large percentage of the patients getting the disk that they need to know more about how it will wear over decades and the health impact on patients when it fails.

Laboratory tests submitted to the F.D.A. suggested that the disk can last 80 years. But critics say that conclusion does not square with the condition of some disks retrieved from ailing European patients or with X-rays showing relatively rapid deterioration of the disks in some patients.

"The lab tests do not represent what happens in the body," said Dr. Steven Kurtz, a biomechanics expert who has analyzed wear and tear in five failed Charité disks for Exponent, a consulting firm. "Some patients might go 20 years or more with no problems but I wouldn't advise anyone to count on more than 10. And some could be less."

Johnson and supporters of the disk say that nearly all the problems to date have been in cases where the wrong size disk was used or the disk was not properly centered.

The F.D.A. required Johnson to show that the Charité matched spinal fusion in terms of safety and

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Who Pays for Healthcare in the US?

Private Payers

Employers
- Self-funded or not

Unions

Health Plans
- Blue Cross/Blue Shield Plans
- United Healthcare
- Aetna US Healthcare
- Anthem Wellpoint
- Others

Public Payers

Medicare
- Federal
- Seniors, disabled, ESRD

Medicaid
- Federal/state
- Indigent, women, children, indigent seniors, chronically sick

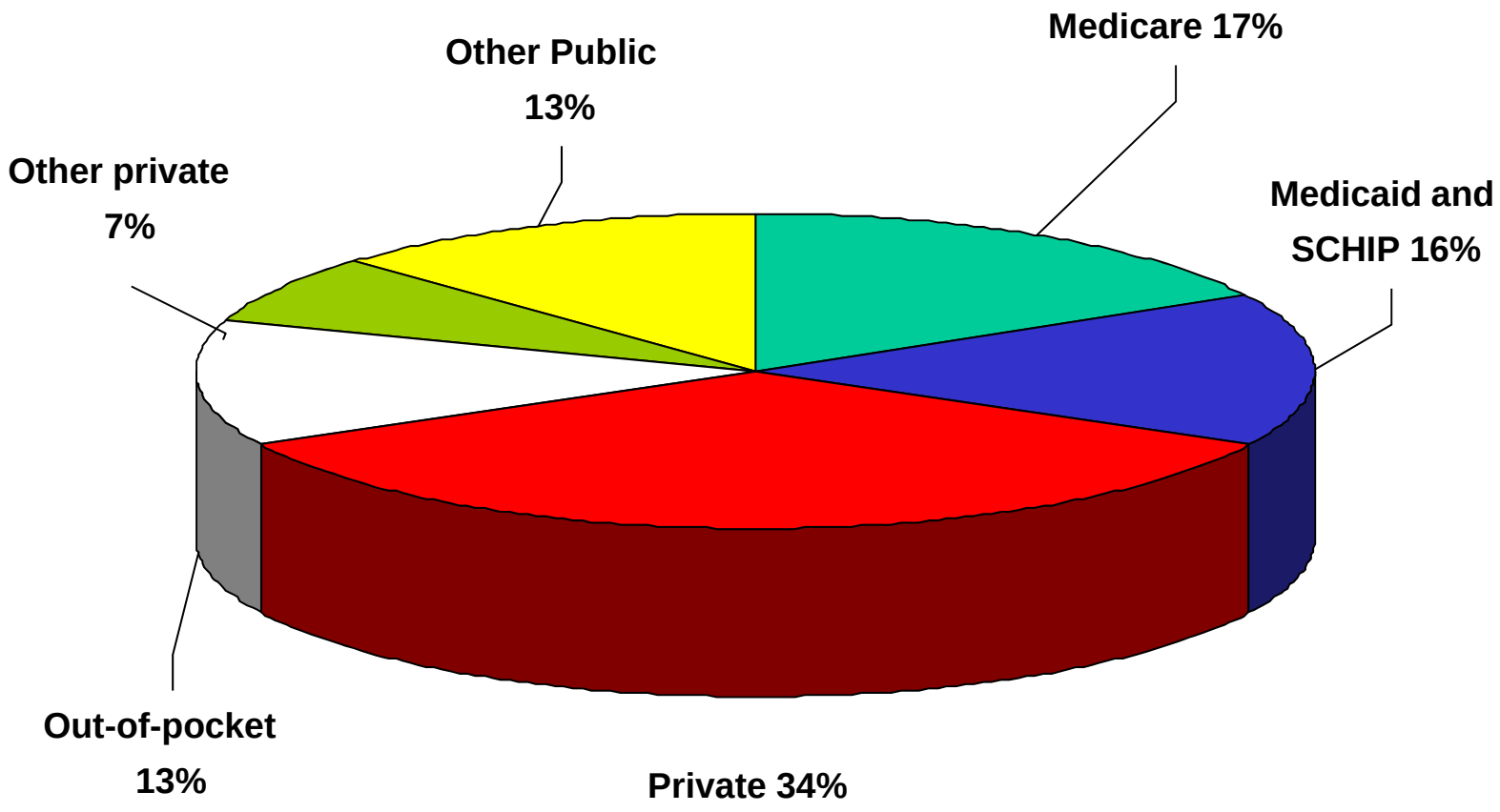
Veterans' Administration
- Federal

TriCare
- Federal
- Military dependents

SCHIP
- Federal/state
- Children

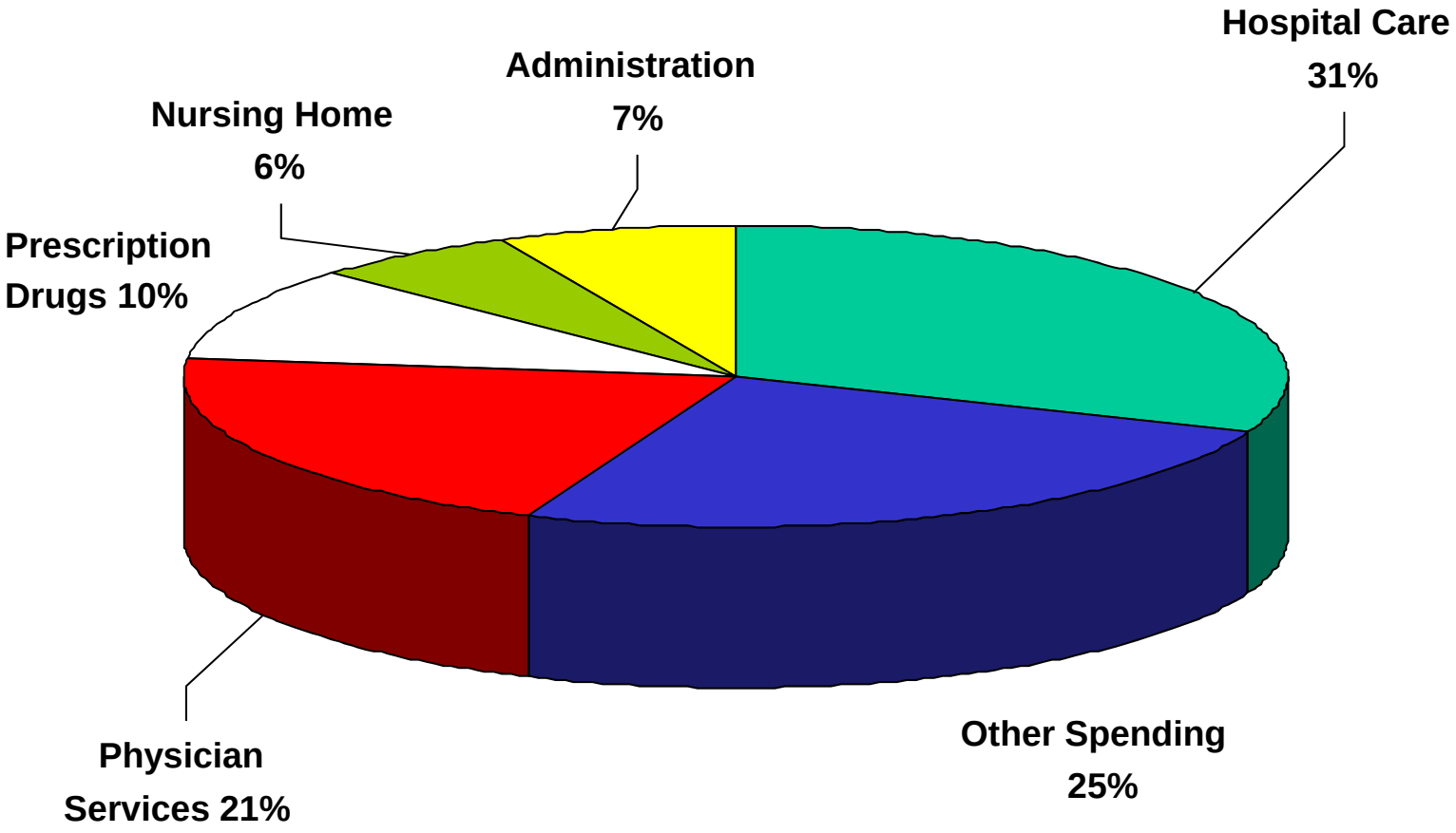
U.S. Health Care Coverage

(Source: Centers for Medicare and Medicaid Services)

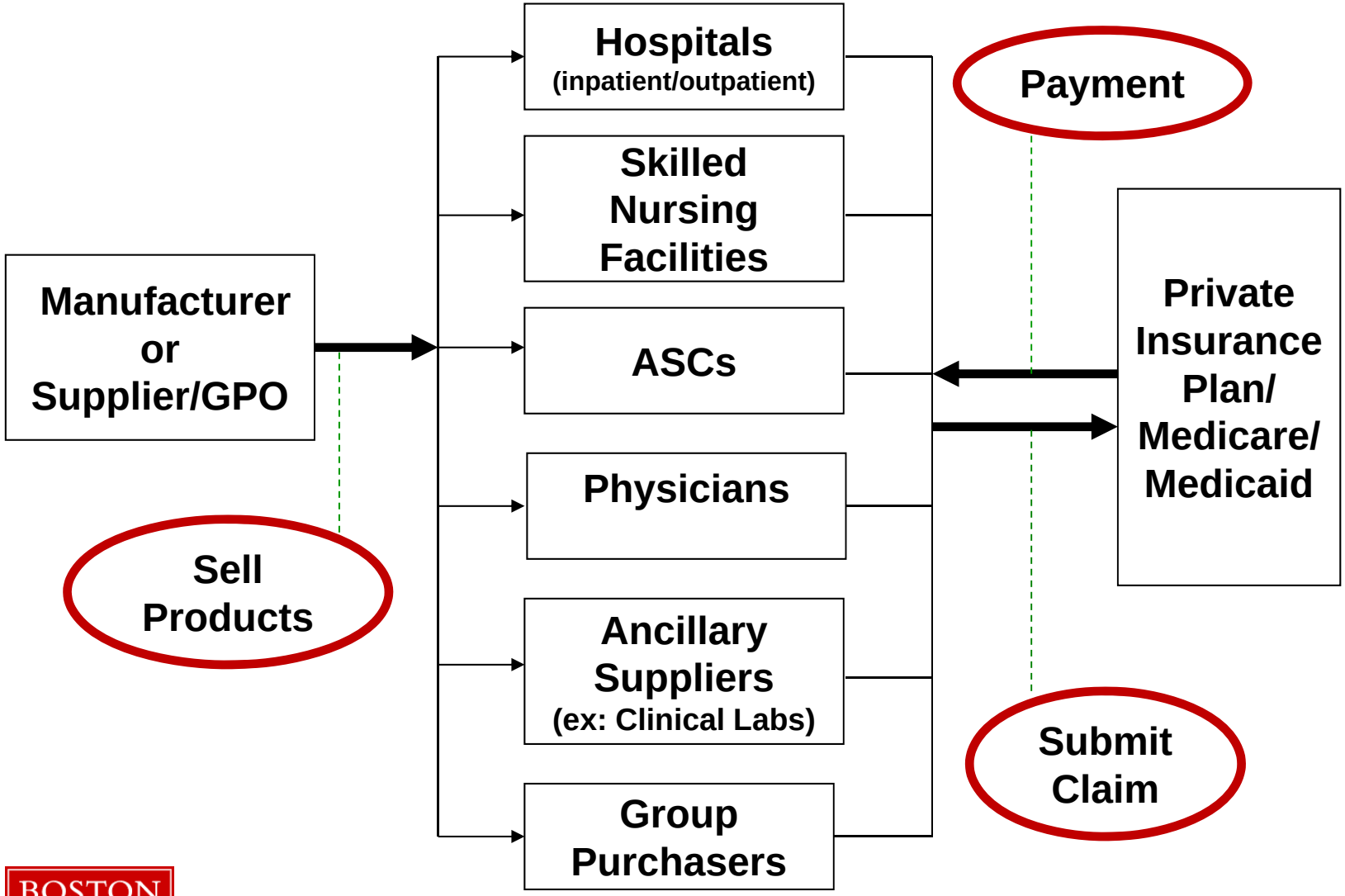


U.S. Health Care Spending

(Source: Centers for Medicare and Medicaid Services)



How Does A New Medical Device or Drug Fit Into The U.S. Health Care System?



