

Patent Law Update for Medical Device Companies 2018

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Medical Device Patents and IPR Proceedings

- What is an IPR?
- Latest trends in IPR filings
- Important changes in IPR proceedings

Background on IPR proceedings

- IPR stands for *Inter Partes Review*
- The procedure was initiated on September 16, 2012 upon the signing of the America Invents Act (AIA)



IPR Stages

- **Initial Petition** – “reasonable likelihood” of proving patent is invalid
- **Three judge panels** of administrative law judges in the Patent Office (Patent Trial and Appeal Board – PTAB)
- Within 6 months, PTAB reviews petition and decides whether to proceed
- Parties hire **expert witnesses** and conduct **discovery**
- **Trial ending with oral hearing**, followed by **written ruling** within 1 year
- **It's expensive**: typical cost for full proceeding is several hundred thousand dollars, but usually much cheaper than litigation in court

IPR Trends Over Time

- Patent Trial and Appeal Board at Patent Office demonstrated early that it would be **aggressive** in invalidating patents



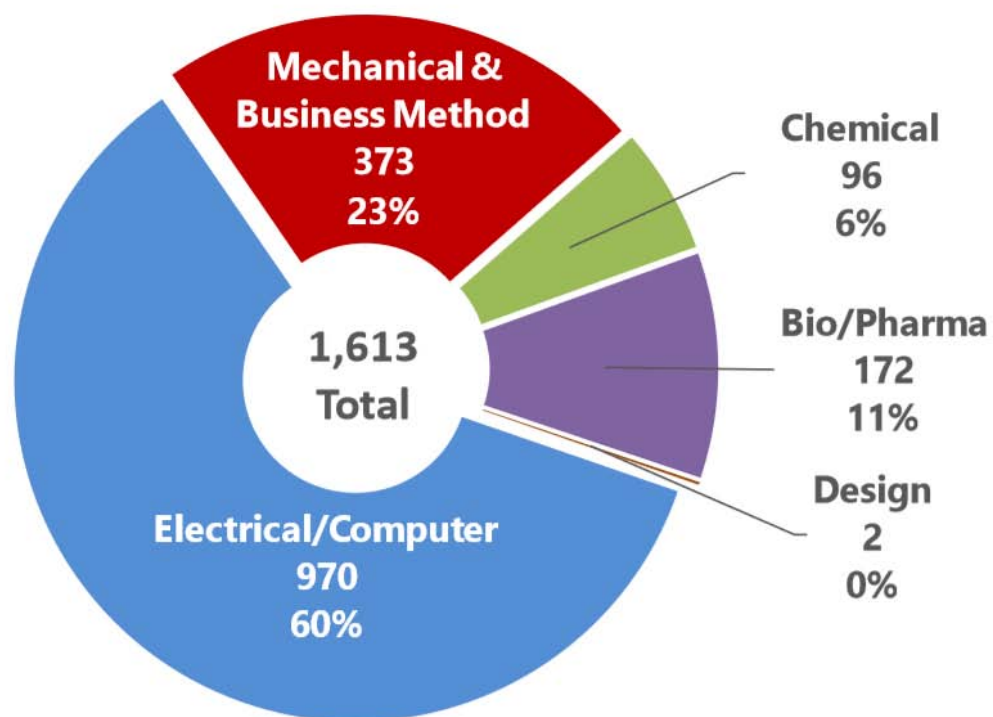
- Initial concerns of Chief Judge of U.S. Court of Appeals:
“**acting as death squads**”
in “**killing intellectual property rights**”



