



## Knobbe Martens

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**CALIT2**  
**5th Annual International Symposium  
on Technology in Medical Devices**

### **Can Your Medical Device IP Portfolio Pass Muster?**

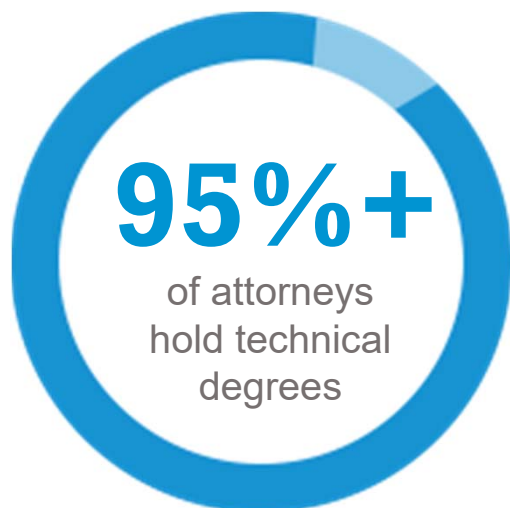
IP Due Diligence in the Medical Device World

Presented by:

Michael Guiliana  
Knobbe Martens  
February 4, 2019

## Firm Profile – By the Numbers

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### Global Practice



through large network of  
Foreign Associates



### Offices Nationwide

Orange County  
Los Angeles  
New York  
San Diego  
San Francisco  
Seattle  
Washington D.C.

**200** Highest number of registered  
patent attorneys in the US  
practicing across a **vast array** of industries

**250+** lawyers &  
scientists

# Medical Device Practice Group – 53 Medical Devices Specialists

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**MEDICAL DEVICE LAWSUIT ALERTS**

- Petition for Inter Partes Review by RTI Surgical, Inc. of LifeNet Health's U.S. Patent No. 9,585,986
- Petition for Inter Partes Review by RTI Surgical, Inc. of LifeNet Health's U.S. Patent No. 9,579,420
- Medline Industries, Inc. v. CR Bard, Inc. (Claim Construction)
- Petition for Inter Partes Review by Medtronic, Inc. et al. of Niazi Licensing Corporation's U.S. Patent No. 6,638,268 (Inter Partes Review Denied)
- Petitions for Inter Partes Review by Intuitive Surgical, Inc. of Ethicon LLC et al.'s U.S. Patent No. 8,479,969 (Inter Partes Reviews Instituted)

[View more lawsuit alerts »](#)

**RECENT MEDICAL DEVICE NEWS**

**BOSTON SCIENTIFIC EXERCISES OPTION TO ACQUIRE TRANSCATHETER ANNULOPLASTY RING DEVELOPER MILLIPEDE INC.**

**By Tom Cowan**

Global medical device company Boston Scientific has announced on December 27, 2018, that it exercised its option to acquire remaining shares of privately-held medical device company Millipede, Inc. upon its recent successful completion of a first-in-human clinical study. Boston Scientific previously announced on January 24, 2018, an agreement to make a \$90 million investment in Millipede. The current press release states the prior agreement included an option for Boston Scientific to "acquire [Millipede's] remaining shares for \$325M at closing, with a \$125M

## 104 Med Device/Biotechnology Deals in 4 years - \$9.2B

Client	Transaction	Technology
Relievent Medsystems, Inc.	\$36 Million	Neurological technology
Ablative Solutions	\$11.9 Million	Medical Device: Drug Resistance
Apama Medical Series C Financing	\$19.5 Million	Med Device: AF Catheter
OptiScan Biomedical	\$40 Million	Med Device: ICU Blood Chemistry Monitoring
Direct Flow Medical	\$27.1 Million	Medical Device: Heart
Apama Medical	\$20 Million	Med Devices, Technology
Intact Vascular, Inc. Series B financing round	\$46 Million	Med Device: Cardiovascular Implants
Solace Therapeutics	\$13 Million	Med Device: Stress Urinary Incontinence
AcuFocus Inc.	\$66 Million	Med Device: Vision Tech
Apama Medical Series C Financing	\$19.5 Million	Med Device: Ablation catheter
Action Potential Venture Capital investment in Saluda Medical	\$40 Million	Med Device
Kit Check Series C Funding	\$15 Million	Medical Services, Software
Sienna Biopharmaceuticals, Inc.	\$46 Million	Biopharmaceuticals: Skin
NightBalance BV Series B Funding	EUR 12.5 Million	Med Device: Sleep Apnea

