

Cedars-Sinai Medical Center

How to Generate Income Through A Robust IP / Technology Transfer Program

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Agenda

- **Overview Of CSMC Technology Transfer Process**

 - What Are We Doing Differently?

 - How Does It Benefit Our Efforts?

- **Understanding Market Potential**

 - Determining & Generating Economic Value

 - Proactive Marketing

- **Vehicles For Creating Economic Rewards**

 - What's Available?

 - Negotiating The Relationship / Determining Value



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- **Overview Of CSMC Technology Transfer Process**

What Are We Doing Differently?

How Does It Benefit Our Efforts?

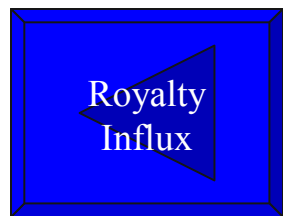
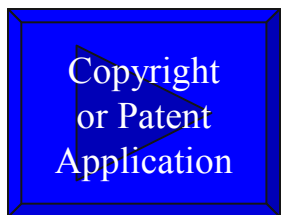
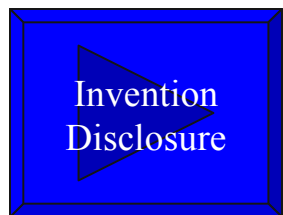


Underlying Principle of Technology Transfer

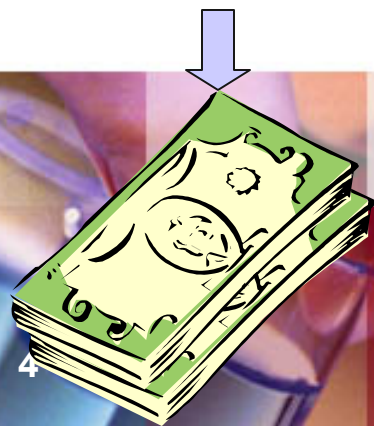


Idea/Invention

Invention
Back to
Inventors



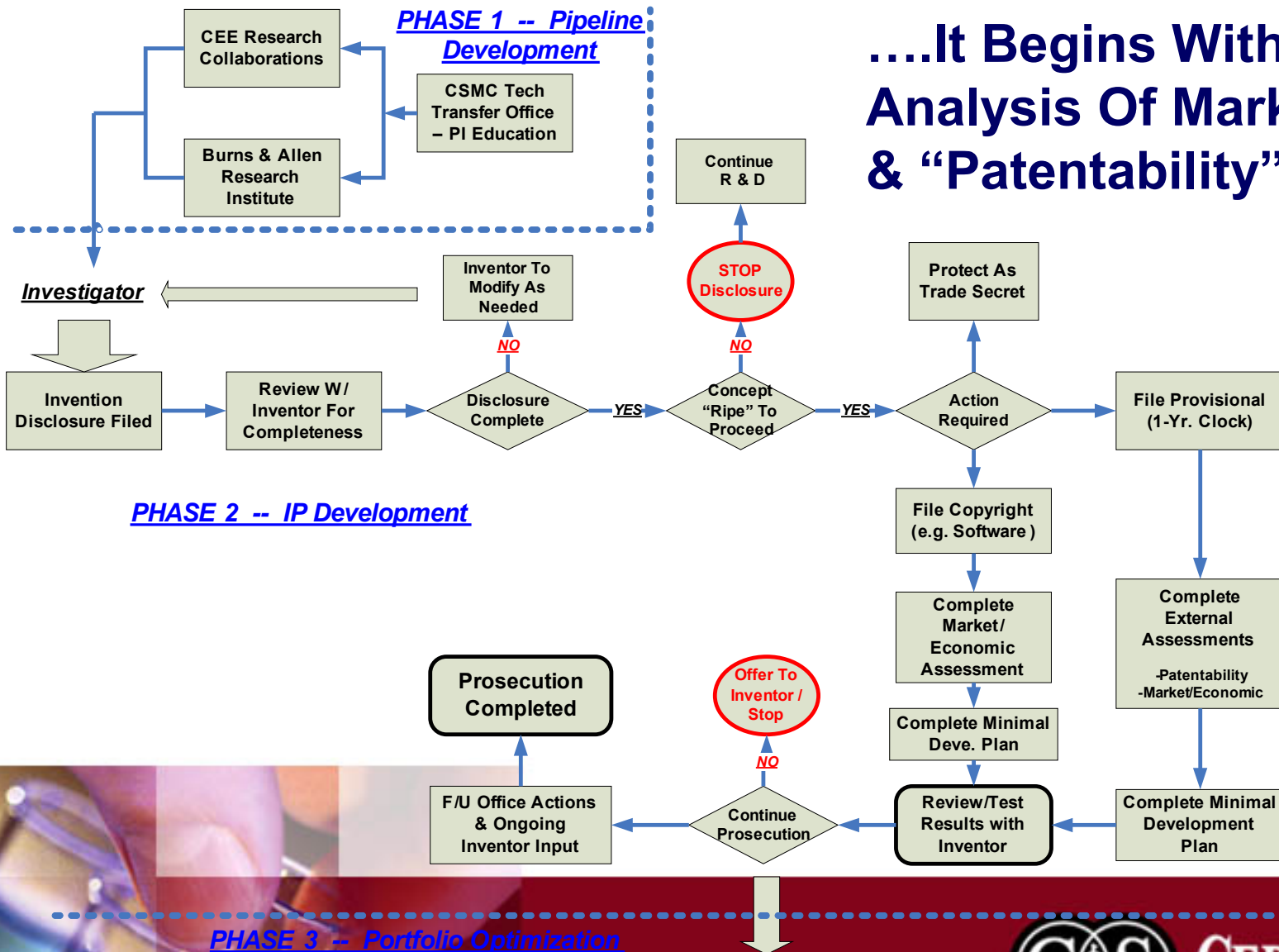
Invention
Back to
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CEDARS-SINAI