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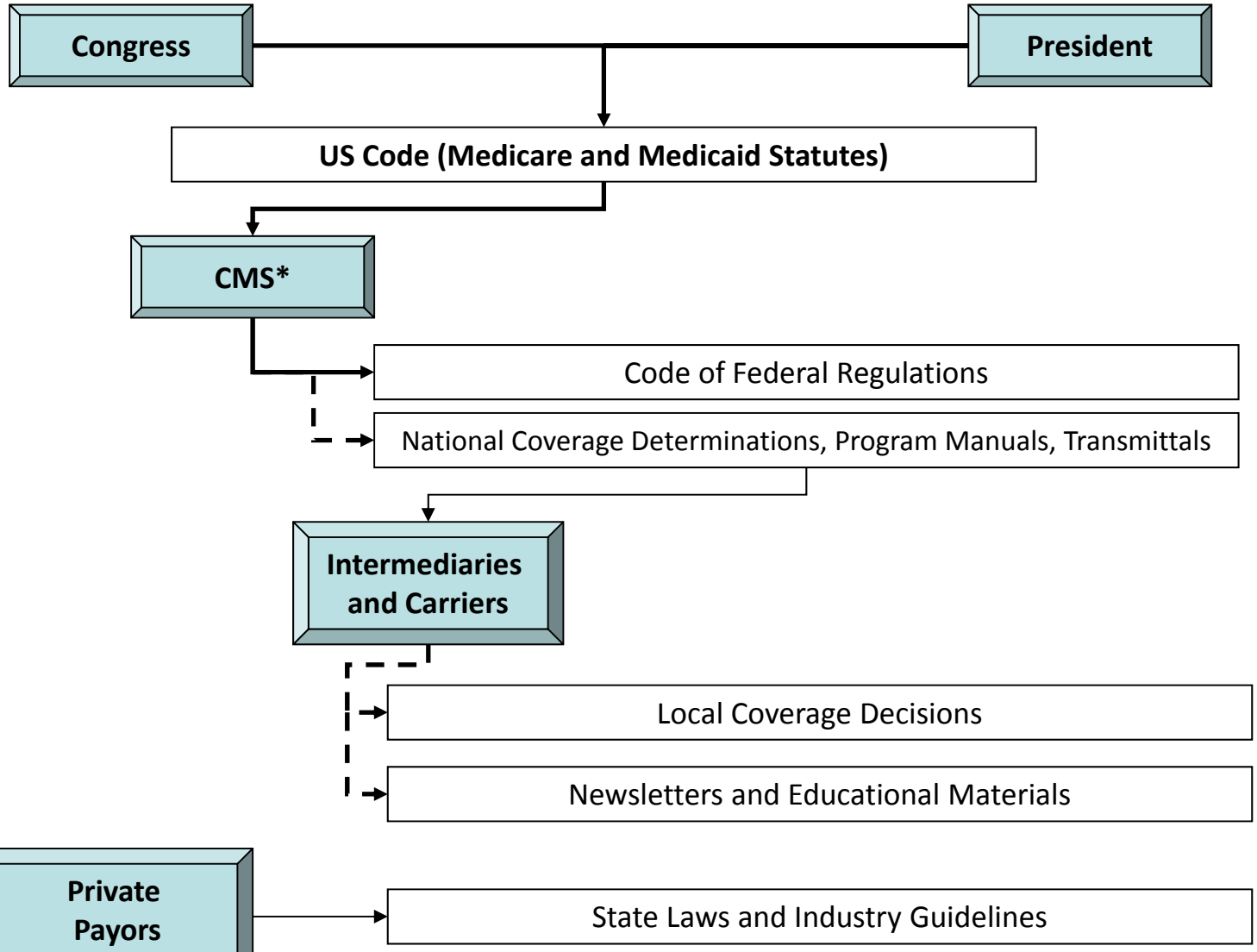
The U.S. Legal and Regulatory Hierarchy



* Centers for Medicare and Medicaid Services, formerly HCFA (Health Care Financing Administration

Three Basic and Distinct Concepts

- Coverage: Terms and conditions for payment
- Coding: Unique identifiers for diagnoses, procedures, devices & diagnostics, inpatient services, and outpatient services
- Payment: Remuneration by health insurance plans, government-funded programs

How Are These Concepts Different?

Coverage

- Is not guaranteed when you receive FDA approval/clearance
- Does not guarantee a new or favorable billing code
- Does not guarantee favorable payment

Coding

- Links coverage and payment with unique identifiers that can be used for electronic claims processing and health research
- Does not guarantee coverage
- Does not guarantee favorable payment

Payment

- Function of coverage and coding
- May be subject to limits
- May be stand-alone or bundled
- May be driven by breakthrough or existing technologies

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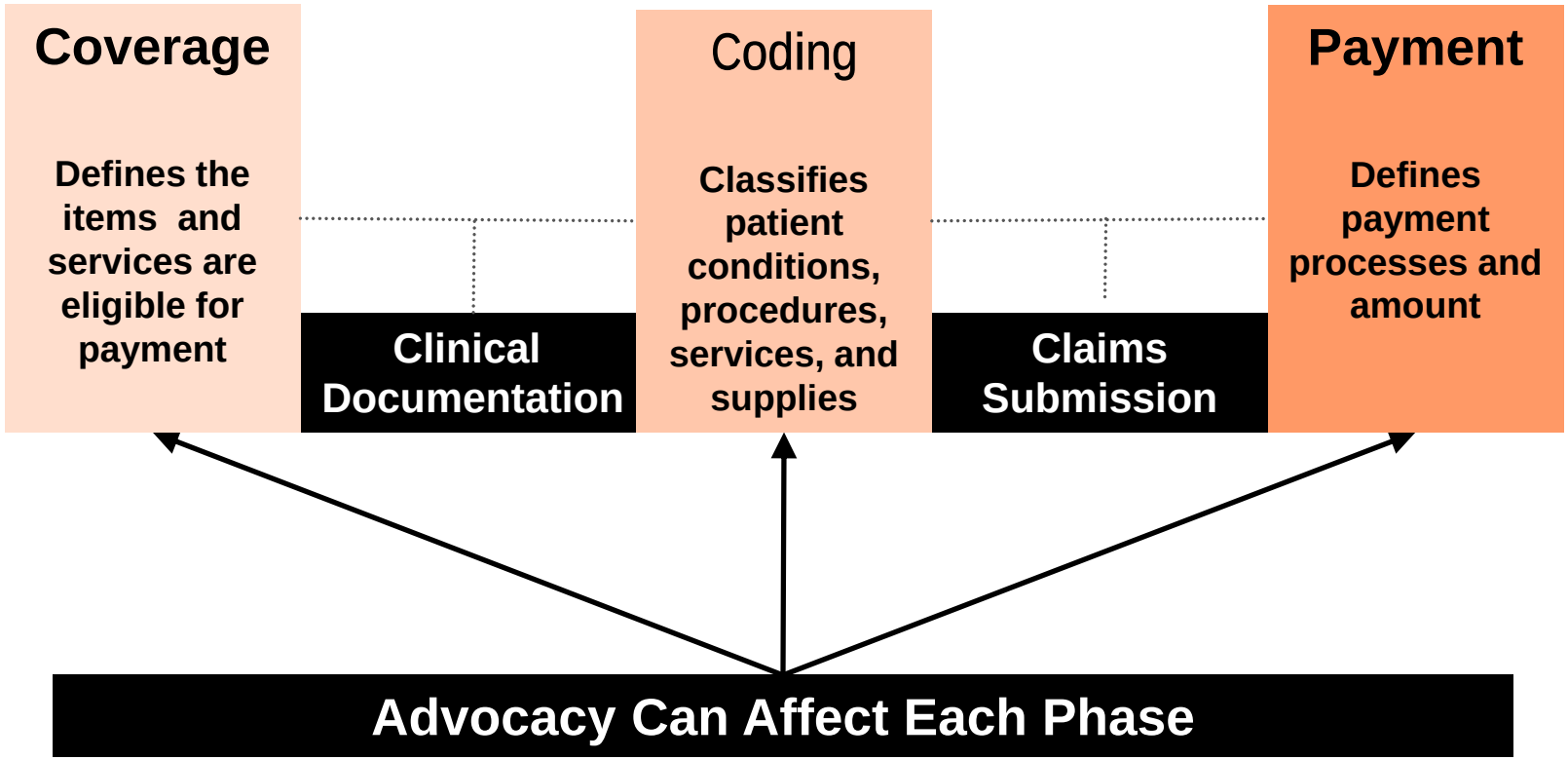
Review of Concepts: Coverage, Coding, and Payment



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Coverage Strategy

- Process starts well in advance of product launch
  - Thinking about coverage at all times beginning with the earliest product R & D discussions as well as when designing clinical trials
  - Investors may demand a rigorous coverage and reimbursement strategy
- Understanding realistic timeframes is critical

Coverage Strategy

Key Coverage Issues

- Who will benefit most?
  - Seniors, children, women, others?
- Where will the benefit be delivered?
  - Institutions, outpatient, home care
- What are the expected clinical outcomes?
- Are there services that are comparable, but inferior or superior?
- What is the expected financial impact for the payer/consumer?
  - Immediate v. long-term benefits?

Coverage Strategy

- Coverage process can range from six months to several years
  - Coverage is distinct from FDA approval/clearance
  - Must take into account the various coverage standards established for government and private players in the U.S. health system
  - Must address indications for “medical necessity”
  - May also address coverage limits, such as required site of service as a condition of coverage or frequency of tests (may have a payment impact as well)

Avoiding Pitfalls In The Coverage, Coding, and Payment Process

- Section 510(k) clearance makes it easier to get on the U.S. market, but more difficult to prove significant difference compared to the predicate device, unless specific indications justify it
- Get articles published in peer-reviewed journals to demonstrate distinction
- Don't argue that a new code is needed to get higher payment – base argument on
  - Technological improvement
  - Clinical improvement
  - Higher and more complex resources
- Don't go it alone - link arms with your allies

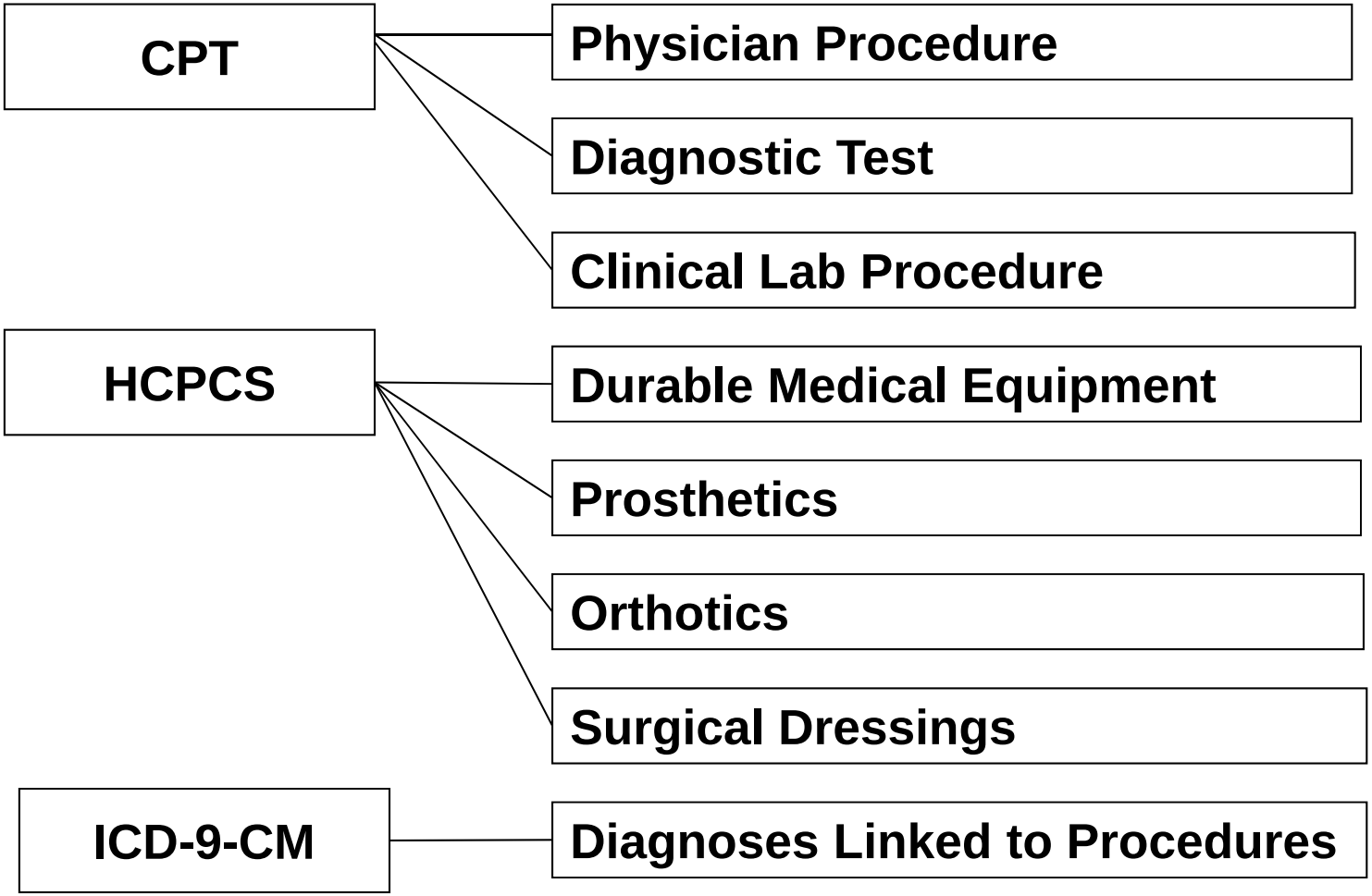
Integrating Coverage Issues Into Clinical Trial Design

- Coverage is driven by evidence of improved outcomes, clinical efficiency, and cost effectiveness
- Clinical trial design should incorporate these factors
- Study design should include gathering data comparing study device to existing treatments or technologies
- Consider factors relied on by the Agency for Healthcare Research and Quality in their evaluations (www.ahrq.com)

Coding Basics

- Coding is an identifier for a diagnosis, drug, device, or procedure
- Coding connects coverage and payment
- Codes allow for rapid claims processing and health policy research
- Coding systems have different timetables for updates and revisions

Find the Right Coding System



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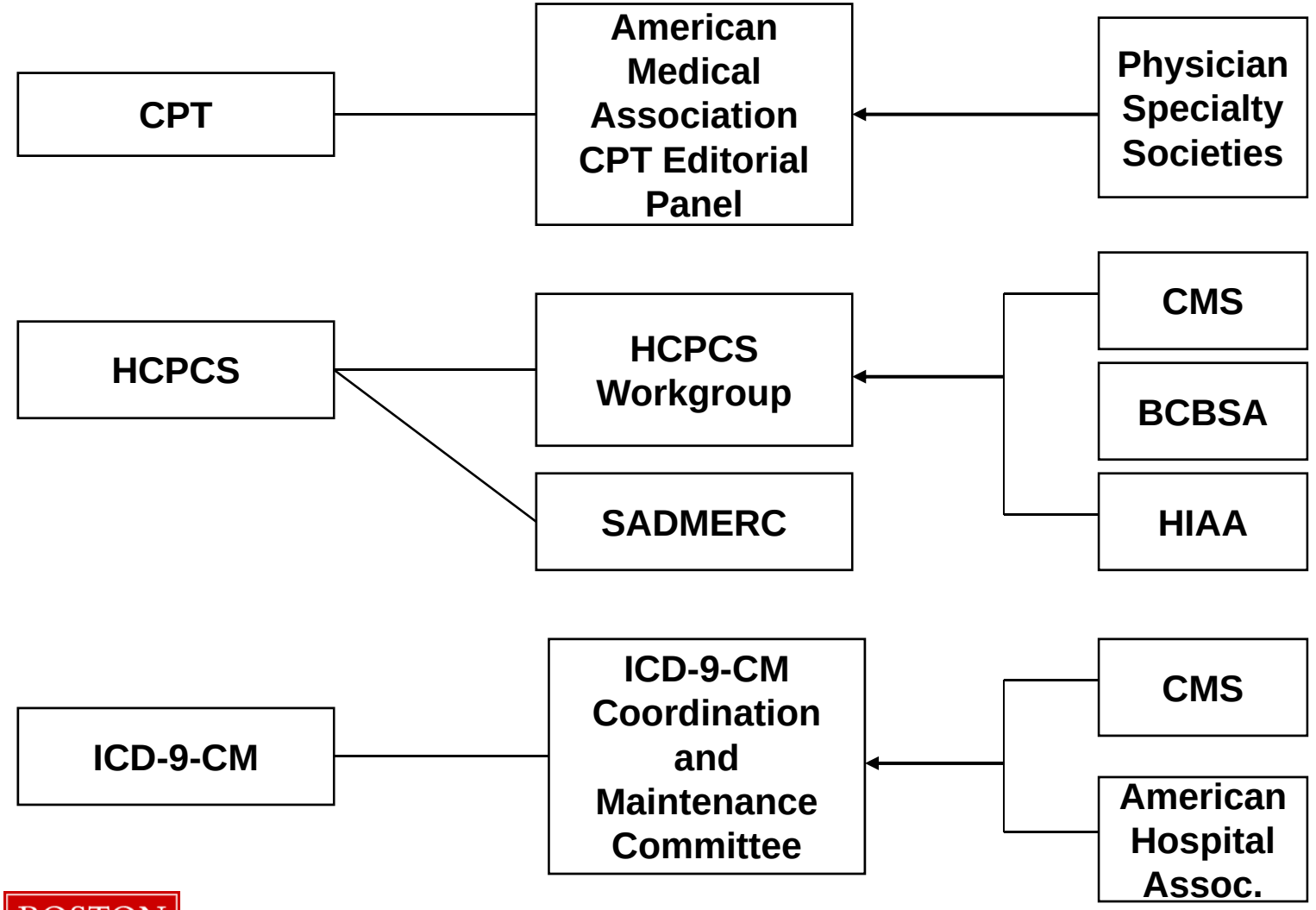
How Are New Codes Established?