Supreme Court confirmed constitutionality of IPRs

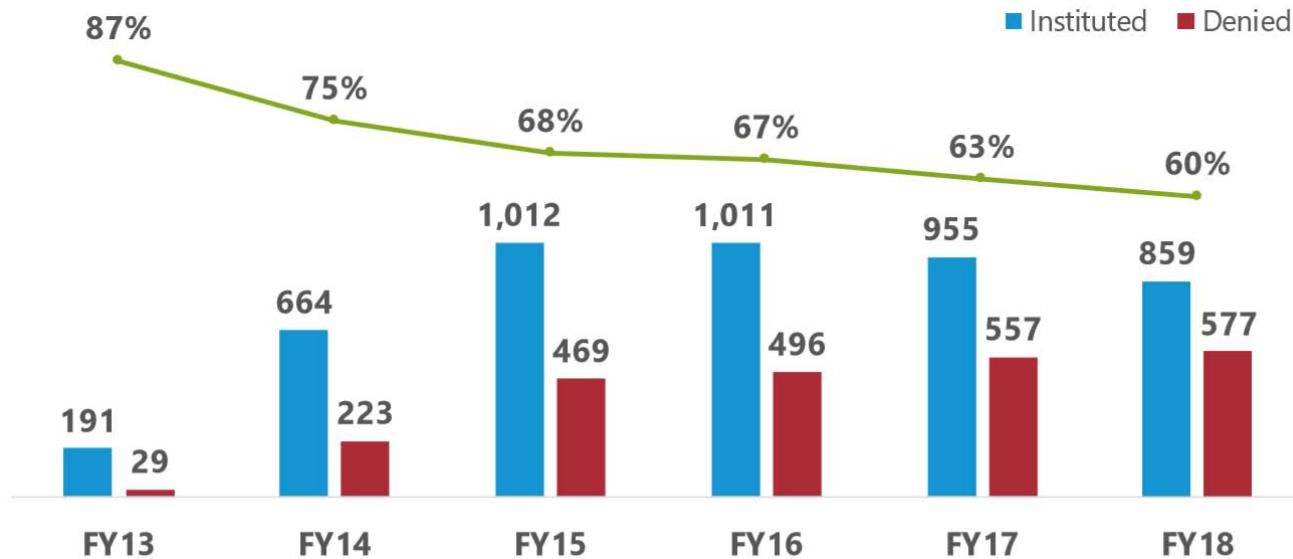
- Last year, we reported that IPR proceedings were challenged as **unconstitutional** in ***Oil States Energy Services v Greene's Energy Group***
- **Summary of argument**: patents are a private right that cannot be taken away without a jury trial
- In April 2018, the Supreme Court affirmed the constitutionality of IPR's
- Dissent by Justice Gorsuch, joined by Chief Justice Roberts

Who is filing IPR's?



Early and current statistics on IPRs in all technology areas

- Initially: fiscal year **2013** had **87%** trial institution rate
- Current trend: **2018** had **60%** trial institution rate
- In most cases, it's about **winning the petition at the beginning** because, after institution, PTAB has **invalidated** some or all claims in **80%** of trials



New Director of the Patent and Trademark Office

- Andre Iancu was appointed by President Trump in February 2018
- Former patent litigator, believer in strong patent rights



Current Patent Office Trends Impacting IPR's

- Institution rate is **decreasing** and invalidation rate is **decreasing** (gradually)
- Patent **claim amendments** will be allowed more frequently
- Patent claims will be **interpreted more narrowly**, consist with court proceedings, resulting in **less claims being invalidated** in IPR's

Patent Litigation Update – Irfan Lateef

Not Everything is Patentable

- 35 U.S.C. § 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”
- *Mayo* and *Alice* Supreme Court decisions:
 - Laws of nature, natural phenomena, and abstract ideas are not patent eligible
- Two Step Test for Eligibility
 1. Are the claims directed to an abstract idea?
 2. Do the claims’ elements, considered individually and as a combination, recite an inventive concept sufficient to transform the claimed abstract idea into a patent-eligible application?

Medical Device Claim Types

- 1. Robots/Control/Sensor Improvements
- 2. Medical Imaging (MRI, CT, etc.)
- 3. Structured User Interface
- 4. Biochem (lab on a chip, test strip, etc.)
- 5. Determination of a Parameter
- 6. Information Management (EMR, cloud storage, telemedicine)

§ 101

Travel Advisory Levels

1	Exercise normal precautions
2	Exercise increased caution
3	Reconsider travel
4	Do not travel

Abstract ideas

- Collecting and analyzing data – *Electrical Power Grid*
- Internet filtering – maybe (*Bascom*)
- Encoding and decoding image data (*Recognicorp*)
- Voter verification and tabulation (*Voter Verified*)

