

SLW Institute Emerging Tech Webinar Series



Top 10 Things You Need to Know About Medical Device Patents



Today's Presenters...



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The background of the slide is a blurred image of a medical setting. It features a stethoscope resting on a surface, with an ECG (heart rate) line visible in the lower portion. The overall color scheme is a muted blue-grey.

Overview

SLW attorneys Ryan Connell and Doug Portnow will provide an overview of important intellectual property topics that executives and inventors should consider when developing medical device technology. Whether you are a solo entrepreneur, starting a company, or running an established corporation, you should be aware of issues such as IP ownership, freedom-to-operate, patentability, patent portfolio management and cost control. IP due diligence during fund raising will also be addressed, as well as models for valuing intellectual property.

Main Topics

1. **Types of IP**
2. **Requirements to obtain a patent**
3. **When should I file a patent application?**
4. **How do I get a patent?**
5. **Where do I need patent protection?**
6. **Medical method claims**
7. **Maximizing patent life**
8. **Ownership of patents**
9. **Freedom to operate**
10. **Everything else**

1. Different Types of Intellectual Property (IP)

Intellectual Property

Types of IP:

- Trademarks
- Copyrights
- Trade secrets
- Patents

Trademarks

Trademarks/service marks: a mark such as a word or symbol used to indicate the source of the goods or service

- Even includes a sound, smell, color, etc.



Copyrights

Copyrights: Protect original works of authorship for an expression fixed in a tangible medium

- 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 medical device 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 of time 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
- Protect various aspects of a device
 - Mechanical features
 - Material features

How to get a patent?

- File a patent application with an invention that is novel, non-obvious and enabled

2. Requirements for Obtaining a Patent

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

Make sure your claims cover your commercial product, a target competitor device, or a likely design around.

Map your claims to your commercial product

- Claims should cover the most important features

How Does the Patent Office Examine

A valid claim must:

- **Be subject matter eligible**
 - More of a concern for biotech and computer software applications
 - But medical device claims must not be construed to claim a human (e.g., must claim a device itself, not able to claim a bone to which the device is implemented)
- **Be novel**
 - The invention is new and has never been done
- **Be non-obvious**
 - Even if the invention is novel, the gap between the invention and the state of the art must not be so small that a person skilled in the art would consider the invention to be obvious
- **Be enabled/adequately described**
 - Your patent application must describe the invention in such terms that a person of ordinary skill would understand:
 - That you indeed possess the claimed invention; and
 - how to make and use the claimed invention

3. When Should I File a Patent Application?

Timing

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
- Note that you do not have to actually make or use your medical device before filing a patent. You need only be able to *constructively* reduce your product to practice, meaning that you can describe the invention in such detail that it is enabled and one of ordinary skill would understand that you possess the invention

4. How Do I Obtain a Patent?

Patent Process

- File US non-provisional patent application
 - Can file directly or one year after filing US provisional patent application or 30 months after filing PCT patent application
- Typically about 18-24 months until an Examiner picks up the case
- Claims are almost always rejected at first
- Negotiate with the Examiner through a series of amendments to the claims
- Potential to appeal Examiner's decisions
- Ultimately, either the patent application is abandoned or receives a Notice of Allowance
- Consider filing continuation applications after receiving a Notice of Allowance but before the patent issues

5. Where Should I File Patent Applications?

Global Considerations

- Where to file first?
 - Just because you are a US company does not mean that you must file in the US first
 - In most cases you can file outside of the US first, just make sure to have obtained a foreign filing license
 - In some cases, you may be required to file in a foreign jurisdiction first, depending on the citizenship of the inventor(s) or the location where the invention occurred.
- Where do you expect sales to occur?
- Where do you expect manufacturing to occur?
- Where are your main or potential competitors located?
- Common jurisdiction for medical device patents tend to include US, EP, CN, AU, and CA. EP validation is typically in UK, FR, and DE.

6. Medical Method Claims: Are They Worth Pursuing?

Medical Method Claims

Common misunderstandings

- Medical methods are not worth pursuing
- You cannot enforce medical method claims
- Why would you sue your customer (the doctor)?

What is a medical method claim?

- A medical method claim is a claim directed to what actions the doctor performs during a procedure

Facts

- Medical methods are generally not patentable except in the US and Australia
- Claim scope may actually be broader than a device claim
- True that you cannot sue a doctor for infringing a medical method patent, but a patent allows you to sue a competitor for inducing or contributing to infringement
- Medical method claims are another tool that will help you protect your invention

7. How Do I Maximize the Life of My Patent?

Patent Life

Standard patent term

- Patent is generally good for 20 years from non-provisional priority date

Extending patent term

- Automatic patent term adjustments (PTA) for USPTO delays
- Patent term extensions (PTE) of up to 5 years under Hatch-Waxman for PMA products
- File new patent applications on improvements
- Sometimes argue against double patenting rejections during prosecution and do not automatically file a Terminal Disclaimer

8. Who Owns my Patent?

Ownership & Assignment

Why is this important

- Without ownership or licensed rights to IP, opens you up to liability for infringement
- If fund raising or going through an exit, investors/strategics want to avoid risk

What should I do?