Deriving value from Intellectual Property Should Start Early

...It Begins With An Analysis Of Marketability & "Patentability"



Patent Theory

A patent is a “contract” between the inventor and the Government.

A patent secures to an inventor the exclusive right to make, use and sell an invention for a fixed amount of time

Inventor agrees to disclose fully the invention to the public.

A patent must be **Useful**, **Novel** and **Non-Obvious**



Patentability Requirements

In the United States: One Year Statutory Bar Rule

The Rest of the World: At Time of Disclosure

Things That Are Patentable

- Isolated genes - native and mutant
- Isolated purified proteins
- Monoclonal antibodies
- Transgenic animals and plants
- Cell lines
- Diagnostic kits
- Methods of treatment
- Biotech tools - sequencing methods

Factors Against Successful Patent Filing

- **Weak market assessment**
 - Limited market
 - Income potential insufficient to cover protection and bring-to-market costs
- **Weak claims, narrow scope**
- **Use dependent upon another's patent and licensing unlikely**
- **Failure to meet requirements for patentability (non-obviousness, novelty and usefulness)**

Agenda

- **Understanding Market Potential**

Determining & Generating Economic Value

Proactive Marketing



Market Potential

Market potential is defined by the same basic factors as with any new business venture

- **Market Demand – How large is the need?**

- Is the condition common or narrow?
- How large is the base population that is likely to need/want what the potential product?
- Are there other similar products that address the same condition?

- **Timing**

- How long before the product can be launched?
- Is the IP fully protected?
- When will the product be ready for launch?
- Are there other alternatives currently on the horizon?



Market Potential

Market potential is defined by the same basic factors as with any new business venture

- **Pricing**

- How much will the cost of R&D, production, etc. drive the cost of the product?

- **Payment**

- Are the products over the counter or covered by insurance?
- What are the impacts of insurance?



Licensing Opportunities

Securing The Opportunities – It Either Finds Us Or We Find it

- **Licensing Opportunities Generally Fall Into One Of Two Categories**

- **Passive:**

- Investigator develops a relationship with a potential licensee; may even obtain some financial support;
- When the research is ready, the sponsor pursuing a license

- **Proactive Marketing:**

- CSMC identifies opportunities



Marketing

Competition Is Fierce And Economic Rewards Are Not Easy To Obtain.....The Answer (We Think)...Pro-Active Marketing