Exergen v. Kaz



The Invention

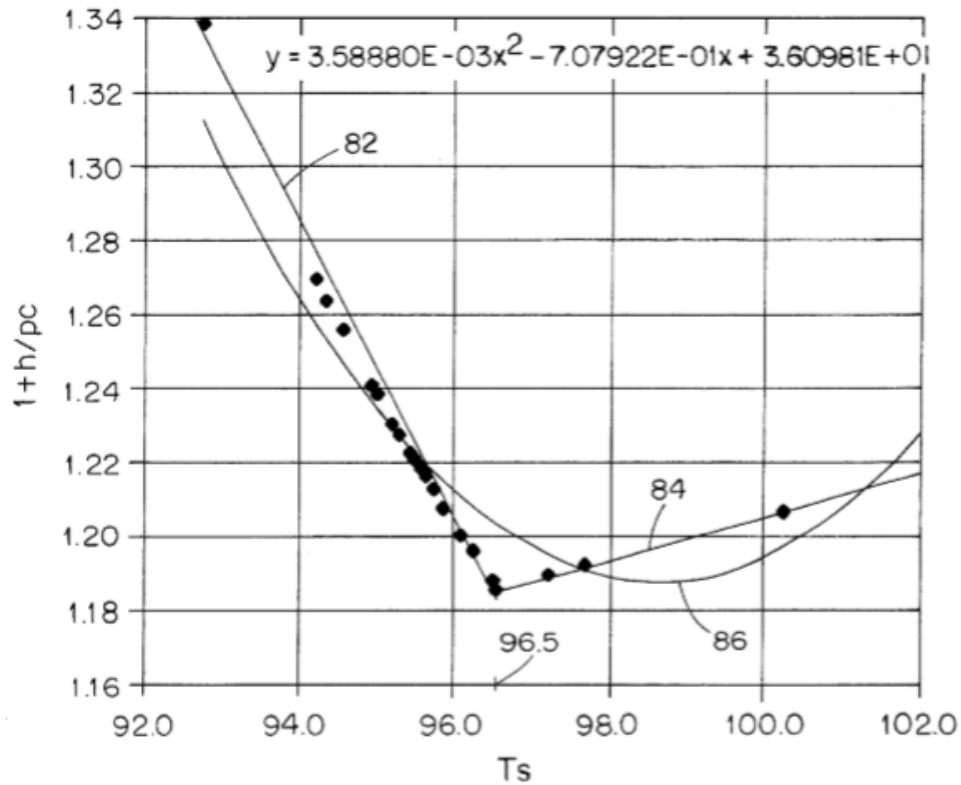


FIG. 5

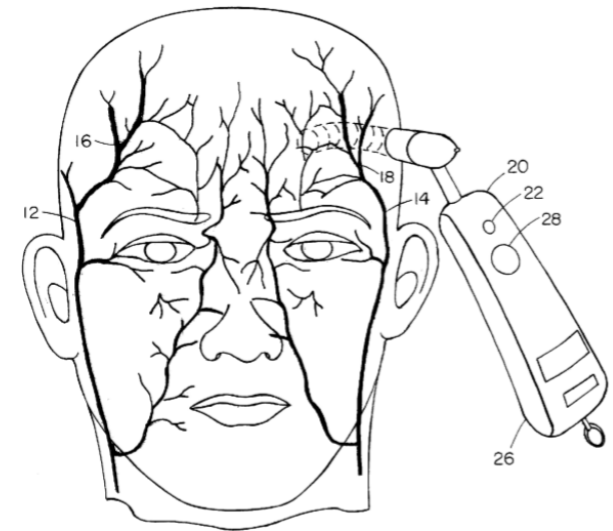


FIG. I

Exergen

- 48. A body temperature detector comprising:
 - a radiation detector; and
 - electronics that measure radiation from at least three readings per second of the radiation detector as a target skin surface over an artery is viewed, the artery having a relatively constant blood flow, and that process the measured radiation to provide a body temperature approximation, distinct from skin surface temperature, based on detected radiation.

Decision?

