

STL Startup Week

# Intellectual Property Strategies for Executives and Entrepreneurs

#STLStartupWeek

# Before We Get Started...



## Recording

A link to the recording and slides will be emailed to all registrants.



## Questions

Type in the question box and we will answer in real time or during the Q&A.



## Social

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## Doug Portnow

- Registered patent attorney
- Adjunct faculty UH Law School
- Formerly Member at WSGR; Associate at Townsend & Townsend & Crew
- Practice focuses on medical device patent prosecution and IP due diligence
- JD, Univ. New Hampshire (formerly Franklin Pierce Law Center); MBA Santa Clara Univ.; MS Bioengineering Univ. of Michigan; BS Mech. Eng. MIT
- Prior 10+ years as a R&D Engineer, QA/RA Manager and Director of Manufacturing in med device industry



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## Ryan J. Connell

- Registered patent attorney
- His practice emphasizes chemical engineering, materials science, biotechnology, and organic chemistry.
- Also has experience in a variety of mechanical and electro-mechanical related arts.
- JD, University of Minnesota; MS in organic chemistry and B.A. in chemistry from the University of Minnesota Duluth
- Volunteers with the Wills for Heroes program





# Linh-Han Nguyen

- Registered patent attorney and Principal, SLW
- Practice focuses on software and electrical engineering
- JD, Chicago-Kent College of Law; B.Eng McGill University





# Episode Overview

- What is IP
- Ownership of IP
- Freedom-to-operate (product clearance)
- Patentability
- Portfolio management
- Cost control
- IP due diligence
- Patent valuation
- Analytics



# Types of Intellectual Property



# Trademarks/service marks

- Word, phrase, symbol, and/or design that identifies and distinguishes the source of the goods (or services) of one party from those of others
- Even includes a sound, smell, color, etc.





# Copyrights

- Copyrights – protects original works of authorship for an expression fixed in a tangible medium
  - Literary, dramatic, musical, and artistic works
    - Examples: Movie, Recorded song, Photograph, Book, Sculpture



# Trade Secrets

- Trade secrets – anything that you can keep secret and lasts as long as you can keep it a secret
  - Manufacturing process
  - A client list
  - A formula
    - e.g. Coca-Cola formula, KFC recipe
- Pros/Cons of trade secret vs. patent
  - Length of protection
  - Public disclosure
  - Enforceability



# Patents

Patents – right to an invention for a limited period of time in exchange for disclosure:

- Utility patents for a machine, a process, article of manufacture, composition of matter
- Design patents for an ornamental design
- Plant patent for plant varieties asexually produced
- Utility models

Today our focus will be on patents

- Often most of value of an early phase startup company is in its patent portfolio



# What is a Patent?

- Does not give the patentee the right to practice the invention
  - There may be regulatory approvals or other clearances required before you can manufacture and sell your product (e.g. USFDA clearance for a medical device or drug)
- Gives the patentee the right to exclude others from making, using, or selling the invention for a limited period in exchange for disclosing the invention to the public, thereby advancing the body of knowledge





# Why Obtain a Patent?

- Patents are important
  - Protect your invention by excluding others
  - Property that can be monetized
  - Helps with company valuation
  - Proof to others that you have something
  - For early-stage companies, patents are often the only property since no sales, no clinical data, no other tangible property
- How to get a patent?
  - File a patent application with an invention that is novel, non-obvious and enabled



# Ownership & Assignment

- Make sure that you can demonstrate ownership of your IP or that you have rights to the IP via a license
  - Inventors should assign the patent to the company
  - Record the assignment with the patent office
  - Include language about ownership of other patent family members
- Failure to have rights to the IP opens you up to liability for patent infringement
  - Investors want to avoid risk

## Ownership & Assignment, cont'd.

- Obtain assignments promptly. Inventors change jobs frequently.
- Record promptly to prevent a second assignment beating your assignment
- Audit your portfolio to make sure there are no issues
  - e.g. Incorrect assignor/assignee name, typos, wrong serial number, etc.
  - Conduct audits well before any IP diligence
- Backup is critical – obtain employment and consulting agreements with all employees and consultants