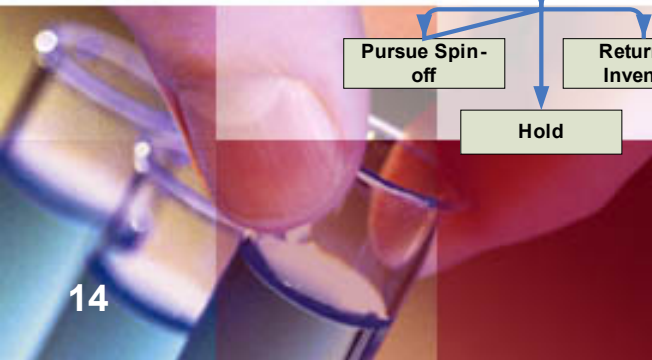
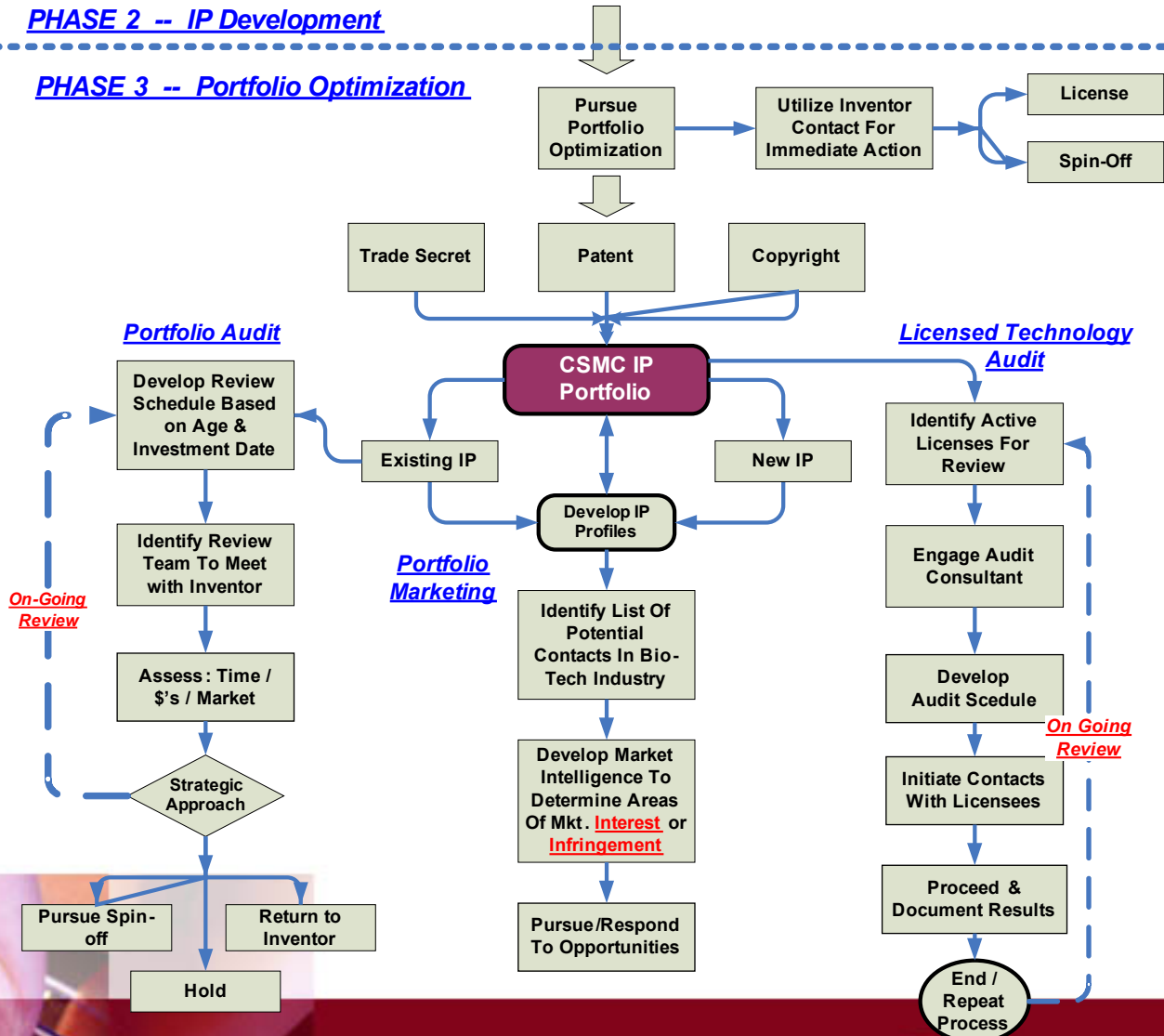
- **Build Portfolio Depth**
- **Identify Market Needs**
- **Match Market Needs With What We Have**
- **Leverage Industry Contacts**
- **Active Sales & Marketing**



Build Portfolio Depth

PHASE 2 -- IP Development

PHASE 3 -- Portfolio Optimization



Pro-Active Marketing

It Starts With Being Able To Tell A Story....What Do We Have To Offer

COMMERCIAL PARTNER NEEDED

- **Description:**

Novel drug treatment reduces growth of androgen-independent prostate cancers.

