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TECHNOLOGY MARATHON

**IP Check-Up: Does Your MedTech Company Have a Healthy
Patent Portfolio?**

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Challenges

- Building strong, resilient MedTech patents and IP portfolios
- Maintaining (or extending) the useful lifetime of key patents and trade secrets
- Preventing invalidation of MedTech patents
- Ensuring that MedTech companies retain meaningful control over their valuable patented technologies
- Extracting the maximum value from MedTech patents

Overview

- Before Obtaining a Patent
- Maximizing Patent Coverage
- Potential Patent Challenges
- Maximizing Portfolio Value

Considerations Before and During Patent Prosecution



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Develop a Strategic Plan or Vision

- What are the relevant overall business objectives?
 - Narrow focus vs. multi-faceted goals
 - Stay current with business focuses
 - Tailor to types of clients
- What type of IP would be helpful in achieving those objectives?
- What would or could be done with a resulting patent?

Due Diligence Considerations

- Conduct patentability and/or landscape searches
- Impart understanding of the potential effect of third-party patents and ways to address them
 - Freedom-to-Operate analyses
 - Tools available to attack patents of others
 - Strategically acquiring IP generated by third parties

Application Preparation and Prosecution

- Inventor interviews:
 - Building a compelling backstory
 - History about the medical need for this technology
 - Inspirations for innovating and problems with the existing technology
 - Details about the advantages of the technology over available options on the market
 - Teasing out the details about how the technology is to be used
- Business side considerations:
 - Budgets and deadlines– provisional patent application?
 - FDA approval for the technology?
 - File a comprehensive application up front?

Good Prosecution “Hygiene”

- Candor and duty of disclosure – 37 CFR 1.56
 - IDS practice
 - Don’t hide unfavorable test results or clinical data
 - Be consistent with the information you submit to different government entities
 - Deal with art head-on
 - Pre-emptively raise art to “inoculate” the resulting patent
- Keep a healthy file history—avoid prosecution history estoppel
- Third-Party Preissuance Submissions

Healthy Patent Family Strategies

- Continuations and Divisionals – keep something pending
 - The value of your portfolio is significantly enhanced if it is still pending
 - This is helpful for infringement, licensing, and financial deals (i.e., bond offerings, acquisitions, etc.).
- Mine comprehensive specifications as business develops
 - Change is inevitable, but if you have a strong application, you can adapt with the market
- Patent “thickets”

Patent Term Adjustment Strategies

- Thorough analysis of prosecution timing upon allowance
- Sparing use of terminal disclaimers if possible
- Use of divisionals where appropriate
- To maximize, respond at strategic times during prosecution!

Considering Both Utility and Design— Medical Devices

- Protect design features of medical devices and accessories
 - Make sure your initial application includes all figures of your accessories
 - Incomplete or inaccurate figures can harm your future design patents
- Is there a disposable associated with your medical device?
 - Third parties will try to erode those sales quickly
 - Design patents can help protect the interface with your device and maintain your brand

Post-Grant Considerations



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Patent Term Extension

- Premarket government approval process?
- Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”)
- Selection of granted patent for use in PTE process: timing, scope of coverage
- Deadlines for applying

Treating “Unhealthy” Patents

- Continuation practice – “design arounds” and modifications of scope
- Re-issue for substantive errors in claims or disclosure
 - Not covering everything you’re entitled to
 - Covering too much – issues with the prior art?
 - Inaccuracies in disclosure or in priority claims?

Strategies for Late-Stage Patent Families

- Breadth of Patent Disclosure
 - Remaining scope to pursue in continuations/divisionals?
 - Cost-benefit analysis
- Has the technology moved on?

Preparation for Potential Patent Challenges



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How can we create the most resilient MedTech patent portfolios for withstanding invalidity challenges?

1. Claim scope preservation
 - a. Pre-emptively prepare for offensive and defensive legal challenges
2. Claim drafting strategies
 - a. Consider scope, type, and features
 - b. Prepare now for changes in the market and the legal landscape
3. Litigation Tactics

Claim Scope Preservation

- Prosecution with an eye toward litigation and invalidity challenges
- Avoidance of estoppel related to claim scope
 - Office action response tactics
 - Put only the strongest technical arguments on the record to avoid unnecessary characterizations of the art
 - Attack legal sufficiency of Examiner arguments
 - Judicious use of Examiner interviews
- Optimize your portfolio
 - Develop a relationship with the examiner
 - Discover the key distinguishing limitation and use to expand the scope of future claims

