



Creative Innovation Consulting

Business Development | Science & Legal Advising

Intellectual Property:

FROM DEVELOPMENT TO MARKET

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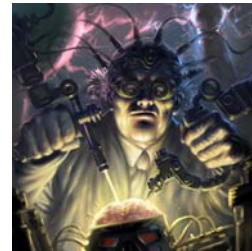
Who am I and how did I get here?

- ▶ PhD in Neuroscience from Albert Einstein College of Med
- ▶ First Faculty-Columbia Medical School
- ▶ Second Faculty-Harvard Medical School

- ▶ JD focusing on Intellectual Property from Suffolk University Law School
- ▶ Consulting for biotech
 - ▶ Some writing, some program management, some regulatory

Who invents things?

- ▶ Engineers
- ▶ Research Scientists
- ▶ Mad Scientists
- ▶ Stay at home parents
- ▶ Person on the bus
- ▶ Anyone!



Why do we invent things?

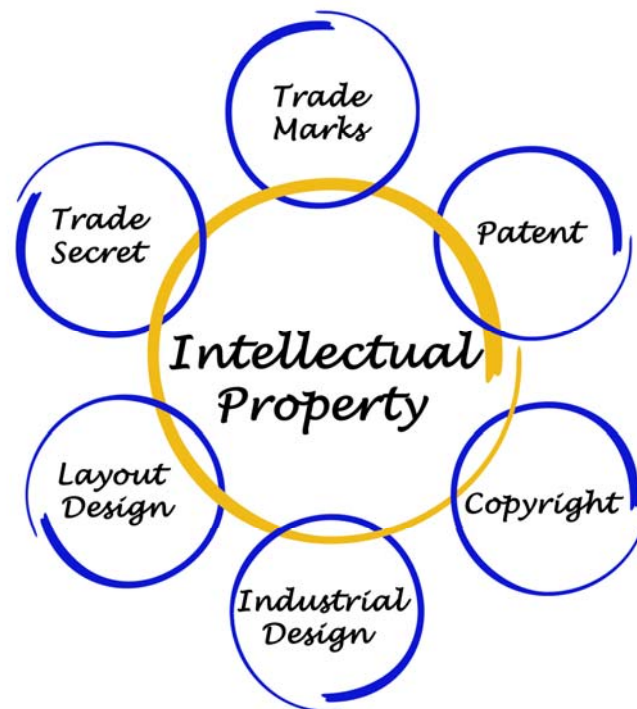
- ▶ We are curious
- ▶ We like to tinker
- ▶ We like to problem solve
- ▶ We want to make a difference
- ▶ We want to make money

- ▶ YOU SEE A PROBLEM THAT NEEDS SOLVING!



Protecting your ideas

- ▶ Intellectual Property is ANY product of the mind
- ▶ Some protections are automatic



- ▶ Some protections require filing a request for protection
- ▶ Some protections are a combination of the two



Trade Marks (Logos) TM





Lanham Act (1946)

- ▶ Defines the protection of trademarks
- ▶ Requires filing (with fees, of course) for US protection.
- ▶ Local trade marks do not require registration but you cannot sue for infringement without a registration.

Trademarks have \$\$ Value!



Burton TM is worth 500 Million dollars
Pepsi TM is worth 19.4 BILLION dollars
Starbucks TM is worth 26 BILLION dollars



The Little Blue Pill

Worth Billions



Trade Secrets

WHAT IS A TRADE SECRET?



Commercially
valuable
information



Creates a
competitive
advantage

Subject to
secrecy
protections



Not readily known,
identifiable, or
ascertainable



- ▶ Requires (demands) NO registration
- ▶ Must take reasonable efforts to keep the secret
- ▶ Common to require a signed non-disclosure agreement when you talk to someone about it

What might be a trade secret?

- ▶ A recipe or method of making something.
 - ▶ Coca Cola is one of the most famous trade secrets and one of the most valuable.
- ▶ A customer/donor list
- ▶ Business method

The Coca-Cola logo is displayed in its classic red script font with a white outline. It is positioned to the right of the text 'Coca Cola is one of the most famous trade secrets and one of the most valuable.'