- **Current status:**

Preclinical and small human clinical study

- **Applications:**

Treatment and prevention [SLS1] of prostate cancer

Targeted for androgen-independent and refractory prostate cancers

- **Advantages:**

Dramatically reverses the progression of the prostate cancer

New use for an existing drug [SLS2]

Potential for more efficient regulatory approval based on known safety issues and side effects

Agenda

Vehicles For Creating Economic Rewards

What's Available?

Negotiating The Relationship / Determining Value

Vehicles For Creating Economic Rewards

Securing opportunities - there are several options

- **Licensing IP For Royalty Payments**
 - Non-Exclusive
 - Exclusive

- **Develop Spin-Off's**
 - Internally Funded
 - Externally Funded



Economic Value

How then is value determined?

Several tools to calculate a number (“Value”)

- Net present value
- Replacement cost
- Comparables

In The End, value is determined by what the parties agree to....**Fair Market Value**

Converting scientific output into “Intellectual Property” with economic value is a challenge....



Evaluation Process

Multiple Steps Leading To Determination Of Value

- Commercial Analysis
- Proprietary Position
- Inventor's Profile
- Stage of Development
- Financial Analysis



Commercial Analysis

- **Ability to define product**
- **Perceived industrial value**
- **Identify end user (customer)**
- **Market size**
- **Competitive edge/product differentiation**
- **Maturity of market**
- **Prospective licensee identified**
- **Regulatory and liability considerations**
- **Predisposition of industry to license**
- **Long product cycle**

Propriety Position

- **Weak claims, narrow scope**
- **Use dependent upon another's patent and licensing unlikely**
- **Multiple owners of intellectual property**
- **Failure to meet requirements for patentability**



Stage Of Development

- Ideas often embryonic
- Products and applications not well identified
- Technology ahead of market demand; Market and customers may not be clearly defined.
- High risk
- Not commercial products, only high risk opportunities and breakthroughs.



The Financial Analysis

Once all the Market/Ownership/Status Questions are answered then comes the financial analysis

- **The Discovery** - Peptide YY
- **Purpose** – Appetite control/suppression
- **Situation** –
 - Patent filed but not fully inclusive for particular delivery of this therapeutic opportunity / Does not cover nasal delivery
 - Potential licensor identified with other claims
 - This would be supportive to their efforts but not absolutely critical
- **Challenges:**
 - How to value this in light of situation?
 - How to measure demand to determine payment?

The Spin-Off

If licensing is not an option or the best option (we think) then we are investigating the opportunity to start a successful
SPIN -OFF

Raising Money: Sources of Fund

- Individual Private Investors
 - “Angels” (accredited individuals)
- Venture Capital Financing
 - Venture Capital is money provided by professional investors in new or developing business
- Self-Financing and Credit
 - Careful management of Internal Funds
- Strategic Alliance and Joint Ventures



Individual / “Angel” Investors

Appropriate only if modest amounts of money are required and the organization is acquainted with the angel

- Advantages:
 - Relatively cheap and quick source of seed
 - Management team can retain control

- Disadvantages
 - Angel usually bring less expertise/talent vs. VCs
 - Not willing to invest as much money as VCs



Venture Capital Financing

▪ Advantages

- VC firms often work closely with young companies and can assist in many ways.
- Often have resources to fund R&D and growth.

▪ Disadvantages

- VCs insist on sharing control
- An existing vehicle must be available within 5 years
- Return On Investment



Strategic Alliances and Joint Ventures

Useful when one party has an essential technology that the other does not possess and needs to obtain it. Many forms of alliances exist

- **Advantage:** Less costly financing vs. VC
- **Disadvantages:**
 - Companies have to cooperate
 - Each may be liable for each other's actions



Business Plan

In any case you still need a Business Plan

- **Nature of the Company and its Business**
- **Products, Market and Technology**
- **Qualifications of management team**
- **Financial goals**
- **Capital required and how it will be spent**
- **Competition**
- **Identification of risk**



Importance of Business Plan

- **Set expectations**
- **Determines milestones**
- **Identifies responsibilities**
- **Determines financial requirements**
- **Defines value**
- **Identifies exit strategies**

Business Requirements

- **Active research pipeline**
- **Interest by PI's to identify discoveries**
- **Interest by university administration to support program**
- **Legal system to support IP ownership**
- **Market relevant IP**
- **Infrastructure to develop relationships and create licensing arrangements**



Do not forget the key to success

Invention Disclosers

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