Coding Basics

Key coding issues for billing codes -- similar to coverage issues

- Site of service
- Financial implications
- Professional v. Technical Components
- CPT Codes versus HCPCS Codes
- Related procedure codes for devices

Technology Licensing, Valuation and Acquisition for The Biotechnology Sector

Lecture 8: Patenting and Technology Transfer Issues with Stem Cells

Biotechnology Industry Research Assistance Programme
Department of Biotechnology

February 11/12, 2013 Bangalore
and
February 14/15,2013 New Delhi

Dr. Ashley J. Stevens
Past President, Association of University Technology Managers
and
Lecturer, Health Sector Management Program
School of Management
Boston University

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Acknowledgements

Andrew DeTienne, Wisconsin Alumni Research Foundation
Stanley Kowalski, U. of New Hampshire Law School

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Agenda

- The science
- Cell line issues
- Patentability issues
- Licensing issues
- Litigation landscape
- Commercial landscape
- Regulatory framework and landscape

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Learning Objectives

- Students will have a detailed understanding of the status of commercialization of stem cells
- Students will understand how stem cell issues are exemplative of the issues surrounding an important biotechnology therapeutic platform

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Core Issues

- Stem cells are a complex intellectual property landscape
  - Three fundamental platforms
    - Hematopoietic stem cells (“HSC”)
    - Human Embryonic Stem cells (“hES”)
    - Induced Pluripotent Stem cells (“iPS”)
  - Hybrid technologies:
    - Patents
      +
    - Know how
      - Cell lines
  - Two primary areas of application
    - Therapeutics
    - Disease models
  - Complex regulatory framework
  - Complex social and ethical issues

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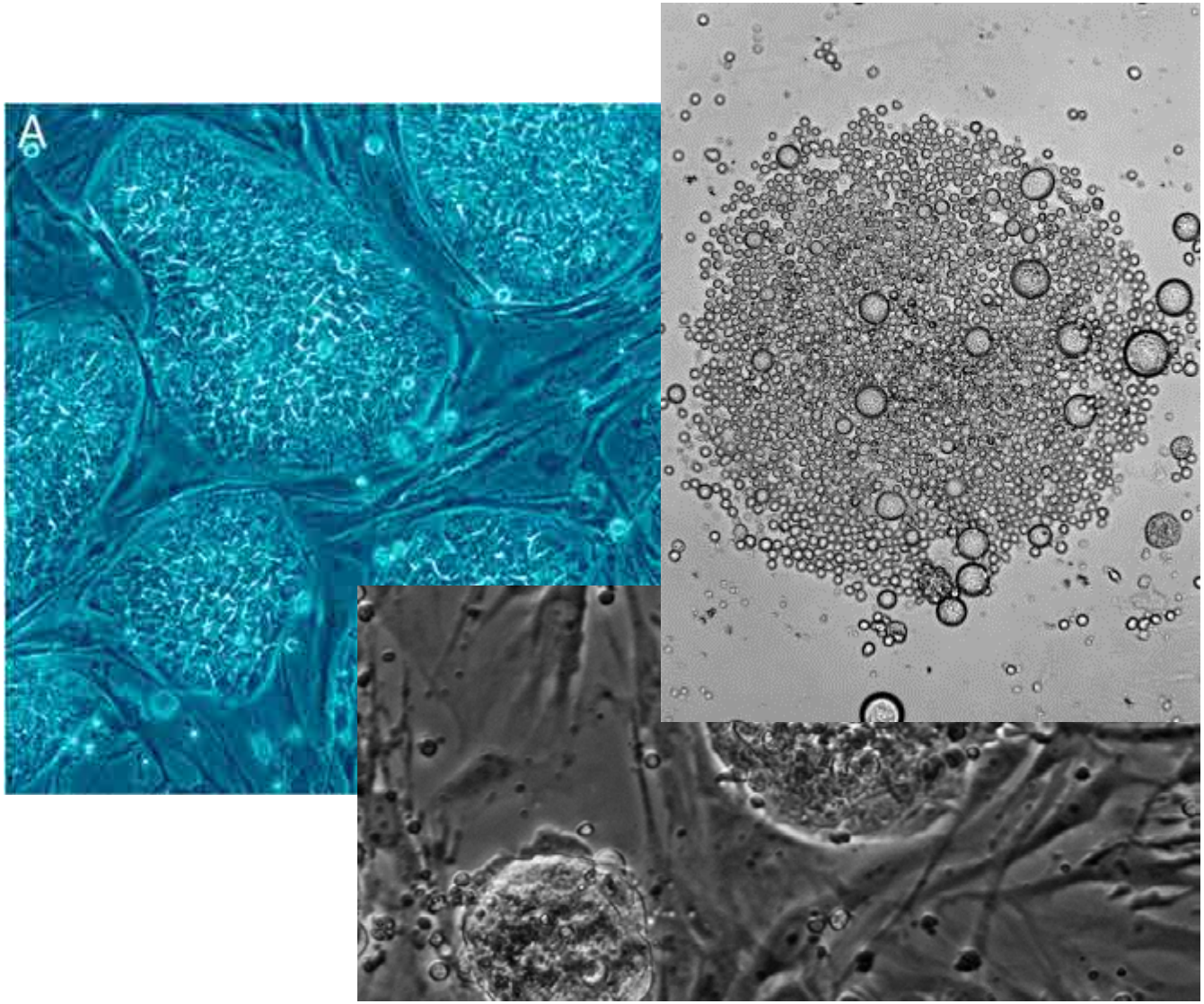
hES



HSC

iPS

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Hematopoietic Stem Cells

- Readily accessible stem cells
  - Umbilical cord blood
  - Bone marrow
- Generally allogeneic
- Least regulatory issues
  - Allogeneic bone marrow and cord blood transplants not subject to FDA regulation
    - Physician's decision
- Most advanced clinically
  - Two autologous products in the market

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Embryonic Stem Cells

- First isolated from mouse embryos in 1981
  - Evans and Kaufman, University of Cambridge
  - Martin, University of California, San Francisco

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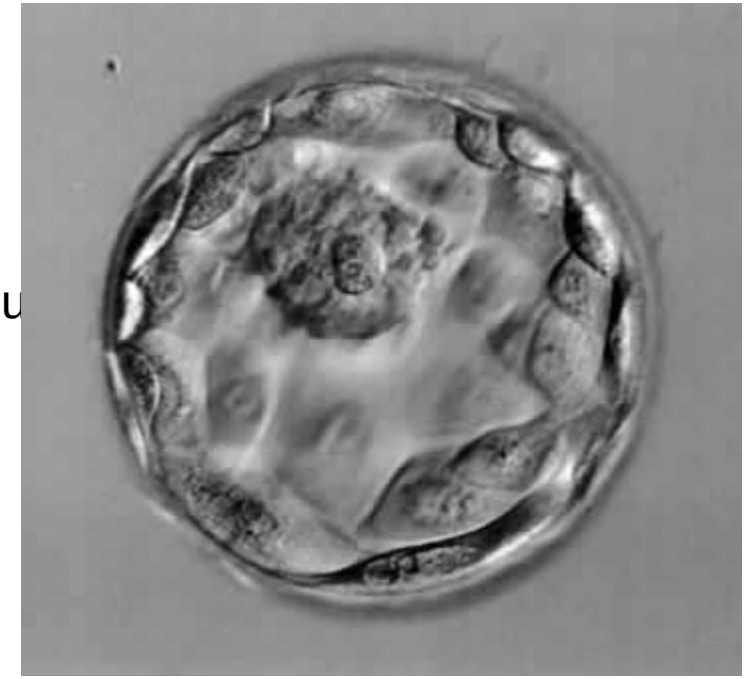
Human Embryonic Stem Cells

- First isolated by James Thomson, U. of Wisconsin, 1998
- Inner cell mass of a blastocyst,
  - 4–5 days post fertilization,
  - 50–150 cells
- Key characteristics
  - Pluripotent
    - Can differentiate into any of 220 hu
  - Can replicate indefinitely
  - Histocompatible



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Human Embryonic Stem Cells

- Embryo is destroyed in the process
  - Offensive to many religions
    - Use of federal funds for hES research banned in the US during the Bush Administration (2000-2009)
    - 21 approved cell lines
      - WiCell at UW-Madison
      - U. of California, San Francisco
      - Novocell, San Diego.
      - ES Cell International, Singapore
      - Technion, Israel
      - Cellartis, Sweden
    - Ban reversed by Obama in 2009
    - Catholic universities and hospitals will not permit hES research

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Human Embryonic Stem Cells

- California established the California Institute for Regenerative Medicine ("CIRM")
  - Proposition 71
  - 2004
  - $3 billion in grants over ten years
  - Funded by bonds

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Human Embryonic Stem Cells

But:

- Large number of embryo's created in *in vitro* fertilization
  - Each cycle ~40% effective
  - Multiple eggs collected and fertilized
    - 400,000 embryos in US clinics
      - 100,000 *in vitro* procedures in US
      - 58,000 births
  - Options for unused embryos at end of treatment:
    - Procrastinate
      - Maintain
        - $600/year
        - Viable for ~10 years
    - Destroy
    - Donate to others for IVF
    - Donate for research
      - Not many clinics offer this

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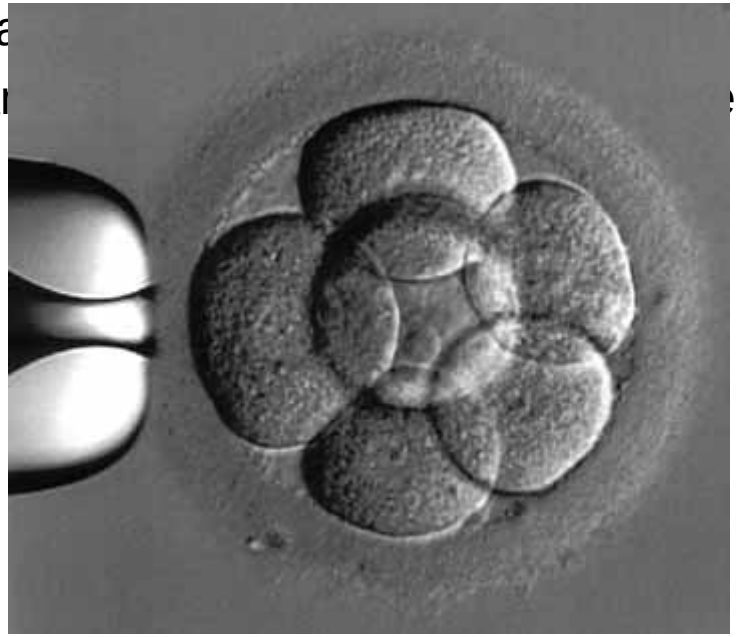
Non-Embryo Destructive Creation of hSC's

- Advanced Cell Technology ("ACT") hSC process does not destroy an embryo
  - Removes a single cell from an 8 cell blastomere
    - Rema normally
      - Sa enetic testing



Induced Pluripotent Stem Cells

- Stem cells created from somatic cells by reprograming them
  - Add four genes using retroviral vector
    - Oct-3/4, SOX2, c-Myc, and Klf4
      - c-Myc, and Klf4 are oncogenes
      - Selectable marker
  - Some methodologies use proteins or other non-genetic methods
- Issues with therapeutic uses of iPS
  - Progenitor cells have differentiated immunologically
    - Can only be used autologously
  - Other issues:
    - Similarity to cancer cells
    - Regulatory issues.
    - Cell memory
    - Cell mutations
    - Epigenomic issues
    - Cost
    - Timing

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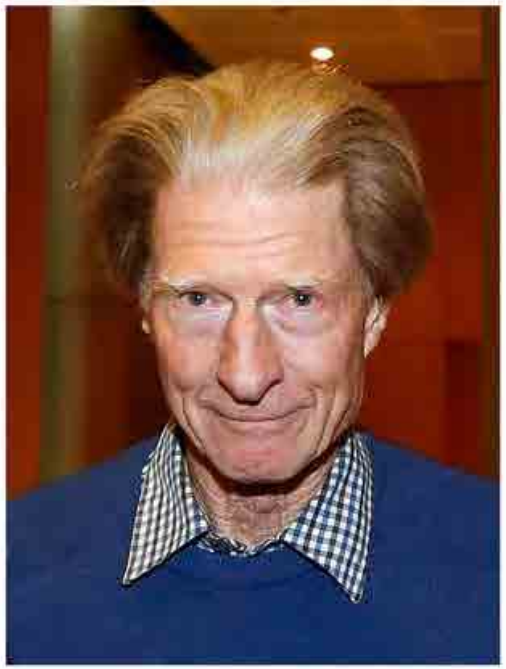
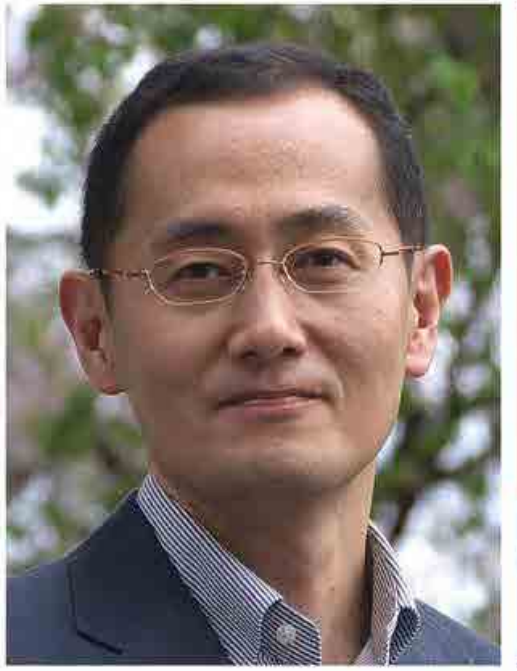
The Nobel Prize