- Step 1: directed to natural law
 - Measuring body temperature
- Step 2: significantly more?
 - “[S]tep two dispute in this case turns entirely on whether the combination of elements was well-understood, routine, and conventional at the time of the invention.”

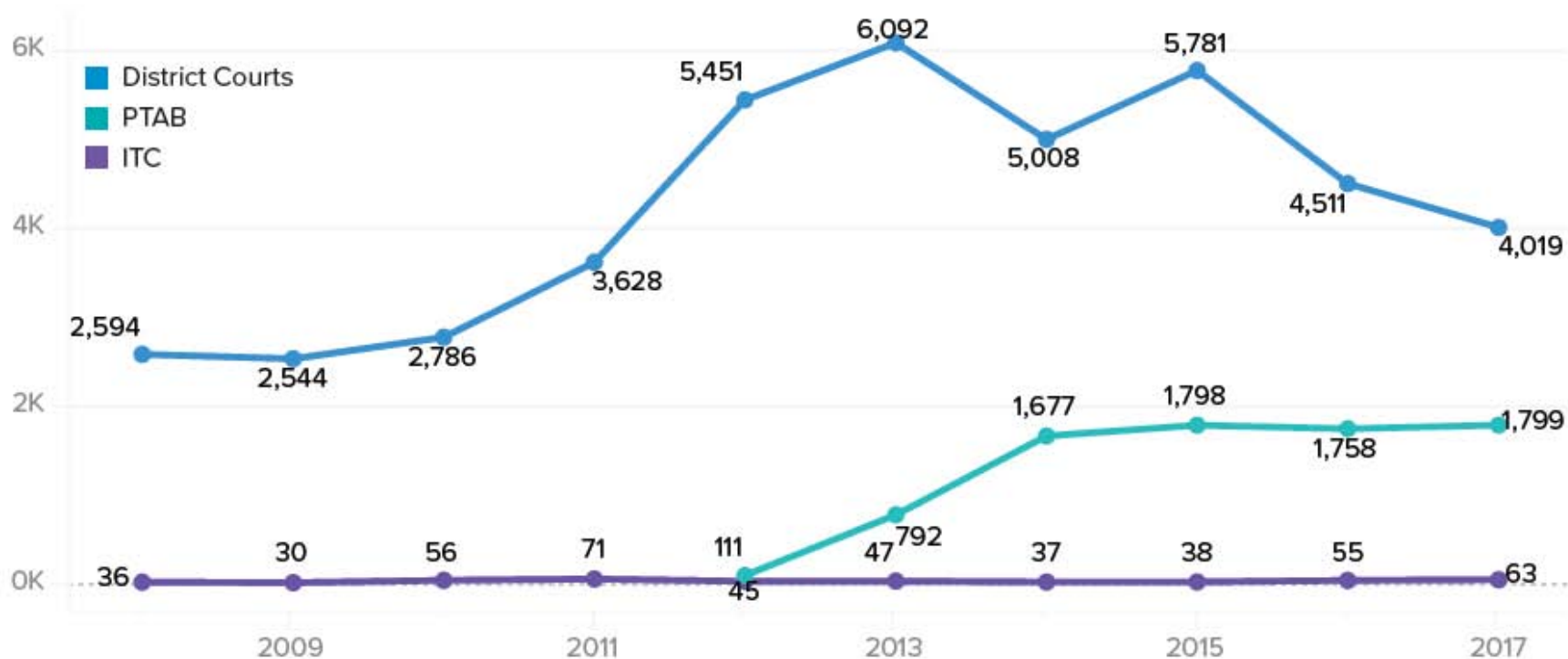
Not “Conventional, Routine, and Well-Understood”

- The district court’s conclusion that these claim elements were not well-understood, routine, and conventional is a question of fact to which we must give clear error deference.
- “Following **years** and **millions of dollars** of testing and development, the inventor determined for the first time the **coefficient** representing the relationship between temporal-arterial temperature and core body temperature and incorporated that discovery into an unconventional method of temperature measurement.”

