# What Every Investigator Must Know about IP in Biotechnology Startups

## BIO BOOT CAMP
## June 2017

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# Types of Intellectual Property

**Patent** – ideas that are novel, not obvious, have utility and satisfy the enablement and written description provisions of the U.S. Patent Statute

**Trademark** – identification of goods and services

**Copyright** – protects tangible expression, including writings, computer code, websites

**Trade Secret** – maintaining secrecy over a process or ingredients of a product




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# Patents –standing in the shoes of the investor/partner

- **Integrity of the patents or patent applications – for each patent or application:**
  - Who owns it?
  - What is really covered by the claims – is the lead product covered?
  - If pending, will a patent issue?
  - If issued, will it withstand challenge?
  - What is the enforceable patent term?






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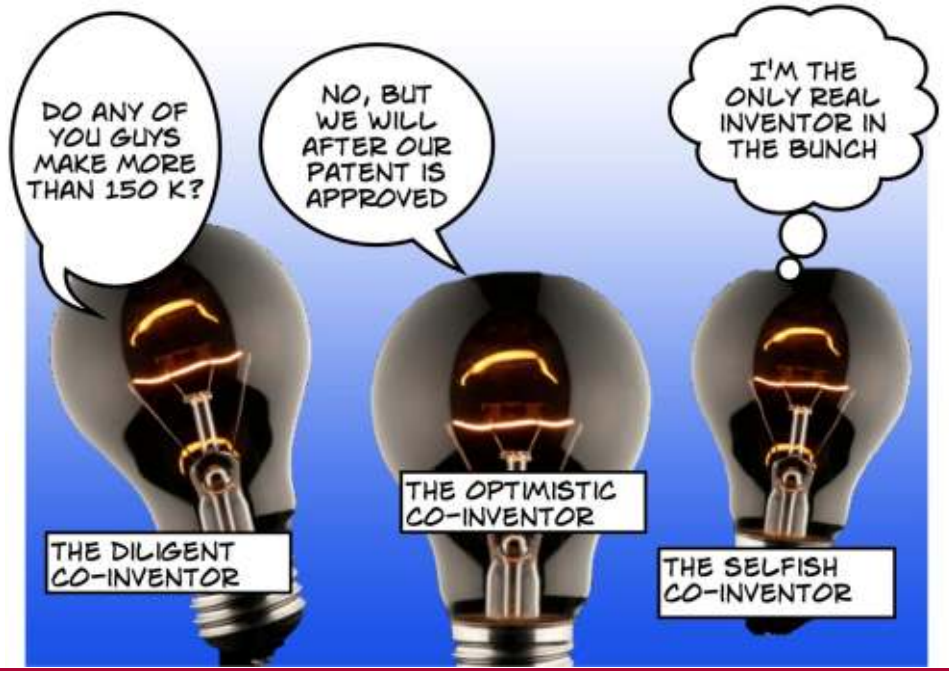
# Ownership

- In the US, ownership resides solely with the named inventor(s), unless there is *an agreement that assigns* the invention to another
- Each co-inventor owns an undivided interest in the entire patent, irrespective of their level of contribution
- A joint inventor who contributed to the invention of only one claim has an undivided interest in the whole patent



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# Conception

A definite and permanent idea of a complete and operative invention, including every feature of the subject matter sought to be patented




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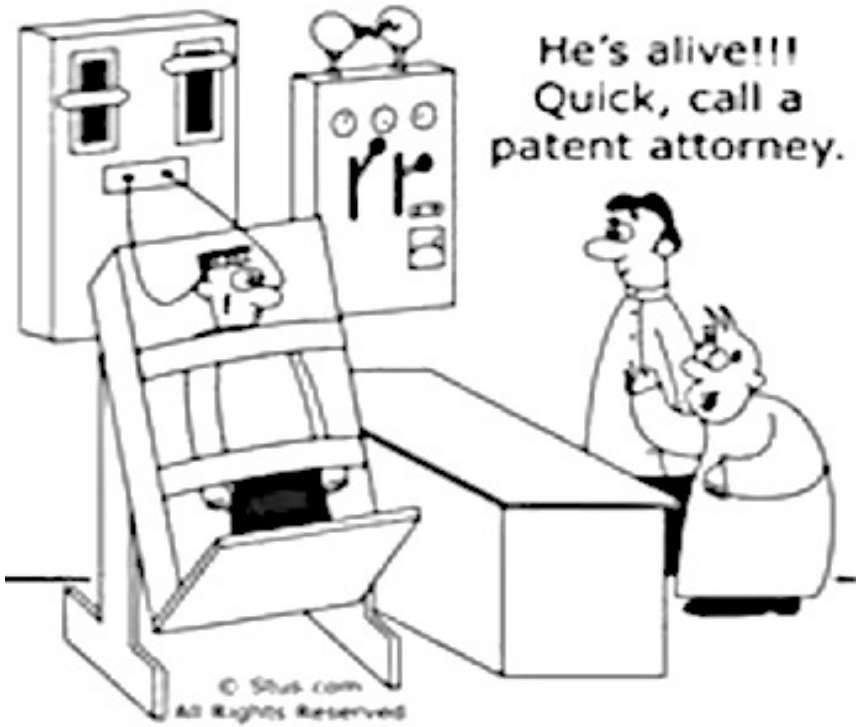
# Reduction to Practice