- 2012



John B. Gurdon
University of Cambridge
Cloned frogs
1962



Shinya Yamanaka
Kyoto University
Four transcription factors
2006

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Cell Line Issues

- Must transfer under an MTA
  - Bailment issues
- Informed consent of donors imperative
- Advantageous to deposit cell lines in a cell line repository

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Stem Cell Repositories

- Roslin Cells
  - Owned by U. of Edinburgh and Roslin Foundation
  - hES
  - Research and clinical grade
- WiCell
  - Former U.S. National Stem Cell Bank
  - hES
    - Clinical grade
    - Research grade
    - All 21 cell lines approved by NIH for federally funded research
  - iPS

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Stem Cell Repositories

- StemBANCC
  - December 2012
    - iPS for research purposes
    - 10 drug companies, led by Roche
    - 23 universities led by Oxford
    - €56 million, EU and others
- ATCC
  - iPS
- NIGMS
  - iPS for neurological conditions
- Coriell
- Various universities
  - Rutgers
  - USC
  - U. Massachusetts closed

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Patentability Issues

- European Court of Justice ruled cell lines not patentable if required destruction of an embryo
  - At any time
  - Invalidated all prior patents
- German Federal Court of Justice affirmed
- Europe divided
  - Britain, Sweden, Belgium – liberal
  - Germany, Norway, Italy -- strict

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Licensing Issues

- Platform technologies
  - New biotechnology therapeutic modalities often involve very broad core patents
    - Genetic engineering — Cohen Boyer, Stanford; Riggs-Itakura, CoH-Genentech
    - Mammalian Cell Expr. — Axel, Columbia
    - Therapeutic mAb's — Cabilly/Boss, CoH-Genentech/Celltech
    - siRNA — Teuschl, Max Planck/MIT/U.Mass
  - Indispensable to practice the art
    - Need to be licensed non-exclusively
    - Enormously valuable

Key Patents -- hES

Patent No.	Inventor	Issue	Assignee	Comp	Process
US 5,843,780	Thomson	12/1/98	WARF	Pluripotent primate ES cells	Method of isolating primate ES cell line
US 6,200,806	Thomson	3/13/01	WARF.	Pluripotent human ES cells	Method of isolating human ES cell line
US 7,682,828	Jaenisch	11/26/03	Whitehead	Yes	Oct4, Nanog, or Sox2., proteins

- Thomson patents close to expiring – 1/20/2015

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Key Patents -- iPS

Patent No.	Inventor	Priority	Assignee	Comp	Method	Genes
JP 2008-131577	Yamanaka	12/13/05	Kyoto U.	No	Yes	Oct 3/4, Klf4, c-myc, Sox2.
GB2450603	Sakurada	6/15/07	Kyoto U.	No	Yes	Oct3/4, Klf4 and Sox2, no c-Myc
US 7,682,828	Jaenisch	11/26/03	Whitehead	Yes	No	Oct4, Nanog, or Sox2., proteins

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Litigation Landscape

- Major concerns about breadth of WARF Thomson patents

  A purified preparation of pluripotent human embryonic stem cells which (i) will proliferate in an in vitro culture for over one year, (ii) maintains a karyotype in which the chromosomes are euploid and not altered through prolonged culture, (iii) maintains the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) is inhibited from differentiation when cultured on a fibroblast feeder layer.

  - Public Patent Foundation (PUBPAT)
  - Foundation for Taxpayer and Consumer Rights (FTCR) (now Consumer Watchdog),
  - Resulted in reexamination by USPTO
- Initially rejected
  - Reissued with narrowed claims
- One invalidated, two survived

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Litigation Landscape

- Not much litigation yet
  - Not many products in the market place
- Neuralstem, Inc. v. StemCells, Inc.
  - Neural stem cells isolated from brain
  - Re-examination
  - Still pending
- Pharmastem
  - HSC‘s
    - Sued cord blood banking centers
      - ViaCell, Cryo-Cell, CorCell, Cord Blood Registry, StemCyte, NuStem, Bio-Cell, and Birthcells
    - Patents invalidated

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Commercial Landscape

- Founded 1990 to work on telomeres
- Michael West, U of Texas SW Medical Center
- IPO 1996
- Funded Roslin Institute in 1997
  - Ian Wilmut/Dolly
  - Acquired Roslin Bio
    - Nuclear transfor

- Funded work by James Thomson at U. of Wisconsin in 1998
  - Geron initially acquired rights to six cell types
    - Option to additional cell types
  - Concern that they had too broad rights
    - Discourage others from entering the field
  - Lawsuit
  - 2002 agreement to divide rights:

Geron	**U. of Wisconsin**
Neural cells	Bone cells
Cardiomyocytes	Haematopoetic cells
Pancreatic islet cells	Cartilage cells.
Non-excl. rights to U. Wi cells	

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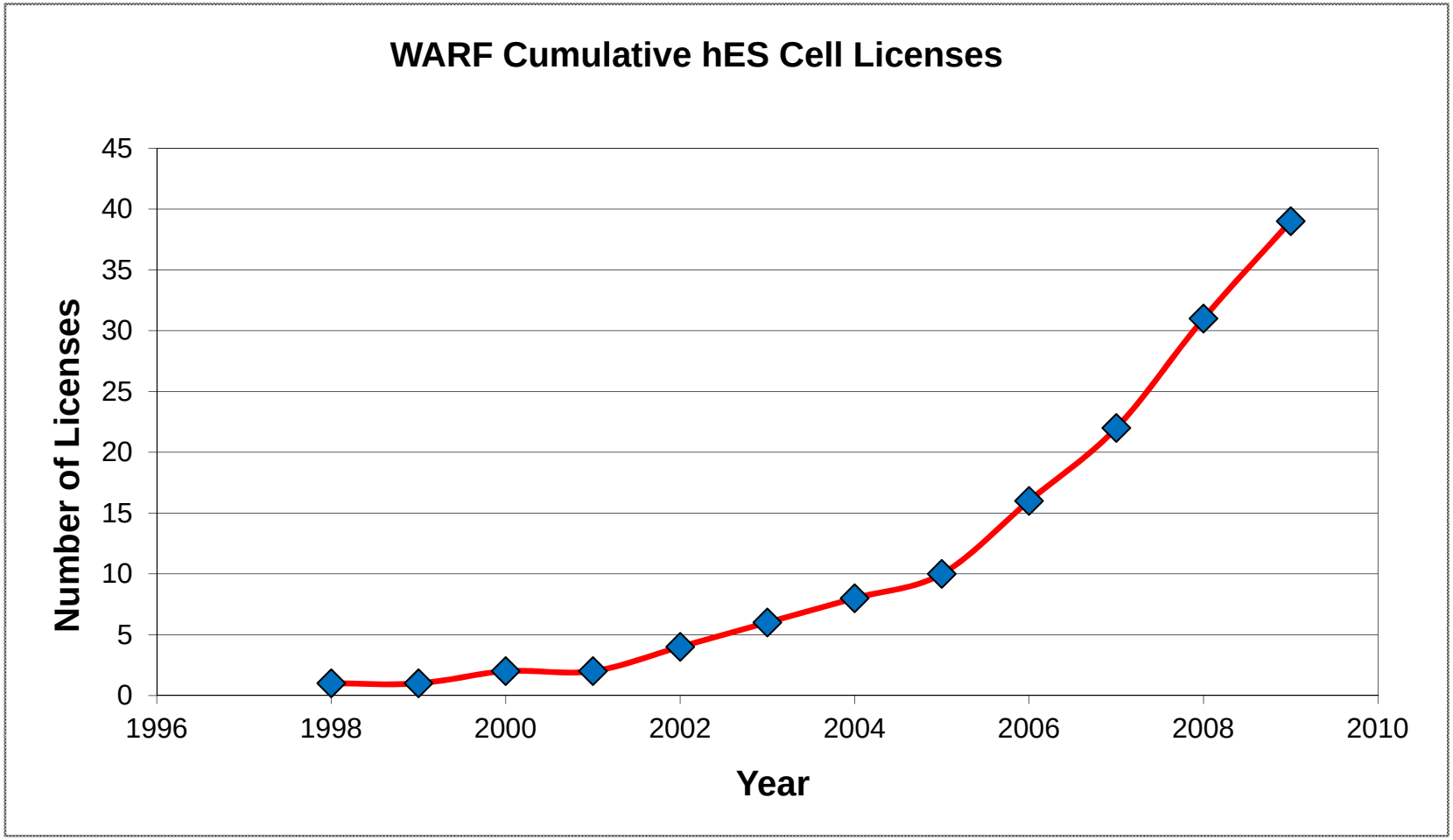
WARF hES Licensing Program Results



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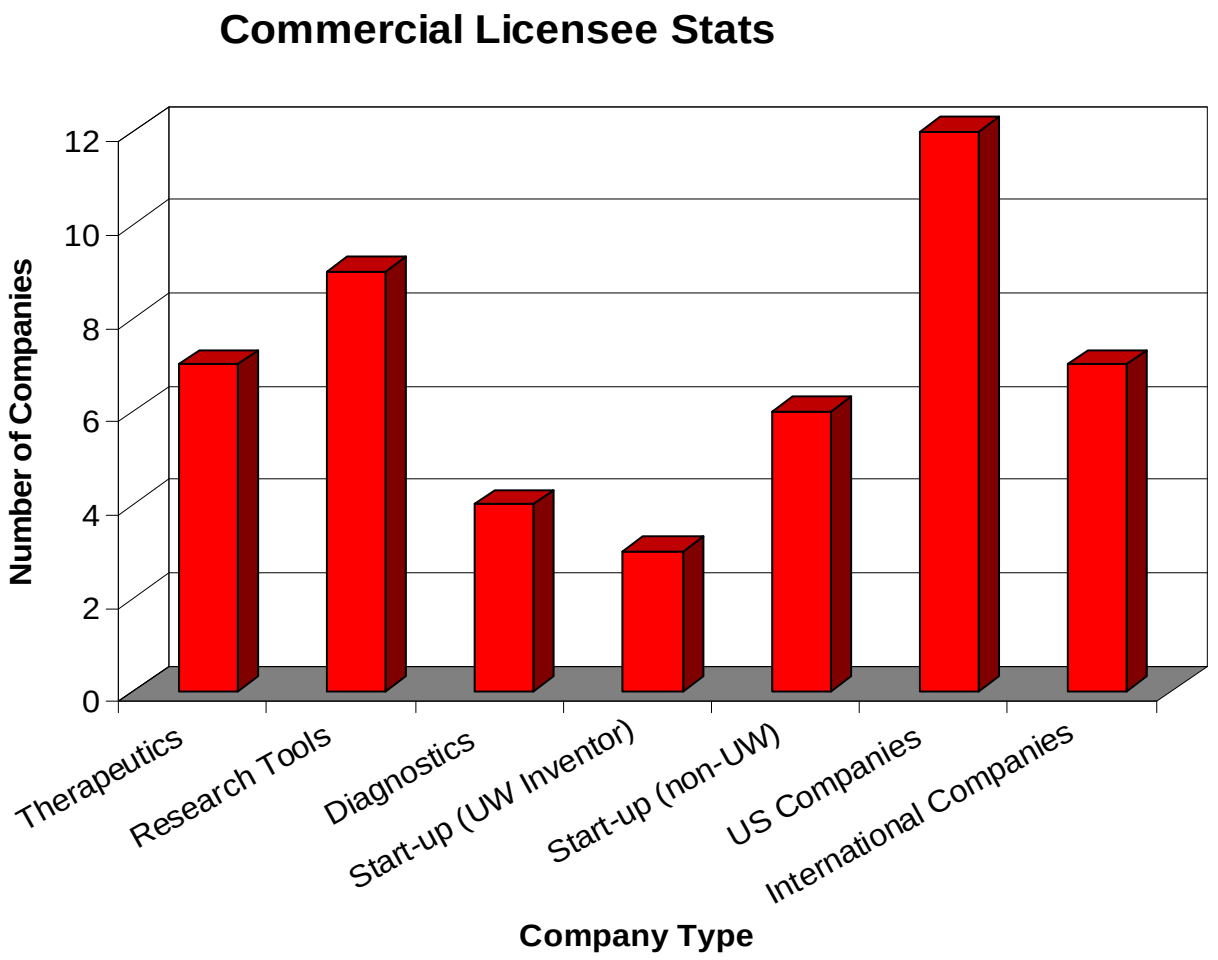
WARF hES Licensing Program Results



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- Founded in 1994
  - Animal cloning
- Michael West joined as CEO in 1998
- Current programs:
  - Retinal Pigment Epithelial (RPE) therapy
    - Degenerative retinal disease
  - hESC-basedHemangioblast (HG)
    - Blood and cardiovascular diseases
  - Mesenchymal Stem Cells (MSCs) from renewable pluripotent stem cell sources
    - Eye, local immunosuppressive effects, tissue repair
  - Corneal Endothelial Cells
    - Corneal blindness
  - Retinal neural progenitor cells
    - Glaucoma

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- Founded by (who else?) Michael West
- Acquired Geron's stem cell program

The Deal Landscape

- Two big deals so far:

- Mesenchymal Precursor Stem Cells platform for bone marrow transplant and degenerative cardiovascular and CNS conditions
  - December 2010
  - Phase II
  - $2.07 billion

The Deal Landscape

- Two big deals so far:

- Prochymal and Chondrogen stem cell products outside US & Canada
  - October 2008
  - Phase III
  - $1.38 billion
- Big pharma largely absent
  - Pfizer most prominent
    - 5 deals
      - Athersys
      - WARF
      - University College London
      - ViaCyte
      - Cellartis

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The Deal Landscape

- Big pharma largely absent
  - Pfizer most prominent
    - 5 deals
      - Athersys
      - WARF
      - University College London
      - ViaCyte
      - Cellartis
  - Glaxo
    - Partnership with Harvard Stem Cell Institute
      - $25million

Regulatory Framework and Landscape

- Depends on:
  - The type of stem cell
    - HSC
    - hES
    - iPS
  - The Patient
    - Autologous
      - To and from the same patient
        - e.g., Bone marrow transplants are an autologous hematopoietic stem cell therapy
        - Unmodified cellular transplants are exempt from FDA regulation
        - If “minimally altered”
    - Allogeneic
      - Unrelated donors

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Regulatory Framework and Landscape