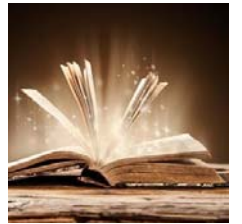


Copyright (1790)

- ▶ One of the oldest IP protections, comes out of British Law (1710, Named "Statute of Anne")
- ▶ US Passed an almost identical copyright law in 1790 which has been revised many times
- ▶ Automatically protects original works of authorship put in a tangible medium

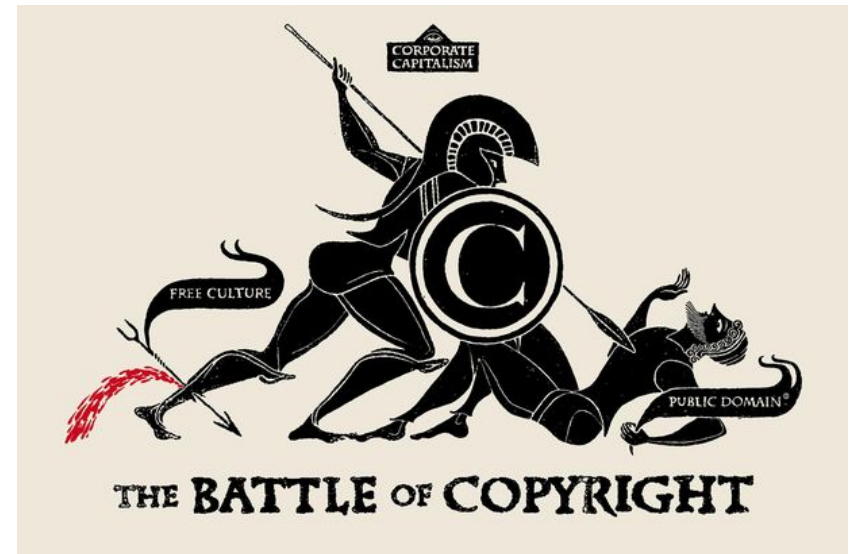
What is a tangible medium?

- ▶ Paper
 - ▶ Books, art, research papers, music
- ▶ Digital
 - ▶ Music download (A&M Records v. Napster)
- ▶ Performance
 - ▶ Television shows, taping public performances



Automatic protection v legal rights

- ▶ While the protection is automatic, your right to sue in a court of law is not.
- ▶ <http://www.copyright.gov/>

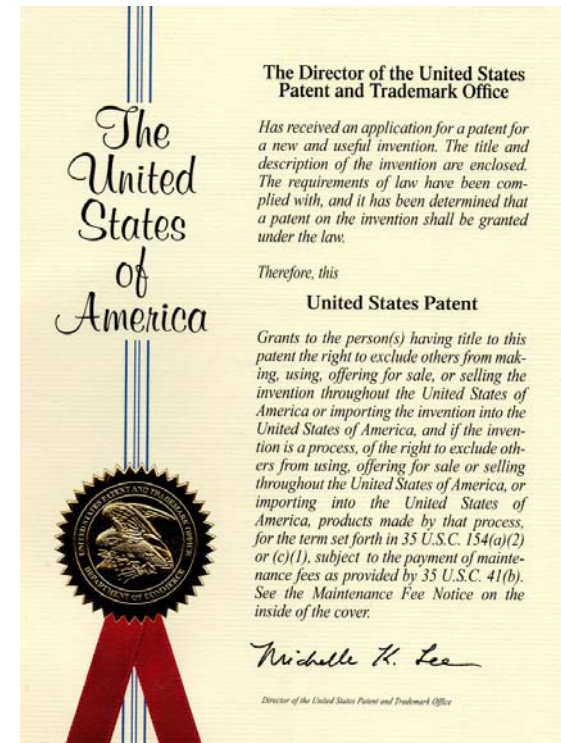


Patents: The life blood of Biotechnology

35 USC § 101

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Note: §100 is just definitions of words used in the statute



What is patentable?

- ▶ New (Novel) 35 USC §102
 - ▶ New, not thought of (or at least not made publicly) ever before
 - ▶ Useful 35 USC §101
 - ▶ Must benefit mankind in some way, no matter how tiny a benefit
- ▶ Non-Obvious 35 USC §103
 - ▶ An improvement on an invention must not be an obvious next step



That leaves a LOT of things to patent!



Reap the rewards



Poop Better.

Learn how to poop like a pro!





What does a patent give you?

- ▶ Twenty years from filing date.
- ▶ It gives you the right to exclude others from making, using or selling your invention (without your permission).
- ▶ It does NOT guarantee you the right to make, use or sell!

How can that be?

- ▶ Imaging a new type of robot....
- ▶ What is new is the type of joint movement and the flexibility
- ▶ You use the design of the plastic outer coat that someone else invented





Freedom to Operate (FTO)

- ▶ The part may be off patent and available for anyone to use.
- ▶ License the part you need from the inventor.
- ▶ Buy the patent so it is now yours (very expensive)



Full patents v. provisional patents

- ▶ You can start with a provisional patent. This lasts 1 year. It is not made public.
- ▶ Then you apply for a full patent, this is released to the public after a certain amount of time.