Client	Transaction	Technology
Hittite Microwave Corp.	\$2 Billion	Semiconductors
EKOS Corporation acquired by BTG PLC	\$220 Million	Med Device: treatment of vascular thrombosis
IDEV Technologies acquired by Abbott Labs	\$310 Million	Med Device: endovascular and interventional
Trius Therapeutics	\$707 Million	Pharma: Antibiotic Drugs
Anokion	\$45 Million	Biotech: Autoimmune
Ellipse Technologies acquired by NuVasive, Inc.	\$380 Million + \$30 Million (2017)	Med Device
Rempex Pharmaceuticals	\$470 Million	Pharma
Obalon Therapeutics	\$75 Million	Medical Device: Weight Loss
iRhythm, Inc. IPO	\$107 Million	Med Device: Digital Healthcare for Cardiac
Ignyta, Inc.	\$107 Million	Pharma
Sienna Biopharmaceuticals, Inc.	\$65 Million	Biotech
Pulse Therapeutics	\$10 Million	Med Device: Stroke
Cala Health, Inc.	\$18 Million	Med Device: Tremor Wearable
CVRx, Inc.	\$113 Million	Med Device: Heart Failure
Alios BioPharma, Inc.	\$1.75 Billion	Biotech: Therapeutics for viral diseases
Sienna Biopharmaceuticals, Inc.	\$150 Million	Biotech

## Hypothetical

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- Hypothetical: Medical Device Startup **XCOM** Raising Funds
  - New Aortic Stent for treating Acute Aortic Occlusion
    - Butter-Eluting Stent - Patented!
      - Original DES patents now expired
      - Patent Search – no disclosures or suggestions for using butter as an eluted drug in a stent
      - 20 issued patents and 15 pending covering
        - ***Butter as an Aortic Therapy*** and
        - ***Butter Delivery Hardware***.
    - Will ***Disrupt YCOM's 80% market share*** for treating AAO with drug eluting stents
  - Seeking \$20M – 20% equity of \$100M valuation
  - No Sales
  - No FDA approval
  - Fully refined product design and mfg. process
- Where is YCOM's value?
  - Almost entirely in the IP
- How much will Investors Spend on Due Diligence?
  - 0.25% - \$50,000 Due Diligence for \$20M Investment