- Autologous cellular therapies furthest along
  - "Minimally altered" products can be used at physician's discretion
    - e.g., Several companies have received FDA warning letters
      - Regenerative Sciences, Colorado – autologous mesenchymal stem cells
        - Addition of antibiotic to stem cell preparation makes it a drug
      - Celltex Therapies, Texas
        - Adipose cells used in other tissues
  - Others treat patients abroad

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Regulatory Framework and Landscape

- hES cells are in clinical development
  - Geron:
    - Phase I trial of oligodendrocyte progenitor cells, GRNOPC1 in patients with complete ASIA Impairment Scale grade A thoracic spinal cord injuries
      - Approved October 2008
      - Put on hold after microscopic cysts found at injection site
      - Restarted in October 2010
      - Terminated for financial reasons November 2011
  - ACT
    - Phase 1/2 trial in Stargardt's Macular Dystrophyand dry-AMD by ACT approved November 2010
      - Safety and limited efficacy published January 2012

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Regulatory Framework and Landscape

- iPS
  - No trials yet approved by a major regulatory agency
    - One of the four genes is an oncogene
  - RIKEN predicting 2013 clinical trial in AMD using retinal pigment epithelial cells induced from human iPS cells

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Commercial Landscape

- Cord blood banking a big business
  - Autologous HSC transplants
  - $4.5 billion globally in 2010
    - 27% CAGR
      - $15 billion by 2015
    - ~300 banks worldwide

Commercial Landscape

- Two stem cell products have received regulatory approval in a major country
  - Both HSC products
- New York Blood Center
  - HEMACORD™
    - Hematopoietic Prog
      - Cord blood derive
    - Approved Novembe
      - IND exemption si

Commercial Landscape

- Osiris Therapeutics
  - Prochymal for GvHD in children approved in Canada
    - Bone marrow derived
    - Notice of Compliance ...nditions (NOC/c) pathway
      - Access to therape...s that address unmet medical conditions
      - Demonstrated ...sk/benefit profile in clinical trials
      - Confirmatory ...g required

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Technology Licensing, Valuation and Acquisition for The Biotechnology Sector

Lecture 9: Technology Acquisition and Introduction to Export Controls

Biotechnology Industry Research Assistance Programme
Department of Biotechnology

February 11/12, 2013 Bangalore
and
February 14/15,2013 New Delhi

Dr. Ashley J. Stevens
Past President, Association of University Technology Managers
and
Lecturer, Health Sector Management Program
School of Management
Boston University

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With grateful thanks to:

- Qingzhi Zhang, Beijing University of Science and Technology
- Michael Boss
- John Gustofson, AstraZeneca
- Susan Frey, BU

Technology Acquisition

- Partnering is the lifeblood of the life sciences industry
- The traditional route from bench to bedside was:
  - University ➔ Biotech ➔ Pharma
    - Pharma's couldn't handle the uncertainty of early stage technologies
    - Preferred to pay more later than less sooner
- The magnitude of the patent cliff has made pharma rethink
  - More creative approaches
  - Universities have got better at translational research

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SPECIAL ARTICLE

The Role of Public-Sector Research in the Discovery of Drugs and Vaccines

Ashley J. Stevens, D.Phil., Jonathan J. Jensen, M.B.A., Katrine Wyller, M.B.E., Sabarni Chatterjee, M.B.A., Ph.D., and Mark L. Rohrbaugh, Ph.D., J.D.

ABSTRACT

BACKGROUND

Historically, public-sector researchers have performed the upstream, basic research that elucidated the underlying mechanisms of disease and identified promising points of intervention, whereas corporate researchers have performed the downstream, applied research resulting in the discovery of drugs for the treatment of diseases and have carried out development activities to bring them to market. However, the boundaries between the roles of the public and private sectors have shifted substantially since the dawn of the biotechnology era, and the public sector now has a much more direct role in the applied-research phase of drug discovery.

METHODS

We identified new drugs and vaccines approved by the Food and Drug Administration (FDA) that were discovered by public-sector research institutions (PSRIs) and classified them according to their therapeutic category and potential therapeutic effect.

RESULTS

We found that during the past 30 years, 153 new FDA-approved drugs, vaccines, or new indications for existing drugs were discovered through research carried out in PSRIs. These drugs included 93 small-molecule drugs, 36 biologic agents, 15 vaccines, 8 in vivo diagnostic materials, and 1 over-the-counter drug. More than half of these drugs have been used in the treatment or prevention of cancer or infectious diseases. PSRI-discovered drugs are expected to have a disproportionately large therapeutic effect.

CONCLUSIONS

Public-sector research has had a more immediate effect on improving public health than was previously realized.

From the Institute for Technology Entrepreneurship and Commercialization (A.J.S.) and Office of Technology Development (A.J.S., J.J.J.), Boston University School of Management, Boston; the Norwegian Radium Hospital Research Foundation, Oslo (K.W.); and the Office of Technology Transfer, National Institutes of Health, Bethesda, MD (S.C., M.L.R.). Address reprint requests to Dr. Stevens at Boston University School of Management, 53 Bay State Rd., Boston, MA 02215, or at astevens@bu.edu.

N Engl J Med 2011;364:535-41.

Number of Products

Type of Product	Number
New Chemical Entity	93
Biologic	36
Vaccine	15
Over the counter	1
In-vivo diagnostic	8
Total	153

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Therapeutic Categories

Therapeutic Area	Number
Hematology/Oncology	40
Infectious Disease	36
Cardiology	12
Metabolic	12
CNS	12
Dermatology	7
Renal	7
Ophthalmology	6
Immunology	6
Gastroenterology	4
Women's Health	3
Allergy	2
Pulmonary	2
Urology	2
Anaesthesiology	1
Dental	1
	153

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Discovering Institution	Number
National Institutes of Health	22
U. of California	11
Sloan Kettering	8
Emory University	7
Yale University	6
Children's Hospital, Boston	5
MIT	5
Salk Institute	5
Wisconsin Alumni Research Foundation	5
Columbia University	4
New York University	4
U. of Michigan	4
U. of Minnesota	4
U. of Texas	4
Brigham & Women's	3
Dana-Farber Cancer Institute	3
Harvard	3
Massachusetts General Hospital	3
Oklahoma Medical Research Foundation	3
Rockefeller University	3
Scripps	3
State University of New York	3
Tulane University	3
U. of Cincinnati	3

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Regulatory Approval of non-US PRSI drugs

Groups	Number
Co-discovered by US and non-US PSRIs and received FDA approval	17
Discovered solely by non-US PSRI's and received FDA approval	19
Discovered by non-US PSRIs and received approval by national regulatory agency(ies)	12
Total	48

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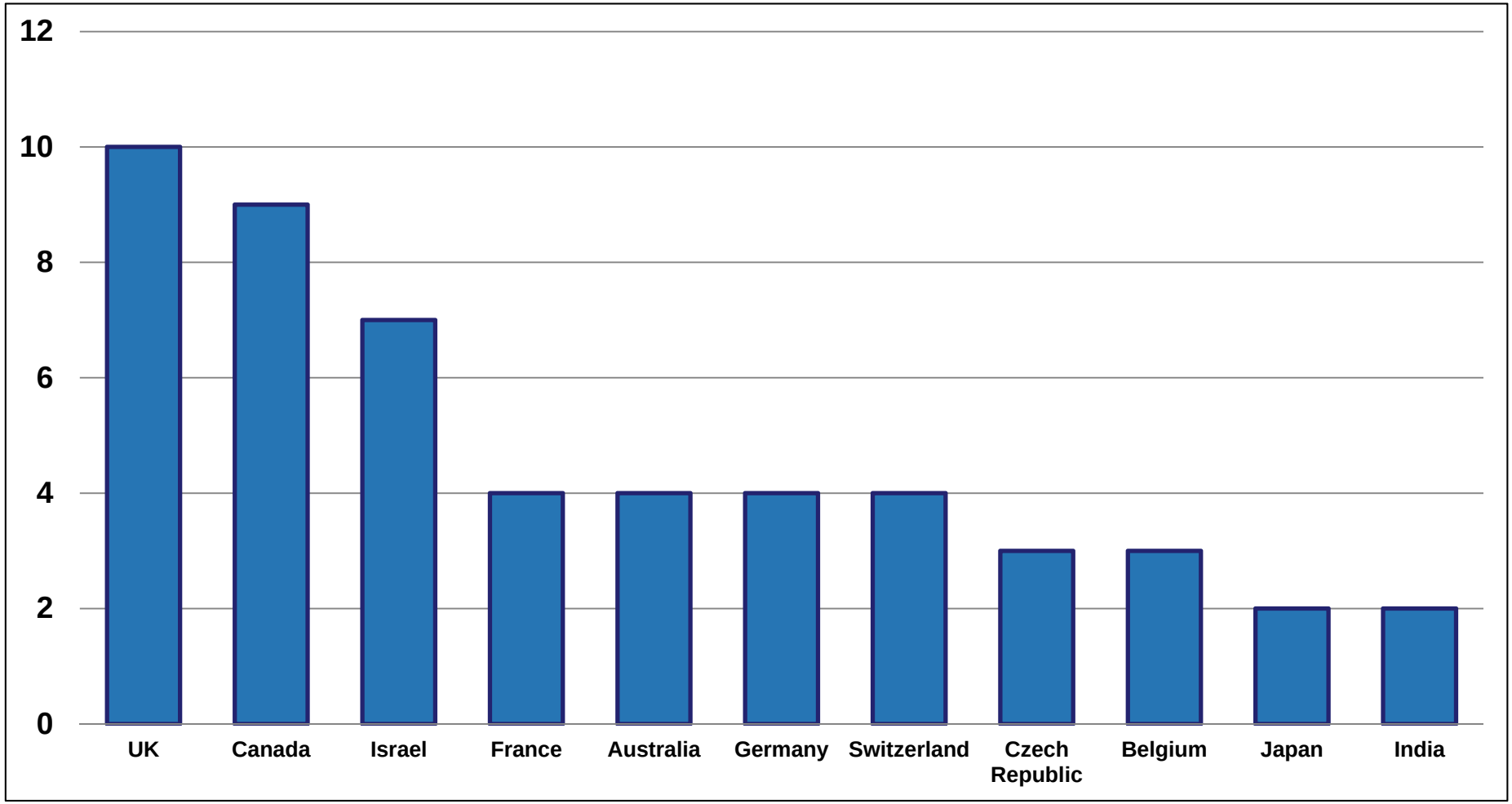
Number of Products

Type of Product	Number
New Chemical Entity	34
Biologic	9
Vaccine	5
Total	48

Number of PSRI Discovered Drugs by Country



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Therapeutic Categories

Therapeutic Area	Number	%
Infectious Disease	20	41.7
Hematology or oncology	17	35.4
CNS	3	6.3
Immunology	3	6.3
Endocrinology	1	2.1
Dermatology	1	2.1
Dental disorders	1	2.1
Gastroenterology	1	2.1
Ophthalmology	1	2.1
Total	48	

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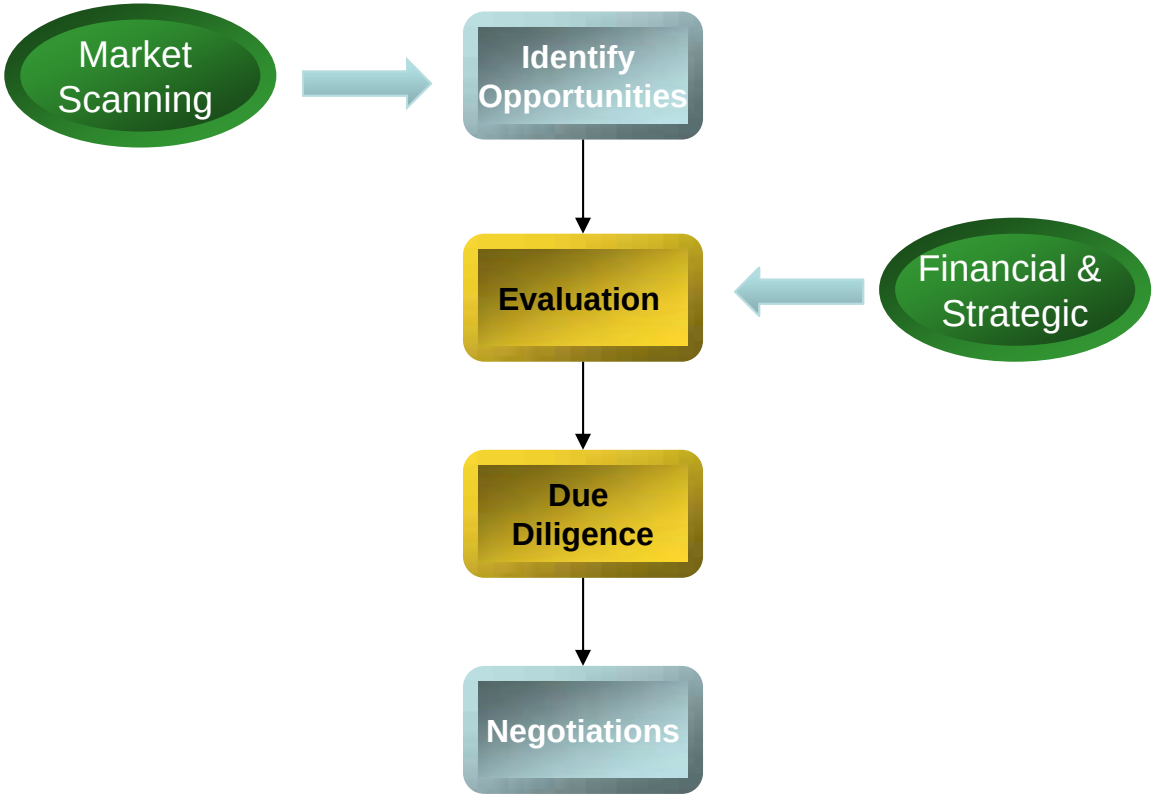
Licensing Process in General



9 -12 months to fully executed contract

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Deal Process: Key Activities and Outputs by Phase

Finding New Ops

- Literature Review
- Attending Medical Conferences
- Discussions with leading physicians
- Discussions with internal researchers

Evaluation:

- Business case modelling
- Construction of deal terms and structure
- Preparation of Briefing Documents

Due diligence:

- Financial & Science Due Diligence
- Update financial model with output from Due Diligence
- Update briefing paper to stakeholders
- On going development of deal terms and structure

Transaction:

- Negotiation of deal terms and structure with counter-party
- Legal contract review
- Continued update of financial model
- Compliances reviews – HSR, SOX compliance
- Continued Stakeholder management

Technology Acquisition

- Three types of transaction
  - University – Start-Up
  - University – Small Company
  - University – Large Company
  - Small Company – Large Company

University – Start-Up Transactions

- Negotiating with an entrepreneur or a VC
- Key issues:
  - For the Entrepreneur/VC
    - Equity
    - Financial
    - Ability to raise funding
    - Sublicensing terms and conditions
  - For the university
    - Conflict of interest
    - Ability to raise funding
      - How long to give them
      - Option vs License with funding due diligence milestone

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University – Small Company Transactions

- Negotiating with the CEO or VP Business Development
- Key issues:
  - For the Company
    - Financial
    - Due diligence milestones
    - Ability to raise funding
    - Sublicensing terms and conditions
  - For the university
    - Capacity to execute a major new program
      - Commitment vs internal programs
      - Due diligence milestones
    - Sponsored research

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University – Large Company Transactions

- Negotiating with the CEO or VP Business Development
- Key issues:
  - For the Company
    - IP
    - Due diligence milestones
  - For the university
    - Are they committed to the deal
    - Time to complete
      - Commitment vs internal programs
      - Internal IP vs university IP

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Vanderbilt-Ingram Cancer Center, AstraZeneca Form Master Agreement to Streamline Research Collaborations

Posted on Tuesday, Nov. 28, 2006 — 1:17 PM

The Vanderbilt-Ingram Cancer Center and AstraZeneca have developed a master scientific agreement to streamline and integrate collaborations in basic, translational and clinical cancer research, officials with the company and cancer center announced today.