Claim Drafting Strategies

- Again, relates to prosecution strategies for litigation preparation
- Selection of claim types, scopes, and structures to pursue to avoid pitfalls of shift in legal landscape
 - 35 U.S.C. §101: patent subject matter eligibility considerations
 - 35 U.S.C. §112:
 - Enablement considerations
 - Written description considerations

Litigation Tactics

- Patent Trial and Appeal Board
 - Petitioner
 - Is the portfolio open
 - Will winning really achieve your goals
 - Is invalidity better paired with non-infringement, or better to address independently
 - Patent Owner
 - Is your portfolio open and can you live with dropping this patent
 - Can you file more patents quickly and still achieve your goals
 - Understand the difference between POPR and POR

Litigation Tactics

- District Court
 - Patent Owner
 - Is the portfolio open
 - Define your object before you file (market share, royalty, brand reputation, etc.)
 - Access case value early to harmonize case with expected outcome
 - Accused Infringer
 - Is your portfolio open and is this merely the first battle
 - There are often non-infringement and invalidity arguments, assess early where you want to have those fights (PTAB or District Court)
 - It's not always about the money. Are there other creative solutions?

Additional Considerations for Patent Control and Value Maximization



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Patent Marking– Consistent and Routine

- Enforcement/maintenance strategies for practiced patents
- Apparatus covered by MedTech patent(s)?

Patent Rights Transfer: Effective Licensing and Assignment Strategy

- Recognizing how to maximize value of portfolio
 - Ongoing royalties
 - Prune the portfolio
 - Focus efforts
- Evaluate based on business needs and goals
- Generate revenue

Third Party Involvement Considerations

- Research and development collaborations?
 - Ownership/transfer arrangements?
 - Craft detailed IP provisions in advance
 - Prepare for any mix of inventorship
 - Anticipate payment structures
 - Consider both licenses and assignment provisions
- Contracting/subcontracting agreements?

Government Involvement and Rights

- Fact-specific
- Prepare in advance for when, how, and if a government entity can lay claim to a particular patented MedTech invention to maximize your rights
 - Bayh-Dole Act and “march-in” rights
 - Government contracts and grants (SBIR, etc.)
 - 28 USC Section 1498

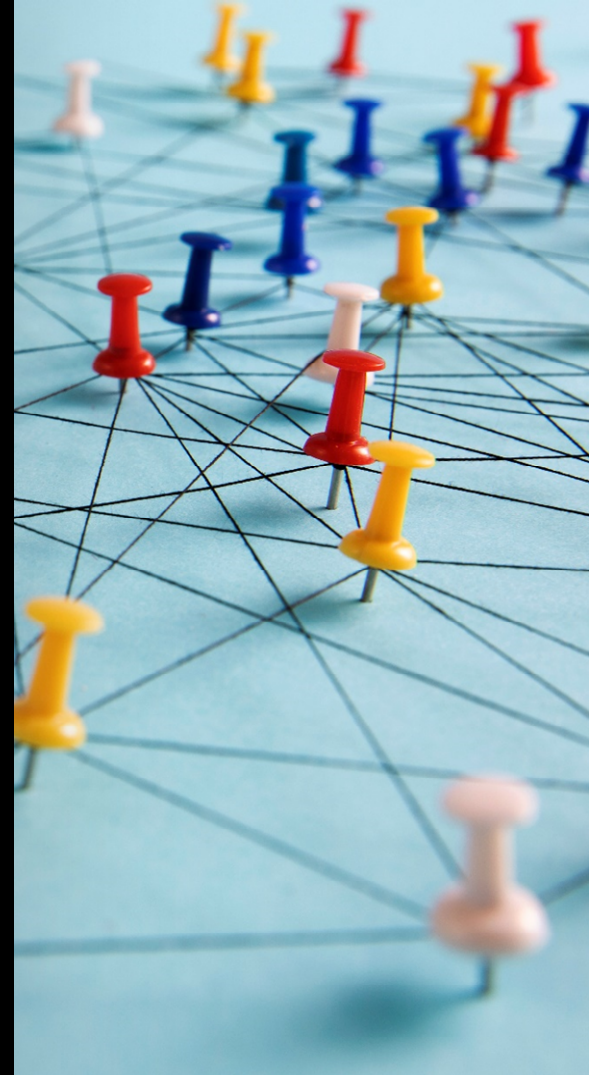
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Biography



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Scott D. Sherwin is a patent litigator with jury and bench trial experience in US District Courts, Inter Partes Review (IPR) experience before the US Patent and Trademark Office (USPTO), and appeal experience before the Federal Circuit. Scott counsels both established companies and startup ventures on intellectual property (IP) matters. He also actively works on pro bono immigration and nonprofit IP matters.