## Intellectual Property (IP) Due Diligence – Overview

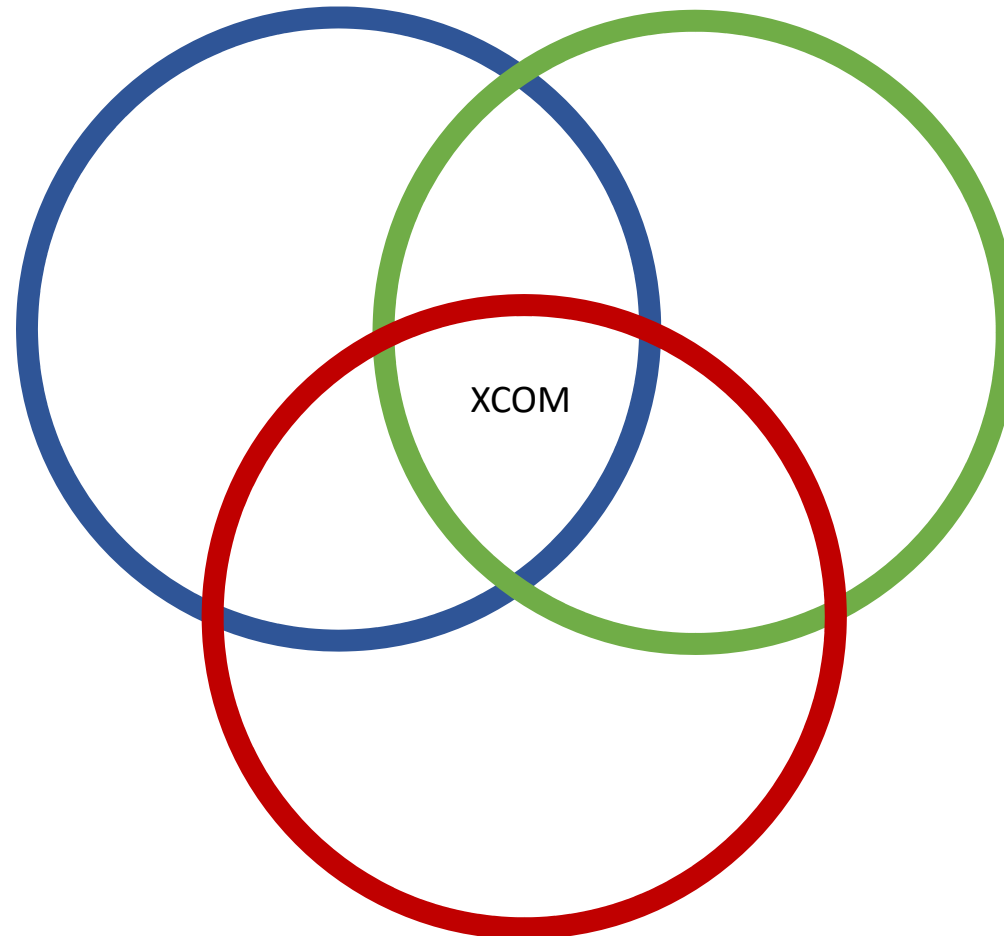
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- Why IP Due Diligence?
  - Validate Target Company’s IP Assets and Assess Potential Value
  - Identify Opportunities for New IP and Potential Capture of Innovation
  - Assess Third Party IP Risk and Identify Risk Mitigation Opportunities
  - Understand IP Marketplace - Major IP Holders and Impact of IP on Business
- What is IP Due Diligence?
  - Review and Analysis of Ownership
  - Review and Analysis of Patentability (Scope of Protection)
  - Review and Analysis of Risk from Third-Party Intellectual Property (Freedom to Operate)
- How to Begin IP Due Diligence
  - Information Required
  - Framework for IP Due Diligence Analysis

### 3 Areas of IP Due Diligence Focus: Ownership, Patentability, Freedom To Operate

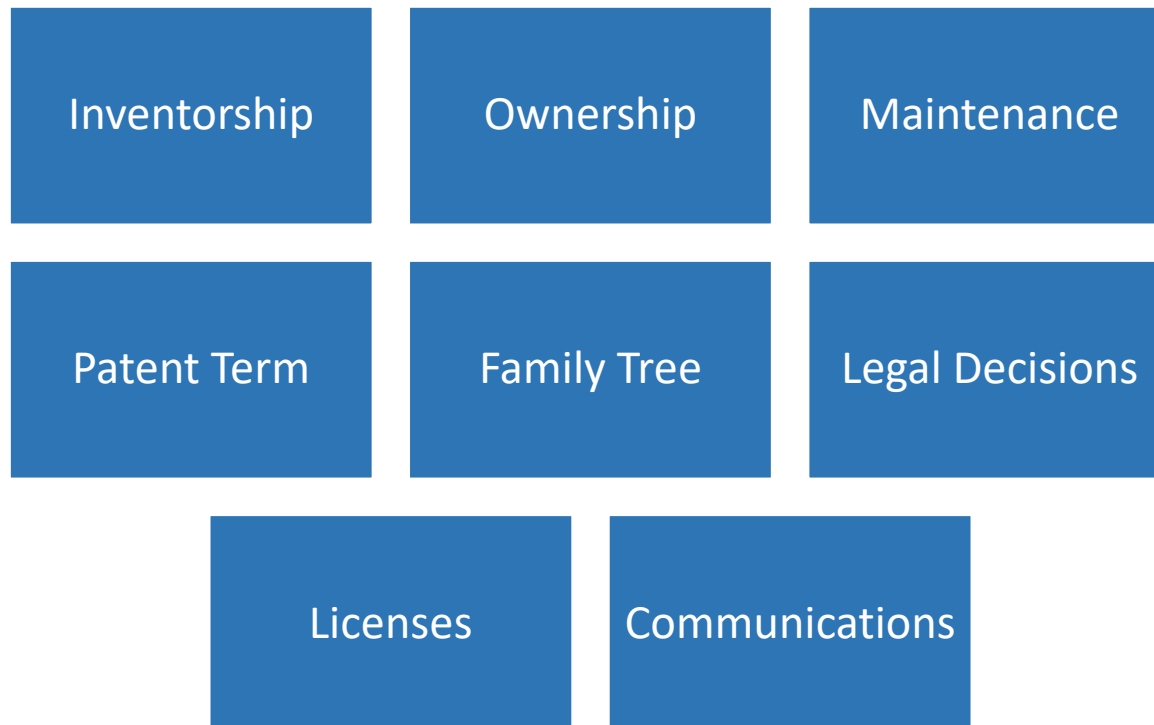
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58 - Point Inspection