"Our ultimate goal is to shorten the time to approval of more effective new drugs and new combinations," said Carlos Arteaga, M.D., Vice Chancellor's Chair in Breast Cancer Research and director of Vanderbilt-Ingram's Specialized Program of Research Excellence in Breast Cancer. "In the end, the patients win."

Such agreements provide a basic framework for the basic contractual issues that would be common to any mutual research project. Separate, specific research plans are then developed that can move forward more quickly under the umbrella of the Master Agreement. Specific terms are confidential.

"This framework will enable us to move more quickly to the research that will lead to better treatments for cancer," said Steve Strand, global director of external scientific relationships for AstraZeneca.

The agreement allows Vanderbilt-Ingram and AstraZeneca to combine their scientific expertise and resources around common goals, which include identifying new molecular targets for therapy and "biomarkers" to assess and predict response to treatment. Under the agreement, these researchers and physician-scientists will have the flexibility to identify projects of mutual interest and work in a variety of ways to accelerate progress, including pilot projects to test pioneering concepts.

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Focus topics
Programmes
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GlaxoSmithKline, Imperial College London, and The Medical Research Council officially open the UK's world-leading Clinical Imaging Centre

Embargoed 00:01 BST, Wednesday 13 June 2007, London, UK

Pioneering collaboration between industry, academia and the public sector to advance the development of new medicines

GlaxoSmithKline's (GSK) new Clinical Imaging Centre (CIC) was officially opened today by the Right Honourable Alistair Darling MP, Secretary of State for Trade and Industry. The new centre represents an investment of over €50 million and is a pioneering collaboration between industry, academia and the public sector. Commenting on the collaboration and state-of-the-art facility, Mr Darling said: "This new centre is right at the forefront of the fight against some of the major diseases in the world. It means a world leading facility based here in the UK bringing the best of industry and academia together backed by the Government. It will give researchers what they need to enhance our reputation as a world leader in science, research and putting great ideas into practice, speeding up the process to deliver the new medicines that patients need."

GSK's CIC is a unique venture undertaken by GSK, Imperial College London and the Medical Research Council - the largest new imaging centre in Europe dedicated to development and application of imaging techniques for clinical research. The collaboration will combine the expertise and knowledge each partner has developed in the use of imaging technologies and will apply it to the development of new medicines across a broad range of diseases including cancer, cardiovascular disease, and psychiatric and neurological disorders. One of the world's largest industry-university-government collaborations, the CIC will create a globally-recognised centre of expertise in West London and substantially increase the entire research base in medical imaging in the UK.

"GSK's investment in this state-of-the-art research facility reflects the positive environment for science and innovation in the UK. The science we conduct here will transform the lives of patients in the UK and around the world. It is important to us, and to the UK, that the environment remains supportive," said Dr Moncef Slaoui, Chairman, GlaxoSmithKline Research & Development. "This facility will allow GSK to partner with Imperial College and the MRC to create a world-class scientific collaboration, utilising the latest advancements in imaging to better understand diseases and how to treat them."

Sir Richard Sykes, Rector of Imperial College London, said, "This centre is a prime example of what can be achieved when universities, government and industry

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This press release is intended for business journalists and analysts/investors. Please note that this release may not have been issued in every market in which GSK operates.

GlaxoSmithKline and the Harvard Stem Cell Institute announce a unique collaboration to enable the discovery of new medicines

- Industry and academia link up in pioneering agreement

Issued: Thursday 24th July 2008, London, UK

GlaxoSmithKline (GSK) and the Harvard Stem Cell Institute (HSCI) today announced that they have entered into a five-year, $25 million-plus collaborative agreement to build a unique alliance in stem cell science, leading to the development of new medicines.

GSK's investment, one of the largest by a pharmaceutical company in stem cell science, will support innovative research at Harvard University and in at least four Harvard-affiliated hospitals in the areas of neuroscience, heart disease, cancer, diabetes, musculoskeletal diseases and obesity. In addition, GSK will fund an annual grant, which supports early stage research in stem cell biology, as part of HSCI's seed grant program.

This agreement marks the beginning of an exciting collaboration with multiple researchers at multiple Harvard institutions, making it possible for academic and industrial scientists to work side-by-side to develop treatments in areas of unmet medical need.

"GSK believes stem cell science has great potential to aid the discovery of new medicines by improving the screening, identification and development of new compounds. We have carefully chosen the Boston biomedical community to collaborate with on this important venture. It has the highest concentration of leading stem cell scientists, and the Harvard Stem Cell Institute is the epicentre of that community," said Patrick Vallance, Head of Drug Discovery at GSK.

The collaboration aims to integrate HSCI's world-class stem cell expertise with GSK's pharmaceutical capabilities to drive advances in drug discovery research. This will include, for example, a staff exchange programme where HSCI and GSK researchers will spend up to several months in each other's laboratories. The collaboration will be overseen by a joint steering committee made up of HSCI and

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SAN FRANCISCO Business Times

Pfizer inks pact with UCSF

San Francisco Business Times - by John Sailors
Date: Tuesday, November 16, 2010, 5:29am PST

Related: Health Care

Pfizer Inc. has formed a partnership with the University of California, San Francisco, the first in a network of research partnerships the company is making with leading academic medical centers.

Under the terms of the agreement, Pfizer (NYSE: PFE) will pay UCSF up to $85 million in research support and milestone payments over the next five years if discoveries in UCSF labs lead to new therapies.

UCSF, Sanofi ink research, intern deal

San Francisco Business Times - by Ron Leuty
Date: Wednesday, January 12, 2011, 6:00am PST - Last Modified: Wednesday, January 12, 2011, 10:09am PST

Related: Health Care, Education

French drug maker Sanofi-Aventis will fund up to five UCSF research projects a year and allow UCSF students or fellows to conduct research as company interns as part of the deals expected to be signed Wednesday morning.

The potential value of the deal wasn't disclosed, but it marks the first industry partnership for the University of California, San Francisco's 14-year-old Program for Breakthrough Biomedical Research.

What's more, Sanofi-Aventis (NYSE: SNY) and UCSF will develop cross-organizational teams in oncology to streamline the transition of drugs and biomarkers into the clinic.

It is the third set of major industry deals inked by UCSF over the past two months. Pfizer Inc. (NYSE: PFE) will pay UCSF up to $85 million over five years in research support and milestone payments, and Bayer Healthcare earlier this week announced that it and UCSF signed a master agreement to collaborate with UCSF scientists.

Under terms of the deal, UCSF and Sanofi will form a committee to select from among UCSF-generated proposals. Sanofi then will make up to five grants to push those projects toward the clinical proof-of-concept stage.

Related News

- Nektar nets $220 million from stock sale
- UCSF harvesting Big Pharma deals
- UCSF harvests Bayer, Pfizer, Sanofi deals
- Nektar Therapeutics plans stock sale
- Protagonist Therapeutics, Ironwood sign peptide drug deal

Cooperation between industry and academia: AK Project (Astellas-Kyoto Univ. Project)

Cooperative research aiming at the development of next-generation immunosuppressants
(using Special Coordination Funds for Promoting Science and Technology)

1. **Screening of targets for drug discovery (by universities) and discovery and invention of new substances (by companies)**

   Kyoto Univ.: utilization of individual research programs based on knowledge of diseases and clinical experience

   Astellas: utilization of established drug discovery technologies and experienced databases

2. **Long-term, large-scale collaboration system**

   - Term: 10 years
   - Budget: ¥600-1,000 million/year
   - Site: collaborative lab (at Kyoto Univ.) and Astellas' corporate satellite lab

3. **Establishment of an intellectual property management system necessary for the industry-academia collaboration**

4. **Fostering of human resources: drug discovery researchers from companies interested in diseases and doctors interested in drug discovery**

- **Started in July 2007**

January 18, 2011

National University Corporation Kyoto University
Takeda Pharmaceutical Company Limited

Open innovation laboratory for drug discovery and development by Takeda and Kyoto University - Basic and clinical research project for CNS drugs – (TK Project)

Kyoto and Osaka, Japan - January 18, 2011 – National University Corporation Kyoto University ("Kyoto University"), and Takeda Pharmaceutical Company Limited (TSE: 4502, "Takeda"), announced today that they have formed a five-year research and development alliance that will focus on discovering CNS-acting drugs for obesity and schizophrenia.

Kyoto University established the Japan's first open innovation laboratory based on Equal Partnership, "Medical Innovation Center", where the TK project is newly initiated, within the Graduate School of Medicine, in order to efficiently conduct industry-government-academia collaborative projects. This Center is aimed at creating innovative drugs and medical instruments as well as new drug discovery models by integrating companies' and university's human resources, capitals, knowledge and management knowhow, and effectively utilizing their intellectual properties. In addition, the center is expected to strengthen human resource development by enhancing participation of doctors and medical researchers in drug discovery process.

Under the terms of the agreement, Kyoto University and Takeda will work closely, and indentify new drug targets and biomarkers for obesity and schizophrenia, and conduct clinical medical research for drug candidates by utilizing not only findings from basic research and clinical data accumulated at the Graduate School of Medicine and the University Hospital, but also its worldwide networks.

"Kyoto University is enhancing development of junior researchers to further step up the medical research in Japan. On the other hand, Takeda is pursing open innovation in drug discovery," said Dr. Nagahiro Minato, Dean of the Kyoto University Graduate of School of Medicine. "TK project, which is our close collaboration in both basic and clinical research, is the epoch-making challenge for strengthening drug discovery capabilities of Japanese healthcare industry"

"We are very pleased to collaborate with Kyoto University," said Dr. Shigenori Ohkawa, a member of the Board and Executive Vice President, Chief Scientific Officer of Takeda Pharmaceutical Company Limited. "Through the close partnership on research and development, we expect that we will be able to create innovative drugs for obesity and schizophrenia where there is a high unmet need for patients."

Contacts:
Kyoto University:
Medical Innovation Center
Tel: +81-75-751-0909

Takeda:
Corporate Communications Dept.(PR/IR)
Tel: +81-3-3278-2037

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SAN FRANCISCO Business Times

From the San Francisco Business Times:
http://www.bizjournals.com/sanfrancisco/news/2011/04/22/agilent-california-berkeley-synthetic.html

UC Berkeley, Lawrence Berkeley Lab start Synthetic Biology Institute

Click to Print Now

San Francisco Business Times - by Ron Leuty
Date: Friday, April 22, 2011, 10:01am PDT

Related: Health Care, Technology, Education, Logistics & Transportation, Environment, Energy

A new institute formed by the **University of California, Berkeley**, and **Lawrence Berkeley National Laboratory** will work to engineer cells and biological systems to tap discoveries in health, energy and new materials, among other [illegible].

Agilent Technologies Inc. is the first corporate partner of the Synthetic Biology Institute. UC Berkeley did not say how much Santa Clara-based Agilent (NYSE: A) will pay, but it said the company made a multiyear, multimillion-[illegible]

Led by UC Berkeley's College of Engineering and College of Chemistry, the institute will work to develop inexpensive drugs for treating diseases, methods for producing transportation biofuels from plants, microbes that target tumors, water purification, environmental cleanup and functional new materials.

"Synthetic biology potentially can have as profound an impact in the 21st century as semiconductor technology had in the 20th," Agilent President and CEO **William Sullivan** said in a press release. "To get there, we need to engineer biological solutions that are scalable, reliable and safe."

The institute will be led by director **Adam Arkin**, a professor of bioengineering and director of the Physical Biosciences Division of Lawrence Berkeley Lab, and associate director **Douglas Clark**, a professor of chemical and biomolecular engineering and executive associate dean of the College of Chemistry.

Ron Leuty covers biotechnology for the San Francisco Business Times.
rleuty@bizjournals.com / (415) 288-4939 / Twitter: rleuty_biotech
Read his blog postings at Bay Area BizTalk.

GSK, The University of Manchester, AstraZeneca establish MCCIR

PBR Staff Writer

Published 13 May 2011

GlaxoSmithKline (GSK), The University of Manchester and AstraZeneca have created the Manchester Collaborative Centre for Inflammation Research (MCCIR), a translational centre for inflammatory dise[illegible]

The project starts out with an initial investment of £5m from each partner over a three year period

The collaboration between two UK based pharmaceutical companies, GSK and AstraZeneca, and The University of Manchester will bring together scientists from both the pharmaceutical industry and academia to work collaboratively on inflammation research and translational medicine.

Such advances are expected to benefit people affected by diseases associated with chronic inflammation, including asthma, chronic obstructive pulmonary disease, rheumatoid arthritis and inflammatory bowel disease

The University of Manchester VP and Faculty of Medical and Human Sciences dean Ian Jacobs said the collaboration builds on the mutual understanding developed between the university and both GSK and AstraZeneca over recent years, and will bring together expertise in biomedical research from the university with the resources and drug discovery expertise from GSK and AstraZeneca to create true partnership and synergy

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Tuesday, May 24, 2011

New MIT center to develop advanced medical systems

By Lori Valigra, Mass High Tech correspondent

MIT, Analog Devices I[illegible], and GE Global Research will coll[illegible]orate to develop next-generation medic[illegible]electronic technologies at a new[illegible]esearch center they have established in Ca[illegible]

The new **Medical Electronic Device Realization Center**, or MEDRC, will work on electronic devices, diagnostics and treatments, and technologies for information-driven health-care systems.

MEDRC co-founder Charles Sodini, who is an engineering professor at MIT, said a radical change is occurring in how medical care is being given, with delivery moving to the point of care rather than having patients travel to a doctor's office or hospital. "MEDRC will develop technologies for patient-monitoring devices, point-of-care instruments, and the communication technology to connect patients to caregivers," he said in a press statement.

The center will create prototype devices and intellectual property aimed at reducing health-care costs throughout the world, according to a press release. It also will bring together large business, venture-funded startups and the medical community.