Dissent

- The novel feature is identification through empirical testing of the coefficient that governs the relationship between core temperature and the temperature of skin above the temporal artery.
- Even under a deferential standard of review, the district court clearly erred by finding that the claims embody an inventive concept.
- Absent the patent-ineligible law of nature, the claimed invention consists entirely of elements already combined by the prior art.

Decreased District Court Litigation due to IPRs

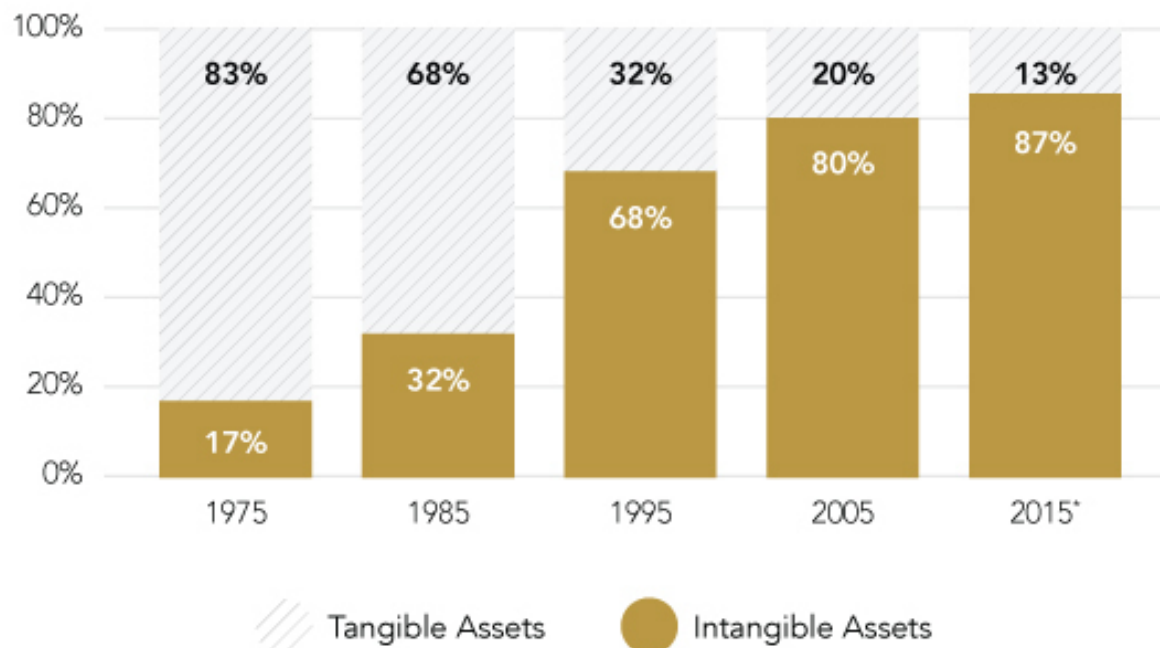


Source: Docket Navigator

Intellectual Property Drives Med Tech – Curtis Huffmire

Increasingly, Businesses Value Intangible Assets

COMPONENTS *of* S&P 500 MARKET VALUE



SOURCE: OCEAN TOMO, LLC

Categories of Intangible Assets

IP Valuation

IP depends on other assets and resources in order to generate economic benefits



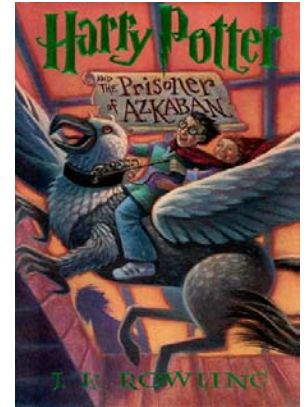
Protecting Med Tech IP

- **Intellectual Property plays a more significant role in valuations and acquisitions of medical device & biotech companies**
 - Non-obvious nature of technical solutions to physiological problems
 - Complexity of the data & its interpretation
 - Novel manufacturing methods
 - Novel materials
- **Focus on all areas of IP protection**
 - Protect ideas developed at your business – **Copyrights & Patents**
 - Protect good-will generated by your business – **Trademarks**
 - Protect trade secrets generated by “sweat equity” – **Trade Secrets**
 - Create barriers of entry to competition – important to attract VC funding
 - Provide legal rights that have value that can be monetized