## Ownership - Investigation and Analysis of Chain of Title and Enforceability

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## Review and Analysis of Ownership

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- Identify and Verify **Inventorship**:
  - Goal: Verify, for each patent in the family, the inventors listed on the patents. Correct any identified inventorship issues.
  - Suggested Action Steps:
    - Review **invention disclosure documentation** and listing of identified inventors. Conduct follow up as necessary.
    - Identify any potential issues related to **improper inventorship**, omitted inventors or violations of jurisdictional rules regarding inventorship (e.g., China, India).
- Identify and Verify **Source of Trade Secrets**
  - Goal: Identify any Trade Secrets necessary for practicing “invention”, verify no misappropriation.
  - Suggested Action Steps:
    - Investigate any claims of Trade Secrets – a critical decision
      - **Secret way of making Extended-Release Butter Concentrate?**
    - Identify differences between Patent Disclosures with actual products and methods.
    - Verify source of trade secrets and no misappropriation.

## Review and Analysis of Ownership (cont.)

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- Verify **Chain of Title** of Intellectual Property:
  - Goal: Clarify ownership of patents by target company.
  - Suggested Action Steps:
    - Confirm that assignments were properly prepared and executed. Assess scope grants of previous assignment to verify that past claims/damages are assignable.
    - Investigate and verify no chain of title issues. Verify recordation of assignments in USPTO database (for US patents).
      - Confirm assignment cover future filings (e.g., continuation applications, international applications, etc.).
    - Conduct UCC-1 lien search.
    - Determine whether there are any joint ownership issues with other companies. Correct any identified chain of title issues.
    - Search for all recorded or unrecorded licenses involving the patent.
    - Identify any potential issues related to violations of rules regarding **corporate transactions** (e.g., South Africa).
    - Review all relevant employment agreements for potential obligations to report/assign inventions
      - **Inventors previously employed by Butter Dairy? Or a DES Company e.g., Boston Scientific?**

## Review and Analysis of Ownership (cont.)

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- Confirm **Maintenance** of Issued Intellectual Property:
  - Goal: Confirm that patents remain in good standing based proper payment of maintenance fees or other required fees.
  - Suggested Action Steps:
    - Identify proper class of payment (e.g., large entity vs. small entity).
    - Determine whether proper maintenance fees were paid based on existing license fees. Correct any missed fees and improperly paid fees.
    - Identify any upcoming maintenance fee obligations. Ensure fees are paid during transition.
- Verify **Patent Term**
  - Goal: Determine and verify term for issued patent assets.
  - Suggested Action Steps:
    - Identify any potential issues with regard to filed Terminal Disclaimers. Correct as necessary.
    - Verify whether Patent Office made any errors with regard to PTA calculations.
- Develop/Verify **Patent Information**
  - Goal: Independently verify family tree identifying all patents, publications, and applications of the patent family. Generate Patent Family trees.
  - Suggested Action Steps:
    - List identifying all patents and publications.
    - Identify any priority claims (e.g., provisional applications). Correct if any issue identified.
    - Identify all submitted ideas and application in process and confirm intent to protect ideas.
      - **New Idea for Sintered Butter, application filed, in process, delayed, abandoned?**