Reduction to practice:

- Actual - doing the experiment, making and testing
- Constructive - file a patent application with an enabling disclosure



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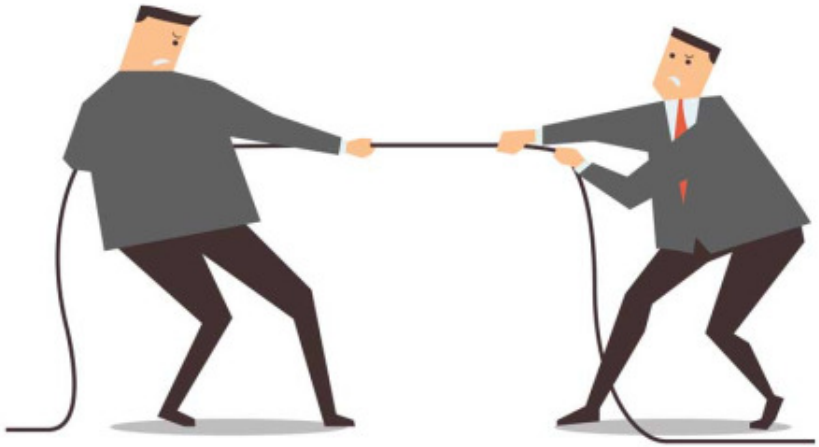
# Joint Invention

Joint Inventors:

- Need not have physically worked together or at the same time
- Must have a collaboration
- Need not make an equal contribution
- Need not make a contribution to the subject matter of every claim0

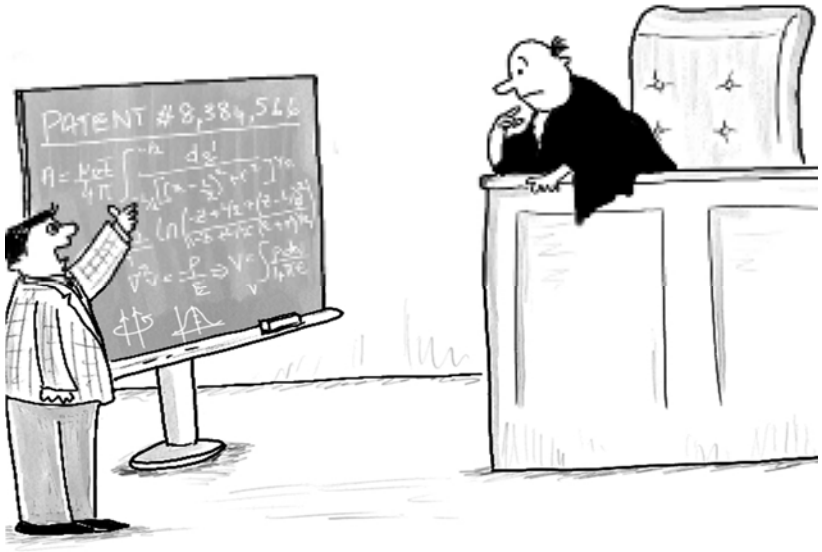
# Joint Inventorship Problems

- Collaborations that do not go well
- One group begins a project and another takes it over
- What happens when chemical compounds invented by one party for which a use is discovered by another party?



# Patent Applications

- **The Disclosure** – all of the text, figures, tables, etc. that disclose the invention and the manner of making and using it




- **The Claims** – a precise recitation of the invention, in numbered paragraphs at the end of the application



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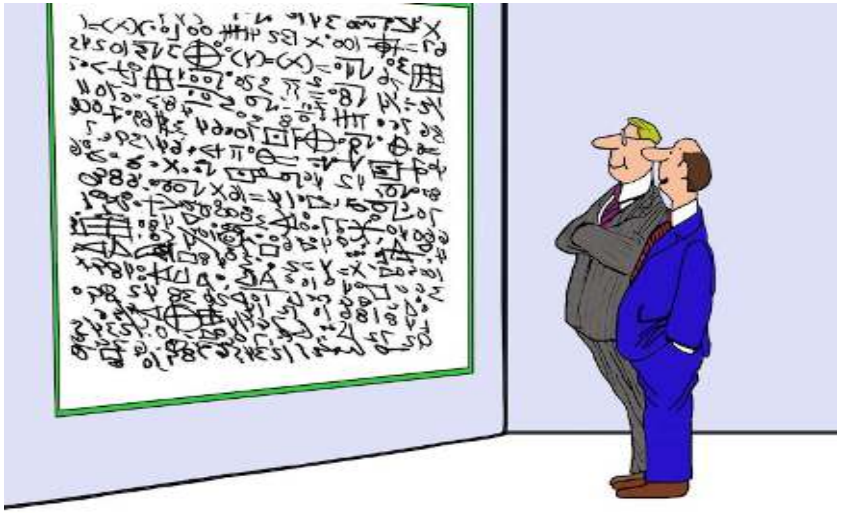
# Patentability