# Patentability – What Sort of Claims Can I Get?

- Claims outline the bounds of your patent protection
  - Want claims as broad as possible to block as much as you can but don't want your claims so broad that they are vulnerable to invalidity attacks
  - Don't want claims so narrow that they are invulnerable to invalidity attacks but only cover your commercial embodiment and nothing else.
  - Sweet spot is in between
  - Consider a range of broad and narrower claims



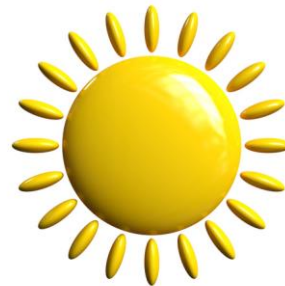
# Patentability – What Sort of Claims Can I Get?

- Make sure your claims cover your commercial product, a target competitor device, or a likely design around
  - Map your claims to your commercial product or competitor's product if targeting
  - Claims should cover the most important features



## Patentability, cont'd.

- Know the most relevant prior art and be able to distinguish your invention from the teachings of the prior art
  - Will help you with patent prosecution
  - Will be needed during IP due diligence
  - Map your claims to commercial product or competitor product
- What can I patent? What should I patent?
  - You can patent anything human made under the sun
  - Cannot patent laws of nature, naturally occurring things, abstract ideas
- What should my patent portfolio cover?
  - Include device claims, medical (computer) method claims, manufacturing claims, system claims, CRM claims, composition claims, and product claims.



## Patentability, cont'd.

- What should I avoid patenting?
  - If no commercial value then probably not worth it
  - You don't think you'll ever practice the invention
  - Don't think a competitor will ever practice the invention
  - Does not make economic sense
- When do I file a patent application?
  - The US and most of the rest of the world are on first-to-file system so file sooner rather than later
  - File provisionals and update them for inventions that are not fully baked





# Freedom-to-Operate (FTO)

- Identify key features in your device and conduct FTO searches on those features
- Be able to distinguish your commercial product/process from third party patent claims
- Can only really conduct a formal FTO analysis when the product design is frozen
  - FTO analysis on a changing design is like trying to hit a moving target
  - Can conduct preliminary FTO analyses

# IP Due Diligence

- When is diligence conducted – e.g. during fund raising or an exit event such as M&A or IPO
- Create a credible story to address your IP
- Risk management for investors





# IP Due Diligence

- How do you prepare for IP due diligence?
  - Ask the opposing party for their list of questions
  - Make sure you have a master IP list and be ready to discuss key patents
  - Use a data room to upload documents
  - Ensure assignments/licenses are up to date
  - Know the prior art and be ready to address patentability and FTO
  - Be ready to address any other issues, e.g. disgruntled ex-employees, cease and desist letters, litigation, etc.

# Portfolio Maintenance & Cost Control

- Periodic reviews of your portfolio will allow you to get rid of IP with low value and save cost as well as identifying where holes are to fill
- Cost considerations – patents are expensive. Prioritize inventions and only file patent applications on the priority inventions.
- Consider foreign protection where you file and validate. Review annuities. Don't be afraid to drop cases.





# Portfolio Management

- Maximize life of patents
  - Take advantage of PTA
  - Take advantage of PTE under Hatch-Waxman for certain drugs and medical devices



# Patent Valuation

- Generally 3 models for valuation
  - Comps (hard to find)
  - Equivalent R&D cost to develop the technology
  - Discounted cash flow method based on future revenue from the invention



# Best Practices – Medical & Mechanical Devices

- Describe your device in a patent application with lots of details including all the components, how they are connected, how they move, their spatial relationship, and their function
- Try to pursue medical method claims in the US and other jurisdictions that permit such claims
- Take advantage of Hatch-Waxman PTE extensions
- File provisional applications if your designs are not frozen
- Choose international jurisdictions carefully
- Obtain employee and consulting agreements with IP assignment clauses
- Be well prepared for IP due diligence during fund raising/M&A