## Review and Analysis of Ownership (cont.)

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- Identify Existing **Legal Decisions**
  - Goal: Identify any existing/past litigations/IPRs involving patents in the patent family that could impact value and enforcement.
  - Suggested Action Steps:
    - Identify all opinions, orders and communications regarding enforcement or Inventorship of the patents.
      - **Separate but related family of Dehydrated Butter for Astronauts**
        - **Court Ruled: Inventor was fraudulently omitted.**
- Review Potential for **Antitrust/Anti-competition Claims**
  - Goal: Confirm that no antitrust issues will arise as a result of our use of the patent in licensing negotiations. Antitrust issues may arise as a result of involvement/membership in standards setting bodies or agreements with other companies.
  - Suggested Action Steps:
    - Investigate all companies having ownership interest in patents as indicated by chain of title. Determination of participation in standards organizations.
    - Review of known attendance/submissions to working groups for applicable standards (if any).

## Review and Analysis of Ownership (cont.)

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- Review Existing **Licenses and License Obligations**:
  - Goal: Identify existing licenses between target company and other companies that may relate to the patent family.
  - Suggested Action Steps:
    - Identify and review any obligation that target company may have to license the patents including individual license agreements and industry/standards group terms.
    - Review and identify terms of licenses granted by target company.
- Review **Existing Communications** (Miscellaneous)
  - Goal: Identify any external communications/discussions related to any patent in the patent family. The communications can include licensing discussions, assertions, standards bodies claims, *etc.*
  - Suggested Action Steps:
    - Google search based on patent numbers, patent titles, assignees and inventors.
    - Determine if there are any issues concerning laches, estoppel, or res judicata. These could result from prior enforcements, communications with potential targets, prior litigations involving the patents, *etc.*
    - Conduct internal search for any correspondence originated by target company (or otherwise attributed to target company) regarding the patents or previous attempts to license the patent.
- Brings us to 32 items.

## Intellectual Property Due Diligence – Patentability / Scope of Protection

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Verify  
Representative  
Claims

Prosecution  
History Review

Specification  
Review

Claim  
Construction

Duty of  
Disclosure

Additional  
Prior Art

Claim Mapping

## Investigation and Analysis of Patentability

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- Verify Representative Patent/Claim(s) (**Patent Claim Scope**):
  - Goal: Verify mapping of representative patent and claim(s) for the patent family. Criteria for selection should be based on applicability to standards, ease of enforcement, and/or geographic scope.
  - Suggested Action Steps:
    - Prepare/Confirm that the mapping of the representative claim is accurate and detailed.
    - Verify that claim chart mapping is accurate and citations to relevant documents (if applicable).
- Prosecution History Review and Summaries (**Patent Office Filings**):
  - Goal: Identify claim amendments and statements during the prosecution history that could limit potential scope of claims.
  - Suggested Action Steps:
    - Prepare/obtain file history summary for each patent in the patent family.
    - Generate summary report (per patent) of relevant prosecution.
- Specification Review and Review Citations from Patent Specification (**Critical Patent Laws**):
  - Goal: Review and analysis of detailed description regarding support for each limitation of the representative claim(s). Prepare citation chart identifying the particular portion of specification.
  - Suggested Action Steps:
    - Identify issues of prosecution history estoppel, best mode analysis and the identification of potential 112 issues.
    - Also identify any locations in the file history that include arguments or amendments to each limitation of the representative claim(s)

## Investigation and Analysis of Patentability (cont.)

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- **Claim Construction**

- Goal: Identify potential claim terms that impact claim scope.
- Suggested Action Steps:
  - Identify potential claim terms that may have ambiguous meaning.
    - Can “Butter” also mean “Margarine” or “Almond Butter”?
  - Identify support from specification.
  - Identify potential external reference sources required.