The claims are assessed by an Examiner to see if they satisfy the following criteria:

- Utility and Non-natural [35 U.S.C. § 101]
- Novel [35 U.S.C. § 102]
- Non-obvious [35 U.S.C. § 103]
- Claims are enabled by the specification as-filed [35 U.S.C. § 112]
- Claims satisfy the written description requirement [35 U.S.C. § 112]



"When you put it like that, it makes complete sense."



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# Claims

1. Hydrogel capsules encapsulating cells,

wherein the capsules consist of three layers, a first an inner acellular core layer, a second hydrogel layer containing cells to be transplanted selected from the group consisting of mammalian secretory, metabolic and structural cells and aggregates thereof, and an outer acellular barrier or structural layer.

2. The hydrogel capsules of claim 1 having a mean diameter of greater than 1 mm and less than 8 mm.

3. The hydrogel capsules of claim 1 wherein the core comprises a therapeutic, prophylactic, or diagnostic agent.

# 35 U.S.C. § 101


- Nature-based product is patentable if it is ***markedly different*** than its naturally occurring counterpart
- Combination of components that ***do not naturally occur together*** in nature, where the mixture has ***changed the functional property*** of each
- Diagnostics - Detecting presence of a component in a sample obtained from a patient is patent eligible but adding a step of correlating with a disease is a law of nature and therefore not patent eligible, unless the ***step is unconventional*** when coupled with the detecting step



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# The Disclosure Dilema
# "PUBLICATION"

"Publications" include the following:

- A scientific article
- A thesis which is cataloged and available in a library
- An abstract which describes data in a poster or talk
- The abstract of a Government Agency Grant which is available to the public after the grant issues
- A public talk or poster which is open to people outside your own institution at which notes can be taken
- Funding/partnering pitch – what does the Business Plan disclose, was it presented under CDA?
- Be mindful of any online publication of the above



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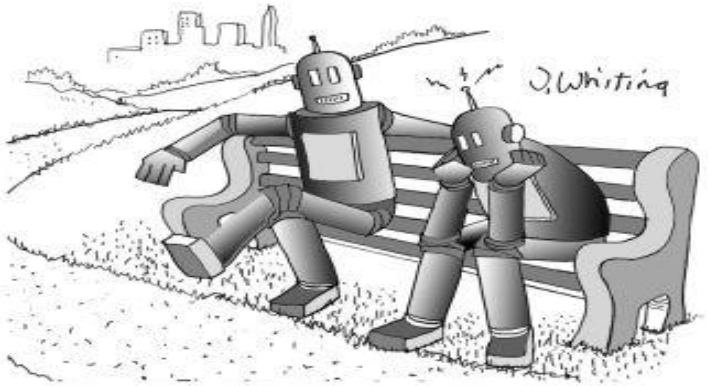
# Patent – The Rights Granted

- The right to **exclude** others from making, using, selling, offering to sell or importing the invention for the active term of the patent (20 years from filing), in the jurisdiction in which the patent is granted. For example, a US patent can only be enforced in the US, a Japanese patent can only be enforced in Japan.
- The right is **not automatic** - You must actively assert your right by putting the infringer on notice that you own the invention and will sue them for infringement if they do not cease their activities




"I used to think I was really special until all my patents expired."



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# Freedom to Operate versus Patentability

There is no relationship between the two.

Freedom to Operate (FTO) – you have the right to make, use or sell the product without infringing third party patents – Doorknob and button analogy

Patentability – whether or not you can obtain a patent for your invention – is your invention *novel, non-obvious, useful and have you enabled it and satisfied the written description requirement*?

# STRATEGIC PLANNING




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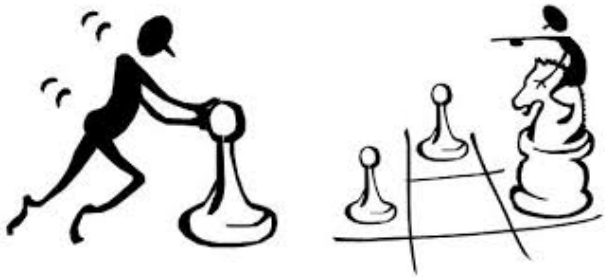
# Strategic Planning

- Does not begin with the patent application
- Begins with the invention and what your plans are for capitalization of that invention.