- Inventors should assign IP rights to the company
- Assignments should be recorded promptly with the patent office
 - Inventors changes jobs and can be hard to track down
 - Prompt recordation can prevent a second assignment from beating your assignment
- Assignments should include language about ownership of other patent family members
- Audit assignments to make sure no typos, misspellings
- Backup – obtain employment and consulting agreements with IP assignment clause

9. Freedom to Operate (FTO)

Freedom to Operate

What is FTO?

- Verifying that your product does not infringe a patent owned by a third party
- Sometimes also referred to as product clearance

What should I do?

- 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

10. Other Important Items

IP Due Diligence

What is IP due diligence?

- A risk assessment of your IP portfolio and third party patents
- Typically performed during fund raising, exit via M&A, IPO, licensing or acquisition of IP
- Goal is to create a credible story to address your IP position

Preparation is key

- Have a master schedule of all your IP
- Ask the other side for their list of questions
- Demonstrate ownership of all IP
- Explain the commercial value of your patent claims
- Know the most relevant prior art and be ready to address patentability and FTO
- Be candid about other potential issues – e.g. disgruntled former employees, cease & desists, litigation, etc.

IP Portfolio Management

Periodic reviews of your portfolio

- Review the portfolio and trim fat in order to reduce costs and to identify holes to fill

Prioritize

- Prioritize inventions to manage patent budgets
- Carefully consider foreign protection
 - Countries in which to file
 - European validation countries
 - US maintenance fees and foreign annuities

Patent Valuation

Three methods of valuation

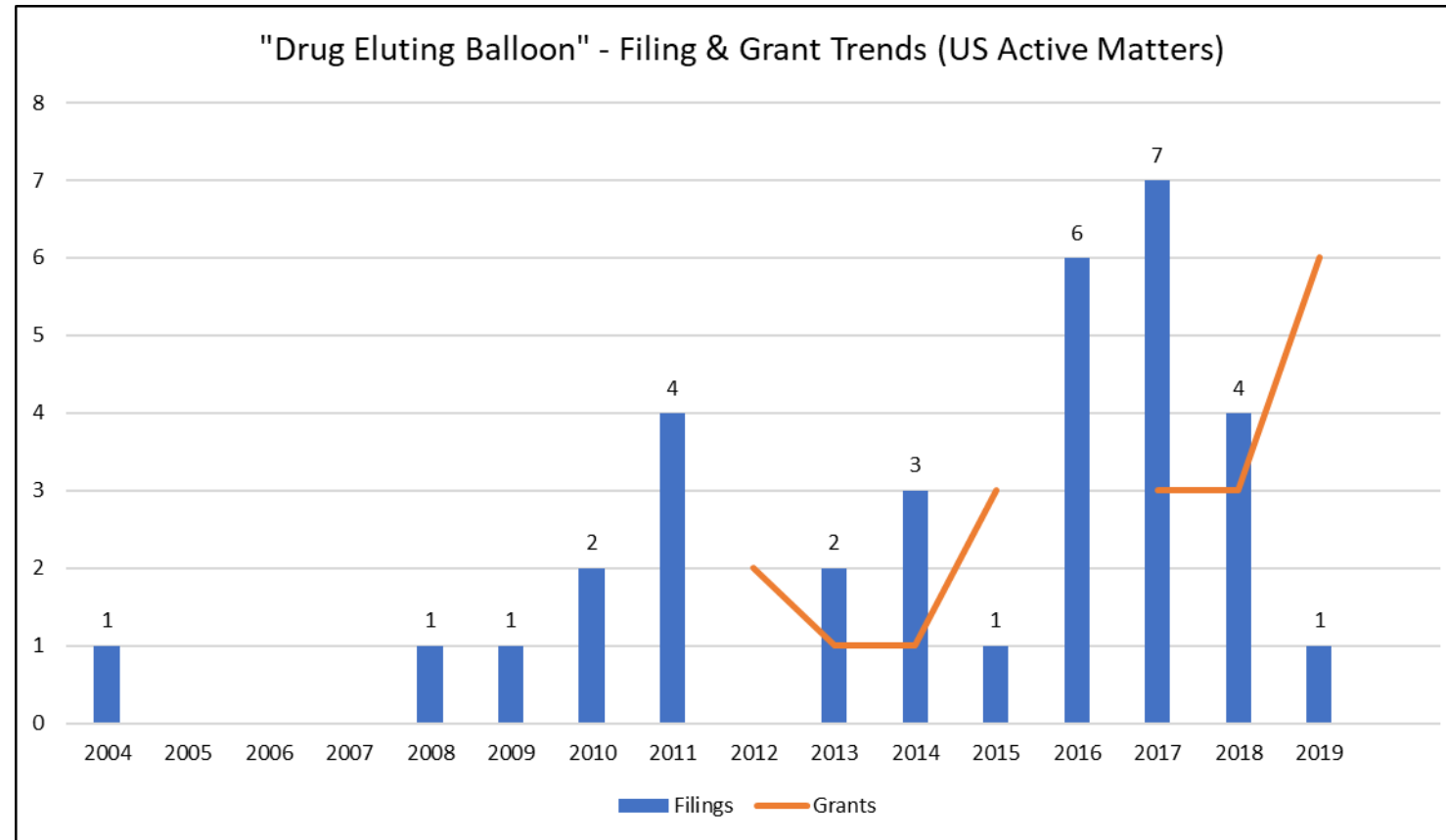
- Comps
 - Like using comps to sell a house
 - Hard to find data
 - Assumes the market is rational
- Equivalent R&D cost to develop technology
 - Educated guess?
- Discounted cash flow method based on future revenue from sales of the invention
 - Semi-educated guess?