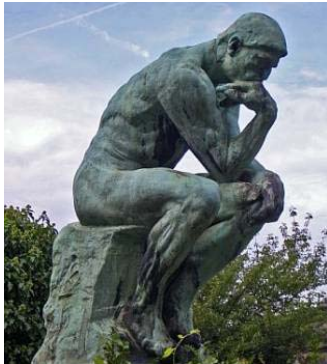
Who Owns Your IP?

- ▶ Your University



Your Idea.....Their Intellectual Property

The Bayh-Dole Act 35 U.S.C §200-212 (1980)



Prior to Bayh-Dole

Universities had to assign all ownership of discovery to the Federal Government (assuming Federal funding of the project).

Almost no incentive to patent and produce inventions

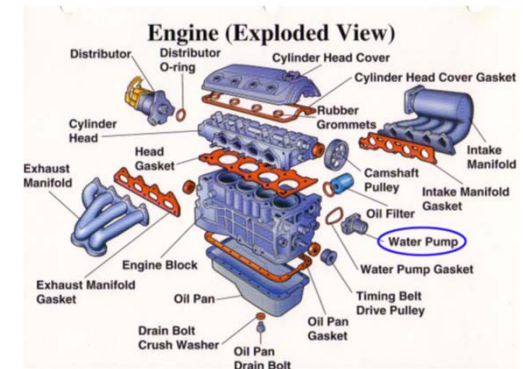
Main Effects of Bayh-Dole

Universities can now assume ownership of patents and may license them to their advantage.

Universities can determine how to spend licensing and royalty monies.

What is an invention?

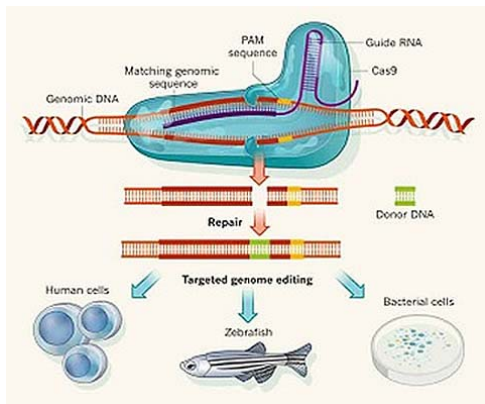
- ▶ It can be a single product
- ▶ It can be a component of a product
- ▶ It can be a “platform” which solves a number of problems or can be applied to a number of problems



Life Sciences Product vs Platform

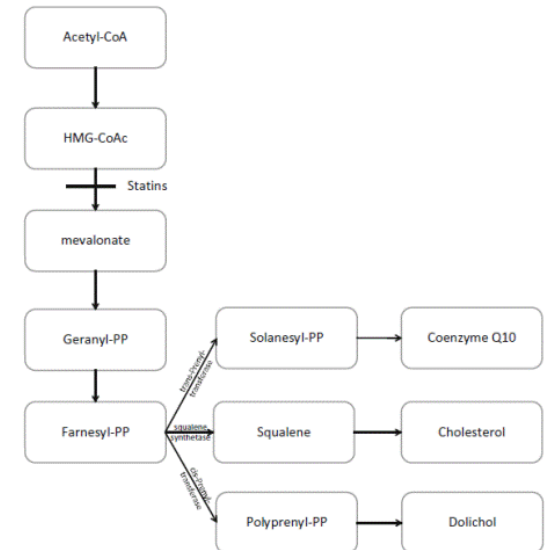
▶ Statins

- ▶ Lower cholesterol by blocking their synthesis
- ▶ Decreases risk of heart disease



▶ CRISPR/cas9

- ▶ Gene editing
- ▶ Can be applied to ANY disease if you know the gene involved





Positioning a product vs. a platform

- ▶ Single indication product is just fine, if you have a large market (like for statins)
- ▶ Platforms are preferred, especially in smaller markets
- ▶ It is all about the monetary opportunities

5 Burning Questions to Ask Yourself BEFORE you start!



- ▶ 1. What problem are you solving?
- ▶ 2. How big is this problem? (Market Size)
- ▶ 3. How competitive is this market?
- ▶ 4. Is your solution truly unique? (HINT-Check other patents!!)
- ▶ 5. Is there any money to be made here?



Question 1: What problem are you solving?