# Objectives of Patent Strategy



- Obtain a Monopoly in your space
- Develop an Offensive and a Defensive IP position

<u>Offensive</u>

- File applications covering your product, processes, treatment modalities, formulations, delivery, packaging, etc.
- Do not ignore filing "follow-on" applications to cover more defined aspects of the base technology

# Objectives of Patent Strategy


- **Defensive**
  - File applications covering broader scope than that which would protect your product alone
  - File applications covering use of your invention with third party products, e.g., a novel insulin product coupled with an insulin pump patented by a third party
  - License in technology from third parties that broadens the picket fence around your technology



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# Bottom Line

- Develop a patent strategy that maximizes patent protection for your products and methods
  - Multiple layers of protection: composition, method of use, method of making, different components or subsystem of a device, etc.
  - International filing:  market potential, enforceability; local considerations, e.g., China, Brazil, India, Europe
  - Timing – PCT vs Paris convention; regular vs accelarated
  - Within the budget



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# Other Aspects to Strategic Planning

- Must have a plan to deal with competitors
- Must have a plan that takes regulatory review into account
- Must have a plan to ensure commericalization of the invention!!




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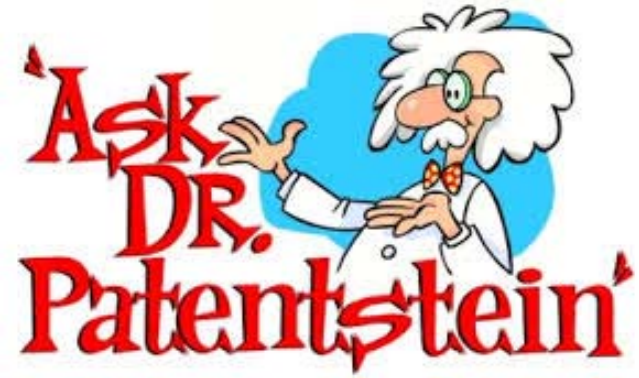
# Implementation of the Strategic Plan




- When should you file?
- Why should you file?
- What should you file?
- What are the competitors doing and how far along are they compared to you?
- What is the status of the technology?
  - Lead technology?
  - Follow-on technology?
  - Time line for development?
  - Time line for funding/partnering/exit?



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# Be Flexible

- Modify the strategy based on the new developments in-house, in the market and in patent law



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# How to deal with third party patents that may block your ability to practice?


## Challenge the validity of the patent

*Inter Parties Review (IPR)*

- Based on patents and printed publications; can be initiated immediately following issuance of patents examined under the first to invent rules or 9 mo after issuance of patents examined under the first to file rules (March 15, 2013)

*Post Grant Review (PGR)*

- Based on any grounds that can be used to challenge the validity of a patent claim; can be initiated within 9 mo after issuance of patents examined under the first to file rules



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# How to deal with third party patents that may block your ability to practice?


Challenge the patent

*Declaratory Judgment*

- Ask a federal court to declare non-infringement, invalidity, and/or unenforceability of a patent
- Need existence of an actual controversy



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# How to deal with third party patents that may block your ability to practice?

License and cross license

- ***IP due diligence***
- ***Future IP***



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# IP Due Diligence

- Different parties will have different objectives and focus
- The VC will be focused on the exit strategy
- Big Pharma, Big Biotech will take a longer view and focus on the product pipeline
- As the technology matures and makes its way through clinical trials, expect more IP and FDA due diligence



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# The "Acid Test of IP"

- **Who really owns the technology?**
  - Assigned?
  - Licensed? What are the terms?
  - Collateral?
- **Integrity of the patents in hand or pending**
  - What is really covered – hopefully the lead product
  - Nature of PTO Office Actions
  - Time to expiration
  - Improvements
  - Position of patent(s) in industry/sector patent mapping
- **Freedom to practice**
  - Does what is covered completely define the product
  - Are there other patents that block entry?
  - Are those patents available for purchase or license?
    - At what cost?



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# The "Acid Test of IP"

**What agreements has the company entered into?**

- MTA, CDA, Collaboration Agreements, Sponsored Research Agreements with academic institutions, etc.
- How do the provisions of those agreements affect your IP?
- Are there agreements that have been terminated where some terms survive and affect your IP?




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# How to Manage Your IP in Preparation for Due Diligence?

- Identify and organize your patent portfolio
  - Include a complete patent docket including all foreign IP
  - Have all IP protocols, invention disclosures and procedures available
- If you have opinions, reports or litigation
  - Be aware of Attorney-Client privileged communications and/or work-product documents
- Make sure you understand your regulatory issues




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