With an academic background in engineering, Scott has patent litigation experience with a variety of technologies, including professional tool systems (Li-ion batteries, power tools, and hand tools) and medical devices (orthopedics and heart monitors). He is a co-leader of the IP MedTech Working Group.

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Nathan S. Smith partners with clients to navigate the complex intersection of innovation, business, and the law. Nate builds teams to conduct IP due diligence on behalf of clients interested in acquiring, defending, or enforcing intellectual property and technology. He helps his clients develop and implement competitive market strategies, complete IP transactions and licensing, and oversee domestic and foreign patent prosecution for utility and design protection. Whether for startup or large-cap companies, from product conception to market release, Nate leverages various tools and strategies to efficiently build value and protect the interests of his clients.

Nathan has technical experience managing IP for a variety of technologies, with a focus on the life sciences and technology industries, and is a co-leader of the IP MedTech Working Group.

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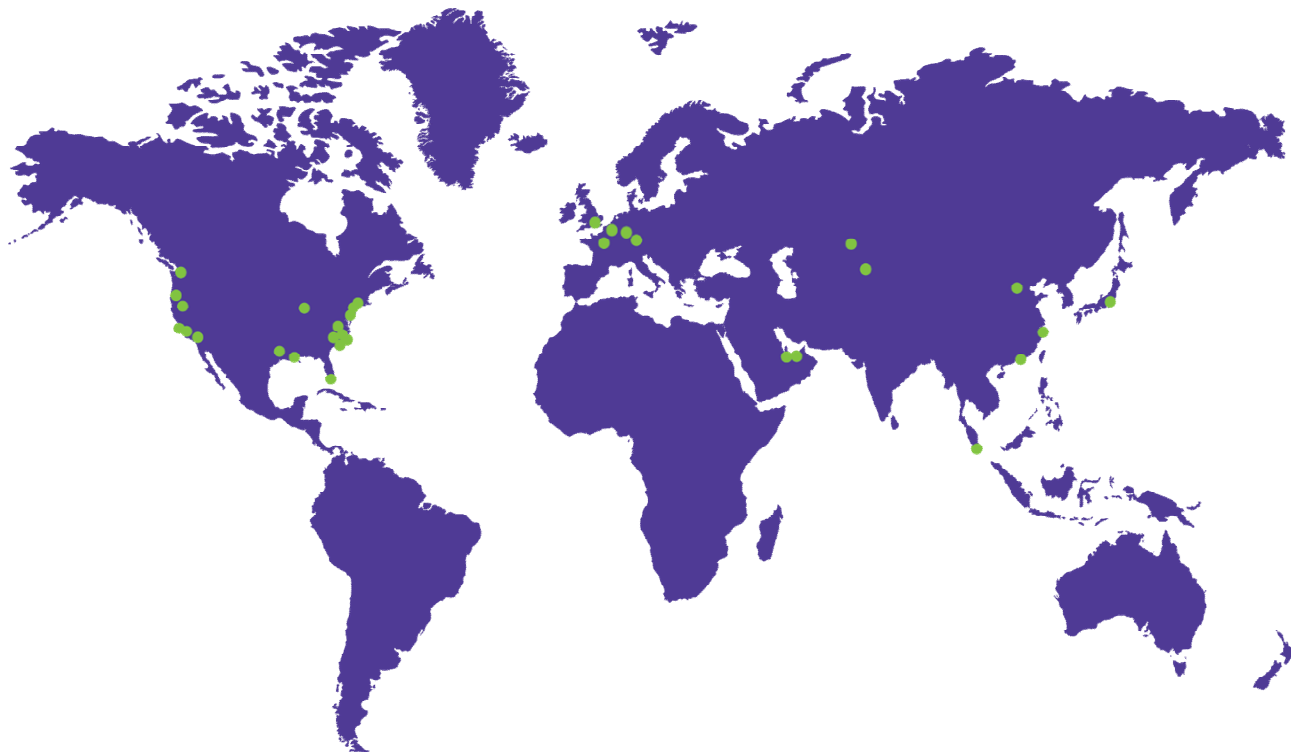
Alyssa R.M. Pugh is a registered patent attorney focusing her practice on intellectual property matters involving the life sciences, with an emphasis on patent prosecution strategies in the biopharma, biochemical, food science, industrial chemical, and medical device industries. With a background in genetics and developmental biology, her practice encompasses a wide variety of technical subject matter, including pharmaceutical formulations, therapeutic regimens, nutritional supplements, food chemistry, industrial chemistry, transgenic organisms, and recombinant DNA technology.

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