- **Duty of Disclosure:** Citation of Known Prior Art Considered (Validity):

- Goal: Evaluate the potential for claims of inequitable conduct.
- Suggested Action Steps:
  - Confirm that: (1) all submitted prior art was considered by patent office (for U.S., verify Examiner initials in Form 1449); and (2) all prior art cited in related family patents/applications was properly submitted and considered in patent within family. Result should be a Prior Art Table identifying all prior art cited in each patent of the patent family.



## Investigation and Analysis of Patentability (cont.)

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- Search for Prior Art (**Validity**):
  - Goal: Identify prior art not considered by patent offices that could materially impact validity of claims, e.g., in light of alternative/broader constructions.
  - Suggested Action Steps:
    - Conduct internal search for all known prior art. Search may be limited according to confidentiality obligations of Target.
    - Search should consider publications, uses, disclosures, sales, offers for sale, and public knowledge.
      - Tahini used for Aortic Therapy?
    - Search will be based on representative claim(s).
    - Geographic scope should be considered.
- Claim Difference Mapping (**Patentably Distinct**):
  - Goal: Prepare claim difference mapping for patent family identifying the representative claim in the first column and each corresponding claim from patents in the family in subsequent columns.
  - Suggested Action Steps:
    - Identify any difference between the representative claim and the related claims of the other patents in the patent family.

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- Identify Existing **Legal Decisions re Claim Construction**

- Goal: Identify any existing/past litigations/IPRs involving patents in the patent family that could impact value and enforcement.

- Suggested Action Steps:

- Identify all opinions, orders and communications regarding enforcement of the patents or interpretation of claim terms.

- **Separate but related family of Dehydrated Butter for Astronauts**

- **Court Ruled: Butter ≠ Margarine**

- Brings us to 49

## Investigation and Analysis of Freedom to Operate

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Landscape Analysis  
Determination

Search Parameters

Work Product and  
Recommendations

Risk Mitigation

## Review and Analysis of Freedom to Operate

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- **Landscape Analysis Determination**
  - Goal: Identify the area of interest and risk tolerance for landscape analysis
  - Suggested Action Steps:
    - Identify key technical and business areas that may impact business and legal interactions.
    - Identify key competitors and IP holders that may impact landscape analysis.
      - **MFGs Aortic Stents and Highly Concentrated Butter**
    - Establish risk profile and decision making logic for processing results.
- **Search Parameters**
  - Goal: Identify the specific parameters (level of detail, cost and timing) for obtaining landscape search results.
  - Suggested Action Steps:
    - Determine regional requirements (US, Europe, Asia, etc.).
    - Identify available service providers and cost parameters. Determine expected work product from service providers.
    - Identify time restraints for results.