Use Data Analytics:

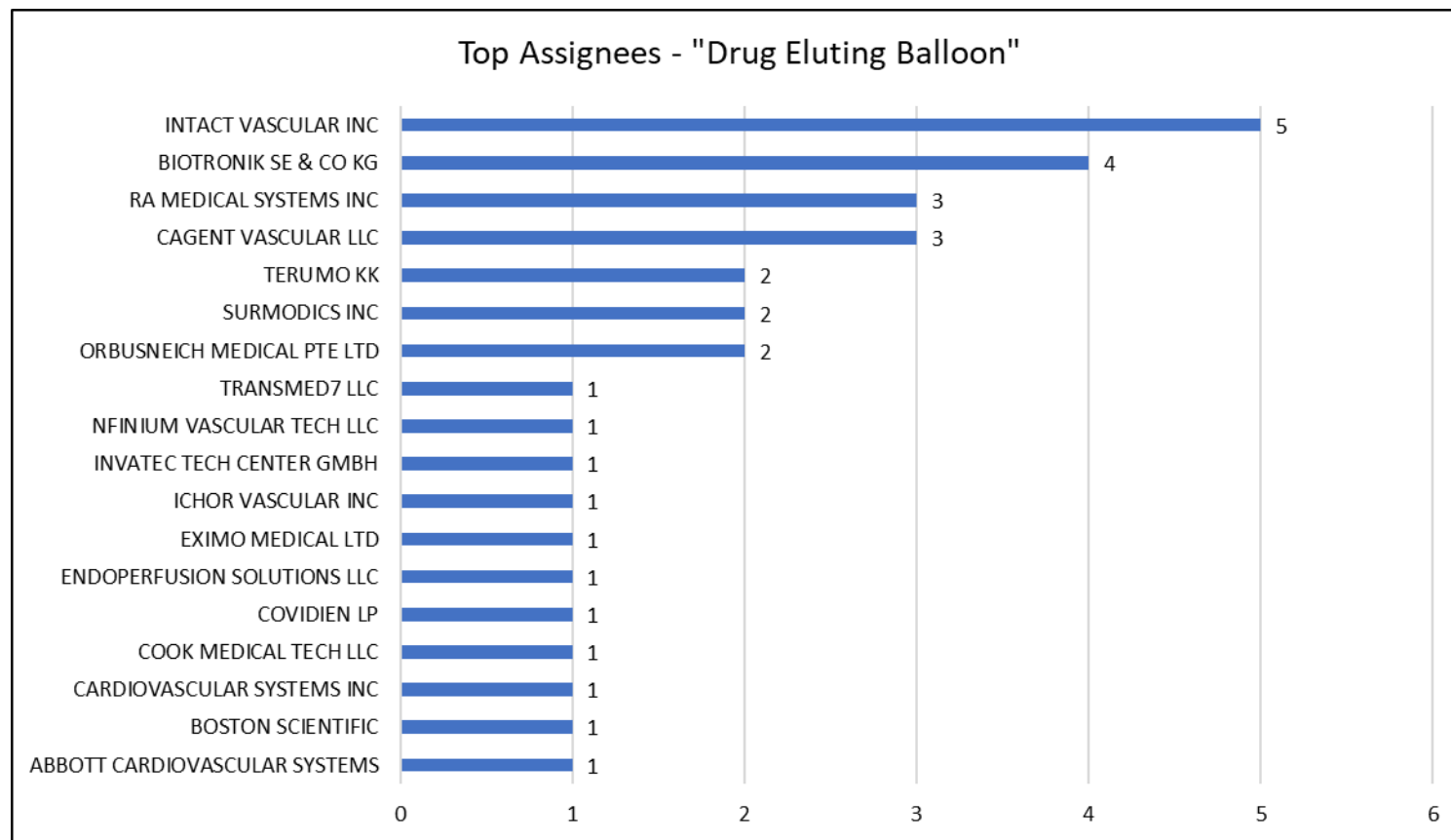
Drug Eluting Balloon Example



“Drug Eluting Balloon” Filing and Grant Trends



Top Assignees: “Drug Eluting Balloon”





Conclusions

Things to consider

- 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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