Along with Sodini, who is affiliated with MIT's Microsystems Technology Laboratories, MEDRC will be led by Brian Anthony, director of the master of engineering in manufacturing program at MIT, and Joel Voldman, associate professor of electrical engineering and computer science.

"A health-care revolution in which modern medical devices are bringing the hospital, laboratory and physician into a patient's home is well under way," said Patrick O'Doherty, vice president of the Healthcare Group at Analog Devices. He added that his company and MIT will research new

Related News

Boston Heart Lab renamed as Boston Heart Diagnostics [May 24, 2011]

Boston IT jobs open, but fewer qualified grads [May 24, 2011]

LeMaitre Vascular closes Calif. site, ends one biz line [May 23, 2011]

Bentley launches Center for Women and Business [May 23, 2011]

T2 Biosystems boosted by $1.7M MassDevelopment loan [May 16, 2011]

Tech Pulse Poll

What does it mean to the rest of us with LinkedIn being the latest stock to soar in its early days of trading?

- Awesome – A sign of great times to come across the tech sector
- Good news – LinkedIn may be an exception, but it's nice to see someone doing well
- Beware the bubble – Don't get carried away; know where the value is
- Funny money – Investors never learn; Think Netscape in the '90s, real estate in 2000s

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Business news essential to Boston's leaders.

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Pfizer to invest $100M in LMA research center

Boston Business Journal – Natalie M. Donnelly
[illegible], June 9, 2011, 1:34pm EDT

Pfizer Inc. said it plans to invest $100 million over five years in a new drug-development center in Boston's Longwood Medical Area as part of its ongoing effort to reorganize its research operations.

The new facility, the Centers for Therapeutic Innovation, will house Pfizer drug-development operations in collaboration with several Boston-area medical and research centers including Beth Israel Deaconess Medical Center; Boston University; Children's Hospital Boston; Harvard University; Partners Healthcare; Tufts Medical School; Tufts University; and the University of Massachusetts Medical School.

The company's planned $100 million investment will support milestone payments for successful drug development by medical

BBJReal Estate Round Up Tuesday, August 9, 2011

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Foreclosure activity continues to cool statewide
Around the Region: Aug. 8, 2011
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EF Education First wins approval to advance Cambridge HQ plan
Government tenants bear fruit for Newton REIT
High-end home sales gain steam in Bay State; Newton leads the pack
Rooney's plan for a Southie hotel is getting harder to sell
Liberty Wharf's owners seek partners as momentum swells

BIOTECH, DEALS, ENTREPRENEURSHIP

Pfizer Adds UC San Diego to its Network of Innovation Centers

Bruce V. Bigelow 8/8/11

Pfizer has extended its chain of drug discovery innovation centers in Boston, New York, and San Francisco to include San Diego. UC San Diego Health Sciences says today it signed a partnership agreement with Pfizer that could be worth as much as $50 million in funding from the New York pharmaceutical giant over the next five years.

Pfizer established its Centers for Therapeutic Innovation (CTI) as part of a drive for more open, collaborative, and entrepreneurial-minded research, with the goal of dramatically slashing years from the time spent in drug development. The local CTI staff will include researchers from Pfizer, the UC San Diego School of Medicine, Skaggs School of Pharmacy and Pharmaceutical Sciences, and other UCSD scientists.

The partnership is intended to build on the expertise in translational medicine that UC San Diego boosted last year, when its Clinical and Translational Research Institute received a five-year, $37.2 million award from the National Center for Research Resources, part of the National Institutes of Health.

Under the partnership, Pfizer will open some of its antibody libraries and technologies to UC San Diego scientists. The pharmaceutical company also agreed to help support the pre-clinical and clinical development of sponsored programs. Pfizer grants intellectual property rights to its partners, who also are granted milestone payments and royalties based on how well drug candidates advance.

Bruce V. Bigelow is the editor of Xconomy San Diego. You can e-mail him at bbigelow@xconomy.com or call (619) 669-8788

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U-M Medical School and MedImmune Join Forces To Accelerate Search for New Therapies

Strategic collaboration agreement will bring scientists together to work toward new biologic options for cancer and other diseases

ANN ARBOR, Mich., Nov. 21, 2011 /PRNewswire-USNewswire/ -- Leaders from the University of Michigan Medical School and MedImmune, the global biologics arm of AstraZeneca, have signed a new agreement to work together on a broad range of projects.

The three-year strategic collaboration will bring scientists from one of the nation's top medical research institutions together with scientists from one of the world's leading developers of biologic therapies.

UMMS and MedImmune scientists will cooperate on studies that aim to translate scientific discoveries from the laboratory into new candidates for treating cancer, heart disease, digestive disease, lung disease and diseases caused by inflammation.

This type of translational and pre-clinical research is designed to identify and confirm the specific molecules and genes involved in causing disease, and potential molecules and cell-based therapies to treat or prevent them.

"We are thrilled to partner with MedImmune in a collaborative and creative way to bring new innovations to market," says Steven Kunkel, Ph.D., senior associate dean for research at the U-M Medical School and Endowed Professor of Pathology Research. "This strategic partnership, one of the first of its kind for our institution, speaks to our desire to collaborate with industry to accelerate translation of U-M's cutting-edge research to impact patients."

The new agreement goes beyond the traditional type of academic-industry research relationship, in which companies fund projects such as clinical trials, or license patents on discoveries made by university scientists and develop them on their own. In this new type of agreement, scientists from medical schools and industry collaborate closely on projects – while also preserving academic freedom, research integrity and both sides' rights to intellectual property for discoveries.

"This new horizon in industry-academic partnership ultimately benefits patients, who demand new and better options for treating diseases," says Norman Greenberg, Ph.D., MedImmune's Vice President for Oncology Research and Development. "New types of partnerships between academic biomedical powerhouses such as Michigan, and industry leaders such as MedImmune, are needed to accelerate the search for those options."

The initial focus on oncology leverages the strength of the U-M Comprehensive Cancer Center.

U-M cancer scientists, led by center director Max Wicha, M.D., have won more research grant dollars from the National Cancer

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Joint Ventures

Elan to create research centre with Cambridge University

DUBLIN / Sun Nov 27, 2011 4:14am EST

(Reuters) - Elan Corp Plc has signed an agreement with Britain's Cambridge University to create a research center focused on therapies for Alzheimer's and Parkinson's, the Dublin-headquartered biotech group said on Sunday.

Elan, whose main research facility is in San Francisco, will spend $10 million over the next five years on the research center and has an option to extend the deal for another five years.

Researchers from Cambridge and Elan want to discover ways of altering the behavior of proteins that can spread neurodegenerative disorders such as Alzheimer's and Parkinson's.

"This agreement is a natural next step in the existing working relationship between our scientists in South San Francisco and scientists at the University of Cambridge," Dale Schenk, chief scientific officer at Elan, said in a statement.

"This collaborative effort complements our portfolio of programmes in neuroscience and supports the process of discovery which we believe may lead to a class of therapeutics that no one has thought possible before."

(Reporting by Carmel Crimmins; Editing by David Holmes)

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Analysis & Opinion

Gingrich fascinated by Romney computer wipe

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AUGUST 6, 2012

NEWS RELEASE

University of Pennsylvania and Novartis Form Alliance to Expand Use of Personalized T Cell Therapy for Cancer Patients

Industry-Academic Partnership Will Establish New Research Center to Expedite Study and Development of Gene Transfer Approach

PHILADELPHIA — In an alliance aimed at bringing a new, personalized immunotherapy approach to patients with a wide variety of cancers, the University of Pennsylvania and Novartis announced today an exclusive global research and licensing agreement to further study and commercialize novel cellular immunotherapies using chimeric antigen receptor (CAR) technologies. The agreement, which follows a Penn research team's 2011 publication of breakthrough results in several chronic lymphocytic leukemia patients treated with this personalized immunotherapy technique, paves the way for pivotal studies that have the potential to expand the use of CAR therapies for additional cancers.

The new alliance represents a marquee achievement in Penn's commitment to translational science aimed at expediting the process of bringing novel therapies to patients. Together, Penn and Novartis will build a first-of-its-kind Center for Advanced Cellular Therapies (CACT) on the Penn campus in Philadelphia -- a venture which will bring full circle the 1960 discovery of the Philadelphia chromosome, the first description of a chromosome abnormality that causes cancer. The center will be devoted to the discovery, development and manufacturing of adoptive T cell immunotherapies through a joint research and development program led by scientists and clinicians from Penn, Novartis, and

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Media Contact

Holly Auer
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C: 215-200-2313

Other Contacts

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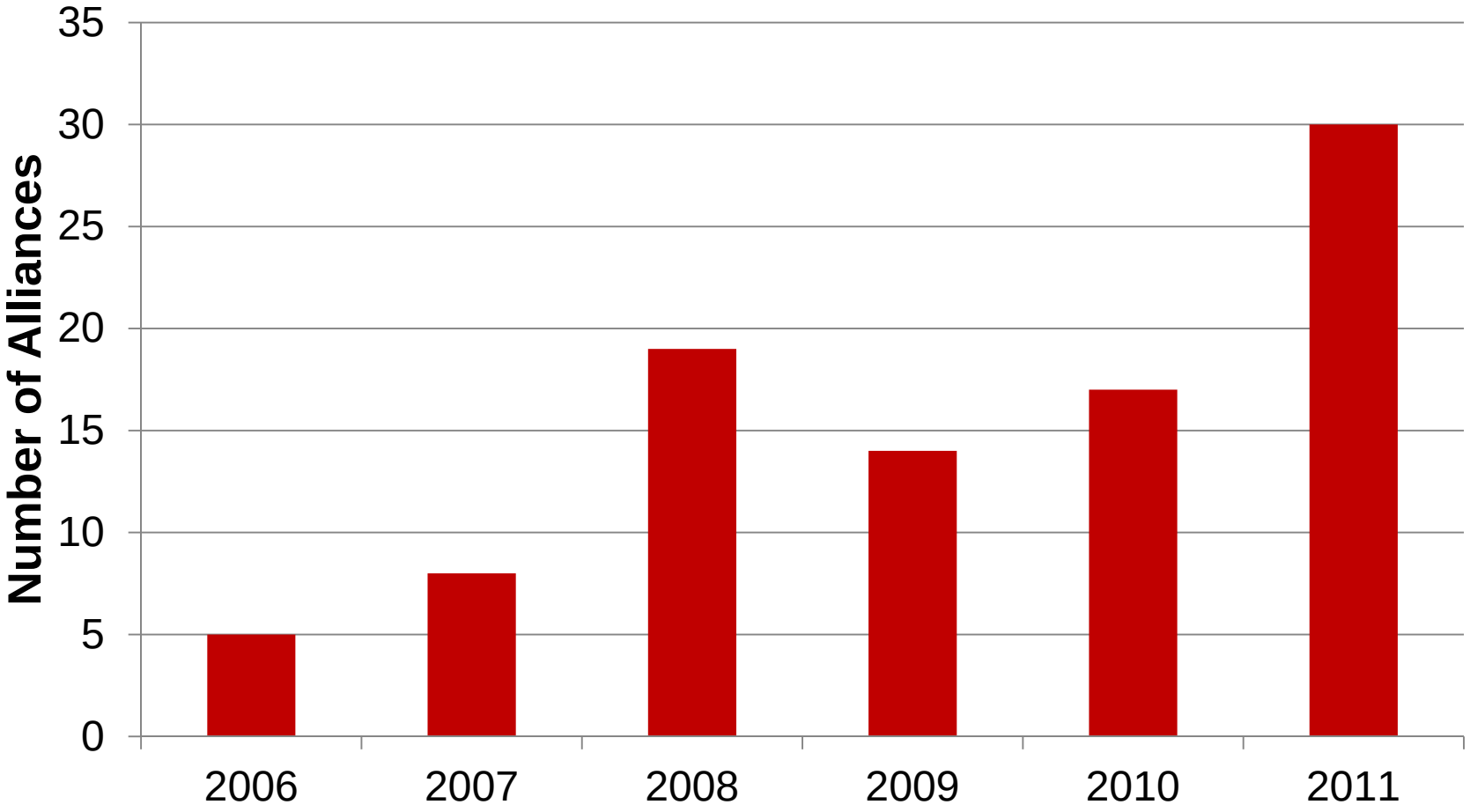

Source: Elsevier's *Strategic Transactions*

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Benefits of to Universities

- To obtain financial support for the university's educational and research mission.
- To fulfill the university's service mission.
- To broaden the experience of students and faculty.
- To identify significant, interesting, and relevant problems.
- To enhance regional economic development.
- To increase employment opportunities for students

Industrial Research Institute, *A Report on Enhancing Industry-University Cooperative Research Agreements* (Washington, DC, 1995)

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Benefits of to Companies

- To access expertise not available in corporate laboratories.
- To aid in the renewal and expansion of a company's technology.
- To gain access to students as potential employees.
- To use the university as a means of facilitating the expansion of external contacts for the industrial laboratory.
- To expand precompetitive research, both with universities and with other companies.
- To leverage internal research capabilities

Industrial Research Institute, *A Report on Enhancing Industry-University Cooperative Research Agreements* (Washington, DC, 1995)

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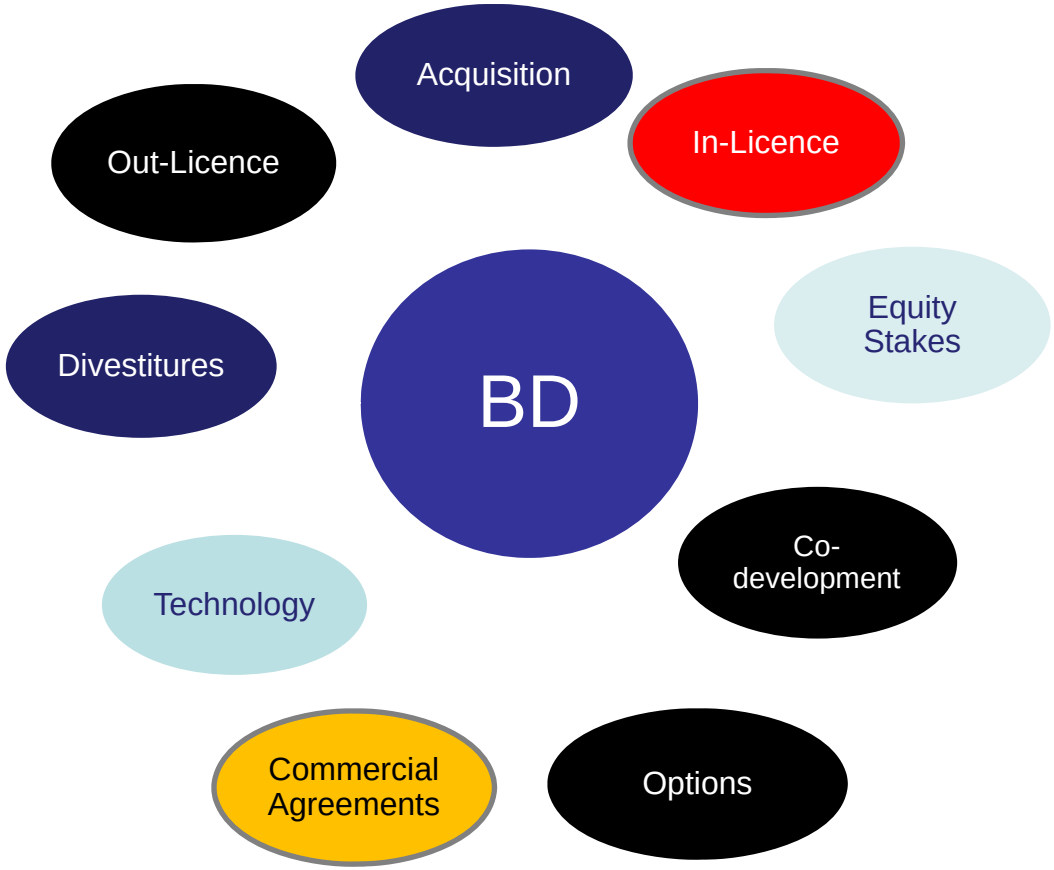
Large Company – Small Company Deals