## Review and Analysis of Freedom to Operate (cont.)

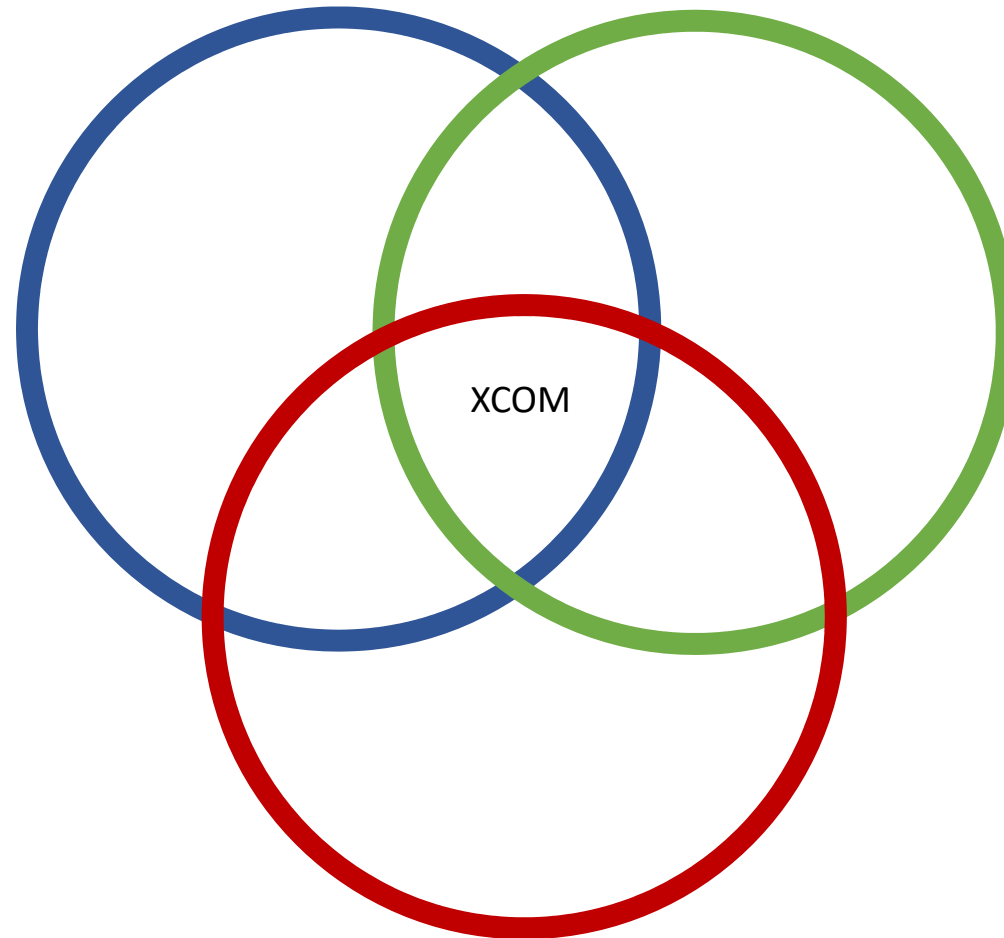
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- **Work Product Definition and Recommendations**
  - Goal: Generate work product summary and recommendations based on the results of the search.
  - Suggested Action Items:
    - Identify key stakeholders and information required.
    - Construct work product in view of willfulness and “need to know” basis (e.g., scorecards vs. claim charts).
    - Filter recommendations based on business and organizational limitations/needs.
- **Risk Mitigation**
  - Goal: For third-party IP that may present risk, identify mitigation options.
  - Suggested Action Steps:
    - Identify IP owner and marketplace role.
    - Identify design around and invalidity positions.
    - Identify licensing and acquired rights alternatives.
    - Identify offensive IP filing “greenspace” for building defensive portfolio.
- Brings us to 58

### 3 Areas of IP Due Diligence Focus: Ownership, Patentability, Freedom To Operate

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58 - Point Inspection



## Preparing for Due Diligence - Recommendations

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- Know what has been done, and what HASN'T been done
  - Many legal services are NOT automatically included in preparing patent applications.
    - Services/Analyses might have been prioritized
- Consider IP “Audit” – Mini Due Diligence
  - Divide and Conquer, reduce costs
  - Be WELL PREPARED for due diligence questions – polished materials make a good impression
- Enhance Portfolio PRIOR to entering deal
  - “Continuation Strategy”
  - Acquire additional patents
  - Investors do not appreciate being “used” for IP audit.

# Knobbe Martens

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## About Us

Knobbe Martens is an agent of innovation, providing clients worldwide with forward-focused Intellectual Property and Technology law service and representation. We are one of the largest and leading IP law firms, with over 250 attorneys and scientists representing the complete spectrum of technologies and IP practice areas.

We combine unmatched technical and litigation expertise to deliver superior results in both transactional and contested matters, for cutting edge start-ups and established Fortune 500 companies. Our work spans all fields—from STEM backgrounds to Media & Entertainment.

But perhaps more impressive than our scope is our skill. We are established in our fields—scientists, engineers and thinkers who blend deep educational and technical knowledge with a strategic focus developed from our real-world business experience.

We know your issues. We know your pressures. And should the need arise, we know how to aggressively protect the assets that give your business its competitive edge.

Our goal is simple: to advance and protect those whose innovations propel the world forward.

## Firm Philosophy

We love competition, just not with each other. We foster a collegial, cooperative atmosphere where every attorney works for the good of the firm, and is focused on providing high quality service for each of our clients. Our attorneys are not compensated based on the number of clients they bring in, rather, they're motivated to match clients with an attorney/scientist team best suited to deliver success. It's a model that puts our clients' interests above our own, which is exactly where they belong.