- ▶ Totally unsolved problem
 - ▶ Rare diseases such as epidermolysis bullosa
- ▶ Problem arising from the solution to a first problem
 - ▶ Excessive bleeding due to blood thinners
- ▶ Problem with other solutions but yours is better
 - ▶ Newly designed integrated robotic hand for injury victims



Shark Tank

- ▶ Entrepreneurs explain their inventions to 5 very rich people (Sharks) that MIGHT want to invest in their companies. This is known as a “Pitch”
- ▶ A pitch, ideally, should contain an explanation of the product, how much it costs to make and how much it sells for AND most importantly to the Sharks-how it is going to make them money.
- ▶ The only products that get investments are ones that have a way to make back ALL of the investment PLUS make extra money on top.

Does your “problem” need to be solved?

- ▶ Cougar Energy Drink
 - ▶ Energy drink for older women who want to date younger men.



- ▶ Sugar Daddy Energy Drink





Question 2: What is your market?



- ▶ How many people would have a need to buy this?
- ▶ How many competitors do you have for this number of people?
- ▶ What are people spending now to solve this problem?
- ▶ What health cost savings can your invention provide?

▶ DO YOUR RESEARCH!



Question 3: How competitive is the market?

- ▶ Is anyone else trying to solve this problem?
 - ▶ Google it
 - ▶ US Patent and Trademark Office search
- ▶ How many groups are “in the space”?
 - ▶ Identify the companies
 - ▶ Learn EXACTLY how their solution works
- ▶ Line up all the pros and cons in a grid and show why your solution is better.

Competitive Landscape Grid



	Efficacy	Side Effects	Ease of Use	Ease of Conversion	Cost to Payor	Cost to Patient
	+++	+	++++	+++	+	++
	++	++++	+++	+	++++	+++
	+	++	+++	+	+	+
	+	+++	+	++	++	+



Question 4: Is your solution truly unique?

- ▶ Easy part-just Google it
- ▶ Go to the US Patent and Trademark web site and search keywords (www.uspto.gov)
- ▶ Do a global patent search using PatentScope (<http://www.wipo.int/patentscope/en/>)

What does it mean to be unique?



Do you have to be 100% unique?



What is this?



Question 5: Is there any money to be made?

- ▶ While saving the world is fantastic no one will fund your idea if they cannot make money on it.





Communicating Your Science

- ▶ Elevator Pitch
 - ▶ 30 second description of your work
- ▶ Pitch Deck
 - ▶ To investors
- ▶ IN BOTH CASES YOU WANT TO PIQUE INTEREST WITHOUT GIVING AWAY YOUR “SECRET SAUCE”



Starting a Business Checklist

- ▶ Validate your idea
- ▶ Protect your IP
- ▶ Identify investors
- ▶ Work!

How to ruin a business in 6 shorts steps

Step 1

- ▶ Always be the smartest person in the room.