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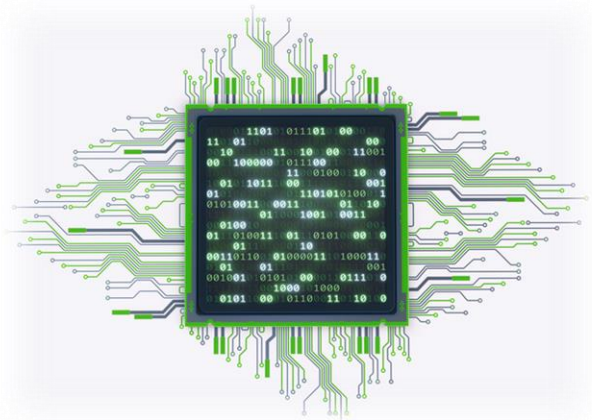
## Best Practices – Chem/Biotech



- Provide detailed examples, including comparative examples to conventional compositions when possible
- Include data supporting unexpected or surprising results, illustrating the advantages of your invention
- Discuss additional embodiments or potential substitute components
- Use quantitative descriptors with nested ranges
- Have your composition and/or product claims cover your commercial products
- Option to add method of making or method of using claims

# Best Practices – EE/Software

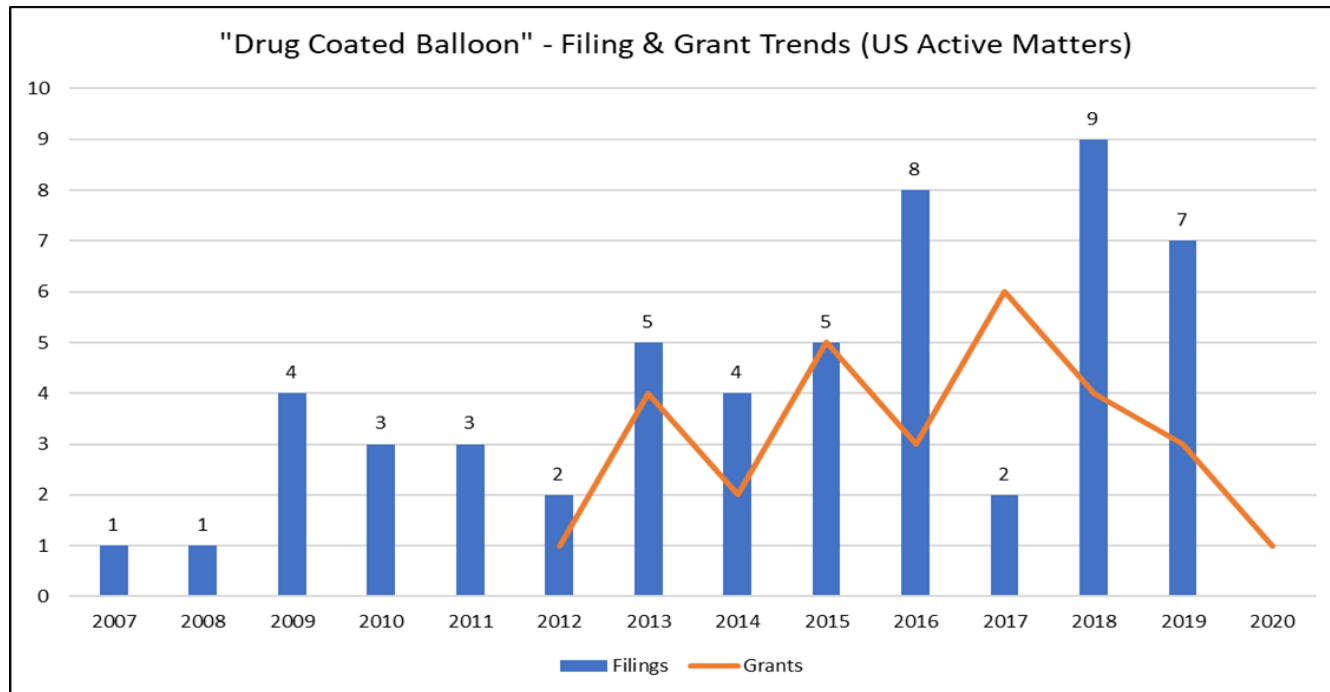
- File your provisionals/non-provisionals early
- Early harvesting sessions with the inventors
  - Mine for inventions ripe for patenting
  - Don't forget about design patents and trademarks
- Different types of claims to cover your invention
  - Servers vs. client devices vs. Methods/CRM
  - Same applies for Artificial intelligence and Machine Learning /Neural Networks inventions
- Alice 101 rejections
  - Draft software applications to be robust against being rejected as an abstract idea – non-patentable
  - Include practical applications and discuss improvements over prior art system
  - Use the USPTO Examples as guideline