## National Rankings and Recognition

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- Ranked Tier 1 Nationwide for Patent Law and Litigation Practice Areas in 2018
  - *U.S. News – Best Lawyers®* “Best Law Firms”
- Ranked a 2018 Leading Law Firm for Patent Prosecution, Transactions, and Litigation
  - *Intellectual Asset Management (IAM)* “Patent 1000”
- Recognized Nationally and Regionally in 2018 for Life Sciences, Patent Contentious, Patent Prosecution, Trademark Contentious, Trademark Prosecution and PTAB Litigation
  - *Managing IP (MIP)* “IP STARS”
- Ranked a 2018 Top Law Firm for Patent Prosecution in California and Recognized for Life Sciences
  - *Chambers & Partners* “USA Guide”
- Ranked Nationally in 2018 for Patent Licensing, Patent Litigation, Patent Prosecution and Trademarks
  - *The Legal 500*
- Ranked #1 Best Intellectual Property Boutique Law Firm in 2018
  - *Vault*

# Firm Recognitions

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## Litigation Rankings

- Ranked Tier 1 Nationwide for Patent Litigation in 2018
  - *U.S. News – Best Lawyers®* “Best Law Firms”
- Recognized Nationally and Regionally in 2018 for Patent Contentious, Trademark Contentious and PTAB Litigation
  - *Managing IP (MIP)* “IP STARS”
- Recommended as a 2018 Leading Litigation Firm in California
  - *Benchmark Litigation* “USA Guide”
- Ranked a 2018 Leading Law Firm in California and Seattle for Litigation
  - *Intellectual Asset Management (IAM)* “Patent 1000”
- Ranked Nationally in 2018 for Patent Litigation
  - *The Legal 500*
- Recognized Nationally in 2017 for Hatch-Waxman Litigation and Patent Litigation
  - *Legal Media Group (LMG)* “Life Sciences”
- Named a 2017 Top Boutique Law Firm in California for Providing Outstanding Legal Services Dedicated to IP and IP Litigation
  - *Daily Journal* “Top Boutiques Supplement”
- Ranked Among “Top 100 Verdicts of 2016” and Among “Top 10 for IP Verdicts”
  - *2017 National Law Journal (NLJ)*



## Firm Recognitions

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### Patent Prosecution Rankings

- Ranked Tier 1 Nationwide for Patent Law in 2018
  - *U.S. News – Best Lawyers®* “Best Law Firms”
- Highly Recommended for Patent Prosecution in 2018
  - *Managing IP (MIP)* “IP STARS”
- Ranked a 2018 Leading Law Firm for Patent Prosecution and Transactions
  - *Intellectual Asset Management (IAM)* “Patent 1000”
- Ranked a 2018 Top Law Firm for Patent Prosecution in California and Recognized for Life Sciences
  - *Chambers & Partners* “USA Guide”
- Ranked Nationally in 2018 for Patent Licensing and Patent Prosecution
  - *The Legal 500*
- Recognized Nationally in 2017 for Patent Prosecution and Patent Strategy & Management
  - *Legal Media Group (LMG)* “Life Sciences”
- Ranked #10 Patent Firm in 2018 based on Patent Applications Filed by Volume and Performance
  - *Juristat Top 100 Rankings*



## Firm Recognitions

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### Trademark Rankings

- Ranked Tier 3 Nationwide and Tier 1 in Orange County and Seattle for Trademark Law in 2018
  - *U.S. News – Best Lawyers®* “Best Law Firms”
- Named a 2018 Top Trademark Law Firm in the U.S. and in California by the *World Trademark Review (WTR)*
  - *Awarded Gold Status for both Trademark Enforcement/Litigation and Prosecution/Strategy. Nine attorneys also named “Leading Trademark Attorneys” in the “WTR 1000” Guide*
- Recognized Nationally and Regionally in 2018 for Trademark Contentious and Trademark Prosecution
  - *Managing IP (MIP)* “IP STARS”
- Ranked Nationally in 2018 for Trademarks
  - *The Legal 500*
- Named a Top Trademark Firm in 2017
  - *Managing IP (MIP)* “North America Awards”