- Many options for deal structure
- Underlying university deal must be compatible
  - May need to be renegotiated



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Current Deal Trends

- **Academic partnerships**
  - Pfizer's Centers for Therapeutic Innovation include Boston (and BU!)
  - UCSF as a hotbed of pharma dealmaking
  - Lilly's Open Innovation initiative: you preen, we screen
- **Corporate Venture Capital**
  - Increasingly popular all around
  - Experimental models: Lilly's Mirror Fund and Merck's Research Venture Fund
- **Option-heavy dealmaking**
  - Both alliances and acquisitions
  - Pushing risk back onto biotechs: a sustainable model?
- **Earn-out Heavy Acquisitions**
  - Contingent Value Rights becoming the standard acquisition model for VC backed companies
  - Creeping into publicly traded deals as well: Celgene/Abraxis, Sanofi/Genzyme
- **Reducing risk with peer relationships**
  - Lilly/Boehringer team up in diabetes
  - Merck/Roche: even competitors can play nice
- **Precompetitive dealmaking**
  - Ablexis' consortium
  - Pharma's awakening: you don't have to own it all

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Importance of Intellectual Property

- Good IP is crucial
- For small molecules easy to copy once lack patent protection
- For biologics an evolving landscape but getting more competitive
- If have no patent for rare indications get 7 years market exclusivity in the US and 10 years in EU
- Patent life is quite short for long development cycle industry
- Value of project estimated from number of years of market exclusivity

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Preparing for a Deal

- Non-confidential presentation
- Confidential presentation
- Confidential summary package
- Market opportunity analysis
- Dataroom assembly – electronic or physical
- Rehearsing team
- Send out teaser summary and email
- Time expectations

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Deal Mechanics

- Non-confidential presentation
- Sign CDA
- Confidential presentation(s) 1-4
- For in-licensing prepare development plan
- Discuss key terms or termsheet
- Diligence
- Negotiate deal
- Finalize deal

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The Ying and Yang of Technology Transfer

- We want to encourage collaboration with industry
  - Then we put in layers of bureaucracy
    - Conflict of Interest
    - Export Controls

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By the way – I'm not kidding

Ex-University of Tennessee professor sentenced to prison

Roth cites age, prior record, health issues in seeking leniency

By Jamie Satterfield
Posted July 2, 2009 at midnight

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J. Reece Roth

He asked for mercy Wednesday but not forgiveness.

University of Tennessee emeritus professor J. Reece Roth, 71, made an appeal before U.S. District Judge Tom Varlan for leniency as he faced sentencing for violating the Arms Export Control Act in his work on a U.S. Air Force research project.

"Your honor, I am nearly 72 years old, and this is the first time I have stood accused in a court of law," Roth said.

After summarizing what he said was a reputation for honesty and hard work, he noted his wife's health woes as well as his own heart-related medical problems.

Most Popular

J. Reece Roth

- U. of Tennessee professor
- Used Chinese and Iranian graduate students – both unlicensed – on an export-controlled Air Force contract to develop plasma actuators to guide unmanned aircraft.
  - Disregarded a warning by university's export-control officer,
  - Took laptop containing export-restricted files to China
  - Had Chinese student e-mail him research information
- University reported him as soon as discovered
- Roth claimed university's policy on non-discrimination trumped export control regulations
  - Are you serious?
- Sentenced to 4 years in prison
- Upheld on appeal
  - Reported to prison in January 2012

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What's In/What's Out?

- The ITAR and EAR control
  - Goods,
  - Technical data, and
  - Technical assistance/services.
- Neither the ITAR nor the EAR control
  - Public domain/published information (e.g., published patents),
  - Fundamental research, and
  - Basic marketing information.

How Does this Impact Biotech?

- Bioweapons
  - Bacteria
  - Viruses
  - Plasmids containing toxins
  - Information on them
    - Select agents
      - H5N1 flu strain modified to be extra contagious

Key Concepts

- US Export Laws
  - Who are “Restricted Parties”
  - What are “Controlled Goods and Technologies”
  - Jurisdiction
    - Why and When?
    - How?
      - Commodity Jurisdiction and Classification Processes
  - Impact on the patent process

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Key Concepts

- EAR
  - Specific information necessary for the development, production or use of a product
  - Most university activity is exempt from regulations
    - Numerous exceptions available
    - Wide scope, narrow license requirements

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Key Concepts

- ITAR
  - Information required for the design, development, production, manufacture, assembly, operation, repair, testing, maintenance or modification of defense articles
    - *Very few exceptions available*
    - Narrow scope, broad license requirements
  - Specifically designed, modified, or equipped for military purposes
    - Aircraft
    - Electronics
    - Radar
    - Toxicological agents
    - All satellites!
    - Technical Data

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Key Concepts

- ITAR
  - Information required for the design, development, production, manufacture, assembly, operation, repair, testing, maintenance or modification of a defense article
  - Information covered by an invention secrecy order
  - Software directly related to a defense article

Key Concepts

- Defense Services
  - Furnishing assistance or training to foreign persons in the use of defense articles
  - Furnishing ITAR technical data to foreign persons
  - Military training of foreign units or forces
- You can provide a defense service with public domain information!

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Prohibited Countries

- It is U.S. policy to deny export licenses for:
  - Afghanistan, Burma, Belarus, China, Cote d'Ivoire, Cuba, Congo, Eritrea, Haiti, Iran, Iraq, Lebanon, Liberia, Libya, North Korea, Sierra Leone, Somalia, Sri Lanka, Sudan, Syria, Venezuela, Vietnam
  - 126.1 Countries

Not Regulated

- Educational information
  - Technology released by instruction in catalog courses of academic institutions
  - Scientific, mathematical, engineering principles commonly taught in universities
  - Fundamental Research
    - No citizenship restrictions, publication restrictions or access controls

Agencies Involved

- US State Department
  - Exports and temporary imports of defense articles
  - US Munitions List
  - ITAR
- Bureau of Alcohol, Tobacco, Firearms and Explosives
  - Permanent imports of defense articles
  - US Munitions List
  - ITAR
- Commerce Department
  - Exports of commercial articles on Commerce Control
  - List under the Export Administration Regulations (EAR)

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Agencies Involved

- Office of Foreign Assets Control
  - Interactions with “restricted” parties such as narcotics traffickers, terrorism supporters, WMD, proliferators, Cuba, Iran, etc.

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What is an Export?

- Sending or taking a controlled article out of US
- Disclosing (including oral or visual disclosure) or transferring technical data to a foreign person, whether in the United States or abroad.
- Examples could include:
  - Giving a public presentation that includes technical data;
  - Emailing technical data to a foreign person;
  - Discussing technical data with a foreign person;
  - Posting technical data on the internet; or
  - Publishing technical data.
- Performing a defense service on behalf of, or for the benefit of, a foreign person, whether in the US or abroad.

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Export License

- Official authorization from the U.S. Government to proceed with a regulated transaction
  - E.g., Foreign Patent Application License
- License Exception
  - Self-executing authorization to export under certain conditions items that would otherwise require an export license
- Technology Control Plan (TCP)
  - Document that explains how to comply with export controls for a specific agreement or project

Foreign Person

- A person who is not a US citizen, lawful permanent resident (i.e., green card holder), or asylum holder
  - A foreign corporation, business association, partnership, trust, society or any other entity or group that is not incorporated or organized to do business in the United States
  - An international organizations, foreign governments and any agency or subdivision of foreign governments (e.g. diplomatic missions)

Restricted Parties

- Before doing business with any foreign party, screen to ensure that they are not on U.S. Government denial, debarment, and blocked persons lists.
- Lists include:
  - Treasury Department, OFAC Sanctions (Terrorists, Narcotics Traffickers, etc.)
  - Commerce Department, Bureau of Industry and Security (BIS) Denied Persons
  - Commerce Department BIS Entity List and Unverified List
  - State Dep't Arms Export Control Act Debarred Parties
  - State Dep't Designated Terrorist Organizations, Nonproliferation Orders

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Foreign Contact "Red Flags"

- Generic email address (yahoo, hotmail etc.)
- General request for technology in defense related or classified program
- Affiliation with banned or suspicious countries notorious for unfriendly relations with US (North Korea, Libya, Sudan, Syria, Cuba, China, Iran, Iraq – etc.)
- Improper use of English or use of foreign language
- Circumstances that indicate the interest may be destined for an inappropriate end use, end user or destination
- Requests for technologies inconsistent with the focus of the company
- Suspicious company background information and literature requests for technologies which are incompatible with the stated destination (e.g., 120 volts in a country with 220 volts)

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Controlled Goods and Technologies

- Defense Hardware, Technical Data & Services controlled for export and import by State Department and BATF
- Commercial Goods and Technologies controlled for export by the Commerce Department
- Public Domain Information/Fundamental Research is not controlled

ITAR-Controlled Defense Articles

- Defense articles specifically designed, developed, configured, adapted, or modified" for a military application, and
- Do not have predominant civil applications or civilian performance equivalent (defined by form, fit and function), or
- Have significant military or intelligence applicability.
- Defense articles includes specifically designed or modified components, parts, and associated equipment and technical data related to defense articles.
- The *intended use of the article or service after its export (i.e.,* for a military or civilian purpose) *is not relevant in determining* whether the article is subject to the ITAR.

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ITAR-Controlled Technical Data

- Information that is required to design, develop, produce, manufacture, assemble, operate, repair, test, maintain, or modify a defense article.
  - Can be in the form of blueprints, drawings, photographs, plans, instructions and documentation.)
  - Classified information relating to defense articles and defense services.
  - Information covered by an invention secrecy order.
  - Software directly related to defense articles.

ITAR-Controlled Technical Data

- "Technical Data" does *not include:*
  - Basic marketing information on function or purpose or general system descriptions of defense articles.
  - Information concerning general scientific, mathematical or engineering principles commonly taught in schools, colleges and universities.
  - Information in the public domain.

EAR-Controlled Materials

- The Commerce Dept's Commerce Control List (CCL) controls *all* commercial goods/technologies, except public domain information.
- CCL has 10 categories of items and multiple Export Control Classification Numbers (ECCN) within each subcategory.
  - All ECCNs will have 5 characters (*e.g., 1A001, 4B994).*
    - First character identifies the CCL category (*e.g., 1 = Nuclear Materials,* Facilities and Equipment, 4 = Computers).
    - Second character identifies subcategory (*i.e., A=Equipment, B=Test* Equipment, C=Materials D=Software, E=Technology).
    - Last three characters identify specific items (*e.g., 4B994=Equipment* for the "development" and "production" of magnetic and optical storage equipment.)

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EAR-Controlled Materials

- EAR99 is a "basket" designation for items that are covered by th EAR, but not listed on the CCL.
- The majority of the commercial exports from the United States fall into this category.

Public Domain Information

- Information which is published and which is generally accessible or available to the public through, for example:
  - Public libraries
  - Patents available at any patent office;
  - Unlimited distribution at a conference, meeting, seminar, trade show or exhibition, generally accessible to the public, in the US;
  - Public release after US Government approval;
  - Fundamental research in science and engineering at accredited institutions of higher learning in the U.S. where the resulting information is ordinarily published and shared broadly in the scientific community.

Fundamental Research

- Fundamental research is basic and applied research in science and engineering where the resulting information is ordinarily published and shared broadly within the scientific community,
  - As distinguished from research the results of which are restricted for proprietary reasons or specific U.S. Government access and dissemination controls.

Fundamental Research

- University research will not be considered fundamental research if:
  - The University or its researchers accept other restrictions on publication of scientific and technical information resulting from the project or activity, or
  - The research is funded by the U.S. Government and specific access and dissemination controls protecting information resulting from the research are applicable
  - Prepublication review solely to ensure that publication would not comprise propriety data or patent rights is not considered a restriction as long as any delay is temporary
- Subject to the EAR when parties have agreed that company may withhold some or all info provided!

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Examples of CCL Items

- Human, animal and plant pathogens
- Vaccines, immunotoxins
- Radar systems
- Computers, GPS
- Related technology

Additional Information

- BIS Deemed Export Training
  - http://www.bis.doc.gov/seminarsandtraining/seminar-training.htm

Patent Applications and Export Controls

- Information contained in a patent application is **excluded** when:
  - It is available to the interested public in the form of a patent and published patent applications
    - Explicit USTP foreign filing license has been granted; or
    - After six months has elapsed from the filing of the patent application in the USPTO

Material Transfer Agreements

- Is the receiving party located outside the U.S.?
  - If yes, treat as a physical export
  - Screen for restricted parties/destinations
  - Identify material – is it on the CCL or the USML?
  - Is a license required?

Licensing Technology

- Know what you have!
  - How is your technology controlled for export?
  - Consider requesting a Commodity Jurisdiction Determination
    - Official determination of jurisdiction and classification
  - Can save time in the long run
- Check for restricted parties
- Address export control compliance

Commodity Jurisdiction Request

- Request for an official jurisdiction determination
- Submitted to DDTC by the manufacturer
  - Description
  - Origin of commodity
  - Current use
  - Special Characteristics
- Decision can take from 60-106 days
  - Binding – be prepared for the answer!
  - Manufacturers, exporters and brokers of defense articles, services or related technical data are **required to register with the State** Dept.
  - Registration fee of $2,250

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Timing

- EAR
  - Average processing time is 28 days
- ITAR
  - With few exceptions, applications must be processed within 60 days
- FACR
  - Average processing time 67 days
- Licenses often contain provisos!

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Best Practices

- DO
  - Check for restricted parties
  - Address export control issues upfront
  - Know what export controlled technology you have
- DON'T
  - Encourage more than a temporary hold on publication
  - Rely on hearsay or assumptions