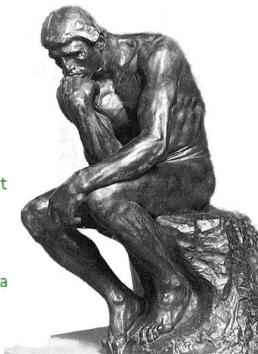


Copyrights

- **Protects your content**
- Provided to authors of “original works of authorship” fixed in a tangible medium of expression
- Exclusive right to a work of expression, such as a written story, a photograph, or a computer program
- Not for things that are functional (that’s utility patents)
- Protection lasts for a very long time
 - 70 years after death; 95+ years for corporate author



```
/**  
 * Simple HelloButton() method.  
 * @version 1.0  
 * @author john doe <doe.j@example.com>  
 */  
HelloButton()  
{  
    JButton hello = new JButton( "Hello, wor  
hello.addActionListener( new HelloBtnList  
  
    // use the JFrame type until support for t  
    // new component is finished  
    JFrame frame = new JFrame( "Hello Button"  
Container pane = frame.getContentPane();  
pane.add( hello );  
frame.pack();  
frame.show();           // display the fra  
}
```



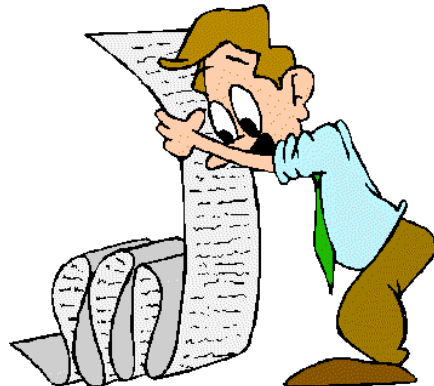
Trademarks

- **Protects your brand**
- Identifies the source of goods and services – Tool for Marketing
- Words, logos, colors, sounds, and more
- Protects consumer from counterfeit goods
- Lasts as long as you continue using it
- Standard of infringement: “consumer confusion”



Trade Secrets

- **Protects your secrets:** Any formula, pattern, device, or compilation of information which has value as used in one's business and gives a competitive advantage
 - Secret formula, internal manufacturing processes, customer lists, internal company know-how (both what does/doesn't work)
- Immediately protectable, uniqueness is not important
- Prohibits misappropriation (stealing) of the trade secret
- Does not prevent reverse engineering or independent creation
- When secrecy is lost, rights are lost

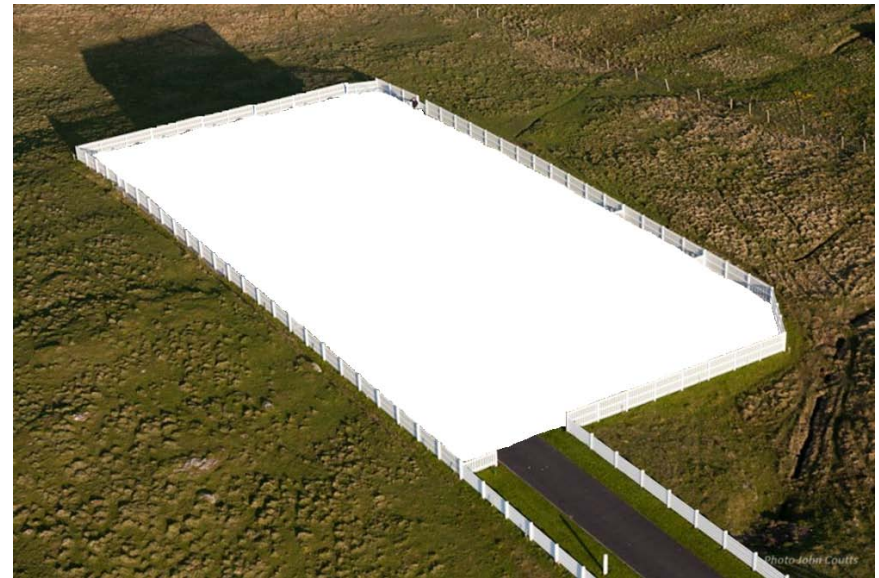


Patents

- **Protects your ideas** that are (1) novel, (2) useful, and (3) non-obvious processes, machines, manufactures, or compositions of matter
- Gives owner ***right to exclude others*** from practicing the patent (~20 yrs)
- Does NOT provide right to practice invention