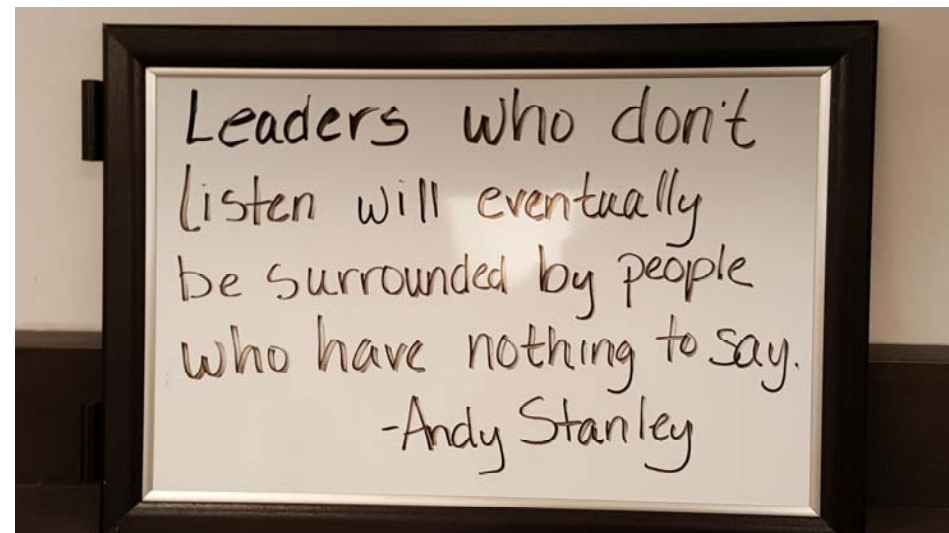


How to ruin a business in 6 shorts steps

Step 2

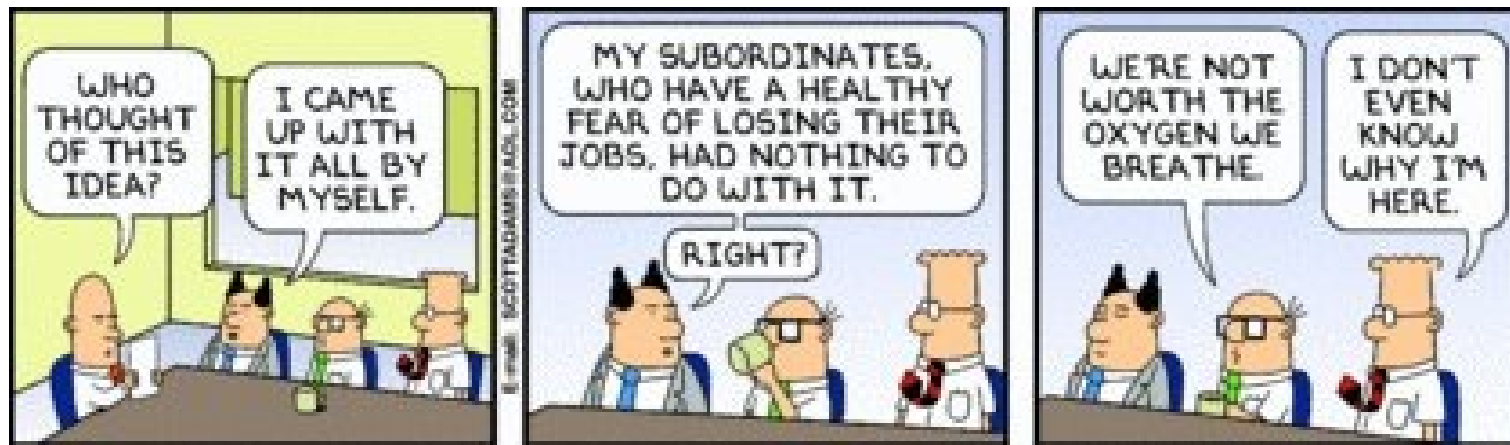


- ▶ Never listen to others



How to ruin a business in 6 shorts steps

Step 3

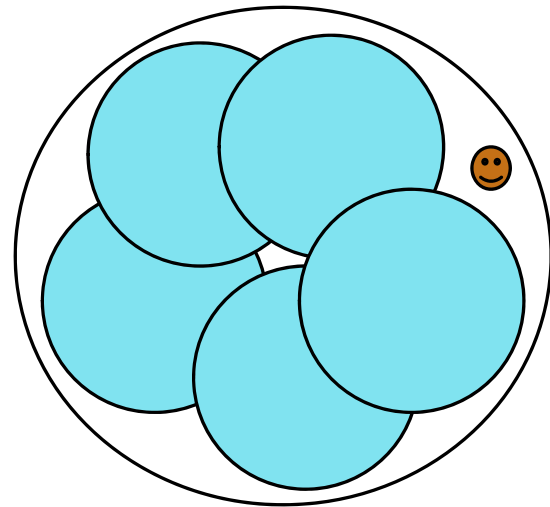
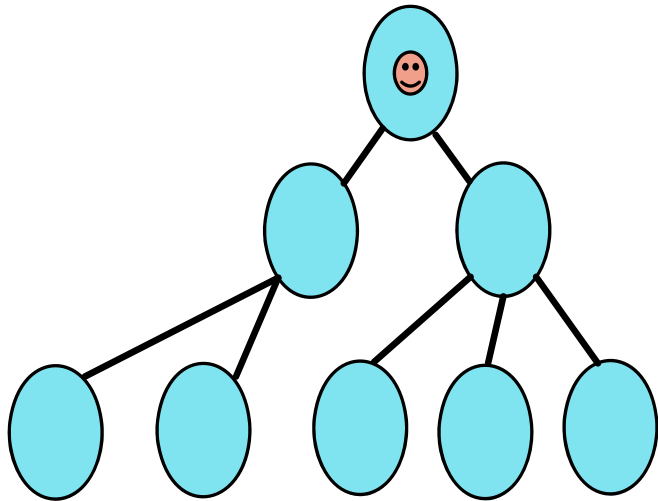


- ▶ Think that only your ideas are good ideas, and if someone else has a good idea----it becomes your idea (without representation)

How to ruin a business in 6 shorts steps

Step 4

- ▶ Care about hierarchy



How to ruin a business in 6 shorts steps

Step 5



▶ Micromanage

How to ruin a business in 6 shorts steps

Step 6

- ▶ Think that management style is something that is personal to you and that you cannot change





In the end.....

- ▶ Entrepreneurship is fun, crazy, scary, interesting, and very very fulfilling!
- ▶ Always keep going, one foot in front of the other
- ▶ Never ever give up!



Thank You!

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