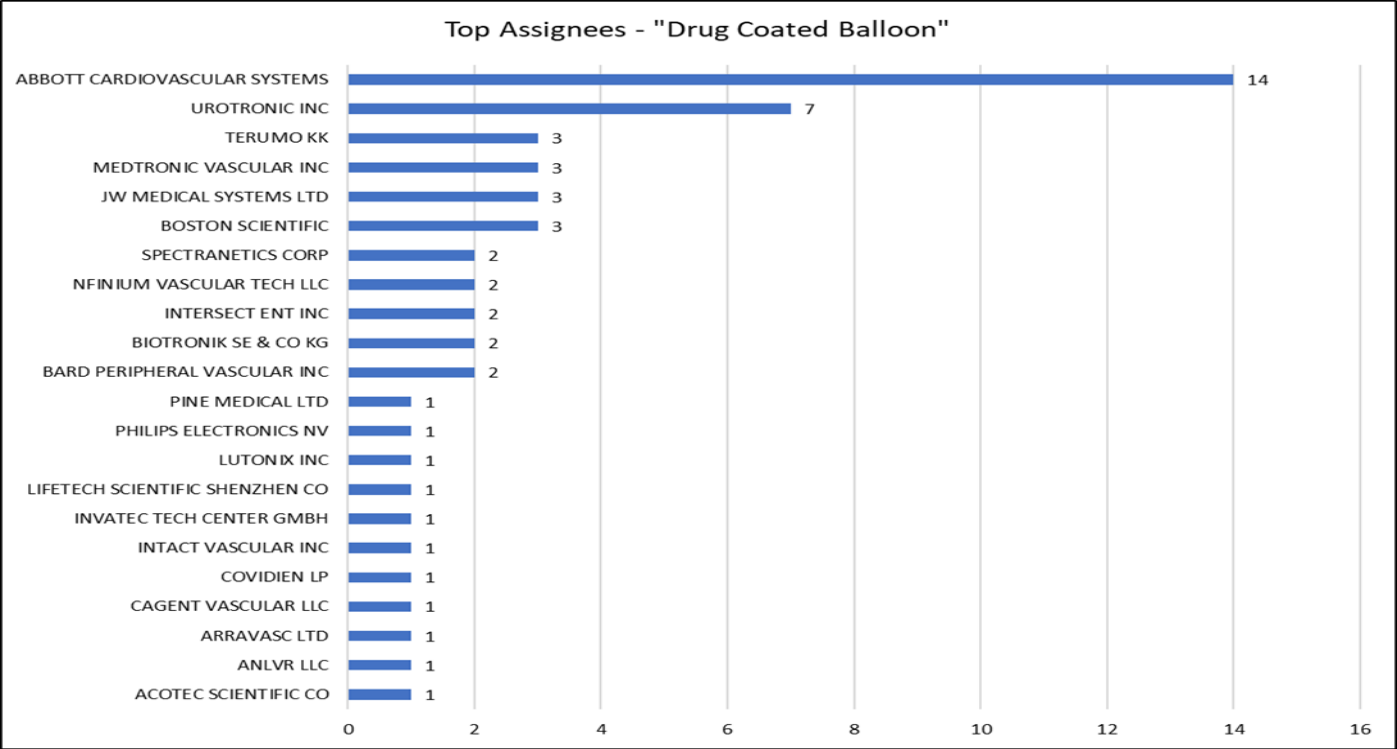


# Use Data Analytics: Drug Eluting Balloon Example

# "Drug Coated Balloon" Filing & Grant Trends



# Top Assignees “Drug Coated Balloon”





# Conclusions

- Patents are important to protect your invention as well as during fund raising or an exit
- Consider other forms of IP such as trademarks, trade secrets, and copyrights
- Create a comprehensive IP story that addresses patents, FTO, patentability, and ownership
- Monitor your portfolio to maximize value and manage cost





Thank you for your interest.

# Questions?

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