Rights you may think a patent provides
(right to do whatever you want inside fence)



Rights a patent actually provides
(right to exclude others from trespassing)

Strategic Tips for Med Tech Patent Strategy

- **Patent strategy should include C-Level consideration**
- **Build strong patent portfolio** – Evaluate your own patents
 - Do claims target key clinical features?
 - Evaluate potential to design around?
 - Consider validity searching?
 - Difficulty of proving infringement?
 - Claims track revenue model? (disposables, kits, services)
- **Know your competition** – Evaluate third party patents
 - Are there patents that can block your technology?
 - What are your options to avoid infringement?
- **Make sure you own the IP** – Evaluate your agreements



Ten Strategies For Aggressively Building A Patent Portfolio

- **1. Educational seminars (online or in-person)**

- What can be patented
- How to document invention and submit for consideration
- Why patents are important to the company
- How not to deal with patents of others



- **2. Provide a simple idea submission form**

- Simple form that can be completed in 5 to 15 minutes
- Periodically email link with reminder message



Ten Strategies For Aggressively Building A Patent Portfolio

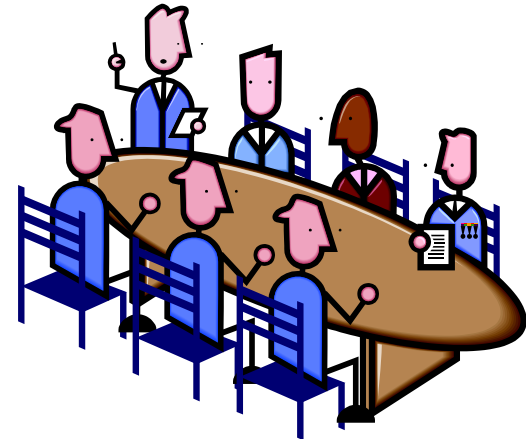
- **3. Implement a patent incentive program**
 - \$1000 to \$3000 per inventor upon filing (typical)
 - Additional award upon issuance (if still employed)
- **4. Conduct periodic “brainstorming sessions”**
 - 1-hour sessions with groups of 5 to 15
 - Not limited in scope to ideas currently being implemented
 - No idea is too basic to be considered
 - Conduct at least once per year



Ten Strategies For Aggressively Building A Patent Portfolio

- **5. Form a Patent Committee**

- Evaluate each identified invention based on various criteria
 - Will infringements be detectable?
 - Is invention important to company and competitors?
 - Will the technology become obsolete in a few years?
 - Likelihood of getting a patent?
- For each invention, decide whether to
 - file regular patent application
 - file provisional application
 - do nothing
 - create defensive publication (e.g., using IP.com)



Ten Strategies For Aggressively Building A Patent Portfolio

- **6. Conduct an IP audit**

- Review (or create) standard employee agreement, consulting agreement, and company NDA ***focused on IP ownership issues***
- Review (or create) internal procedures for making disclosures to, and entering into agreements with, other entities
- Review existing license and joint development agreements



- **7. Reassess pending patent applications**

- Compare claims to current activities of company and competitors; mine specification for unclaimed features

Ten Strategies For Aggressively Building A Patent Portfolio

- **8. Keep a continuation pending**
 - Enables patent owner to: 1) pursue additional claims, 2) eliminate infringement loopholes, 3) have newly discovered references considered, 4) eliminate problems caused by new case law
 - Puts company in much stronger position for licensing and litigation
- **9. Consider Track 1 – Prioritized Examination (PE)**
 - PTO goal of “final disposition” within 12 months; OA in ~2-3 mo.
Cost (PTO fee): \$4,000 for large entities, \$2,000 for small
- **10. Buy patents and applications**
 - Via patent auction, broker, or directly from patent owners

Thank you!

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