



Preparing for Future Litigation: Strategies for Start-Ups

Wednesday, October 5th

FISH.
FISH & RICHARDSON

Meet The Speakers



Betsy Flanagan
Principal



Matthew Colvin
Principal

Overview

- **Housekeeping**
 - CLE
 - Questions
 - Materials
 - <http://www.fr.com/webinars>


FISH.

+ Complimentary CLE Webinar

The Basics of TTAB Opposition and Cancellation Proceedings

SIGN ME UP

 **DATE**
Wednesday,
October 12, 2022

 **TIME**
1:30 – 2:30 p.m. ET/
10:30 – 11:30 a.m. PT

Webinar | The Basics of TTAB Opposition and Cancellation Proceedings

Suppose that another person or entity has applied for a trademark registration at the United States Patent and Trademark Office (USPTO) that is similar to your trademark. Or, perhaps, you learn that another person or entity has already registered a trademark that you do not believe should have been registered. What can you do? One option is to institute either an opposition or cancellation proceeding at the Trademark Trial and Appeal Board (TTAB).

Complimentary Webinar
Wednesday, October 12, 2022
1:30 - 2:30 p.m. ET

REGISTER

Agenda

- **Designing Your IP Portfolio for Litigation**
- **Capturing Inventions and the Stories Behind Them**
- **Avoiding Bad Documents**
- **Keeping an Eye on the Competition**
- **Guarding Against Willfulness**



Designing Your IP Portfolio for Litigation

Designing an IP Portfolio for Litigation

- **Large Portfolio**

- Ability to assert multiple patents
- Covering multiple aspects of the accused product

- **Maintaining Open Prosecution**

- Significantly increases risk to defendant
- Creates ability to target accused product and avoid prior art

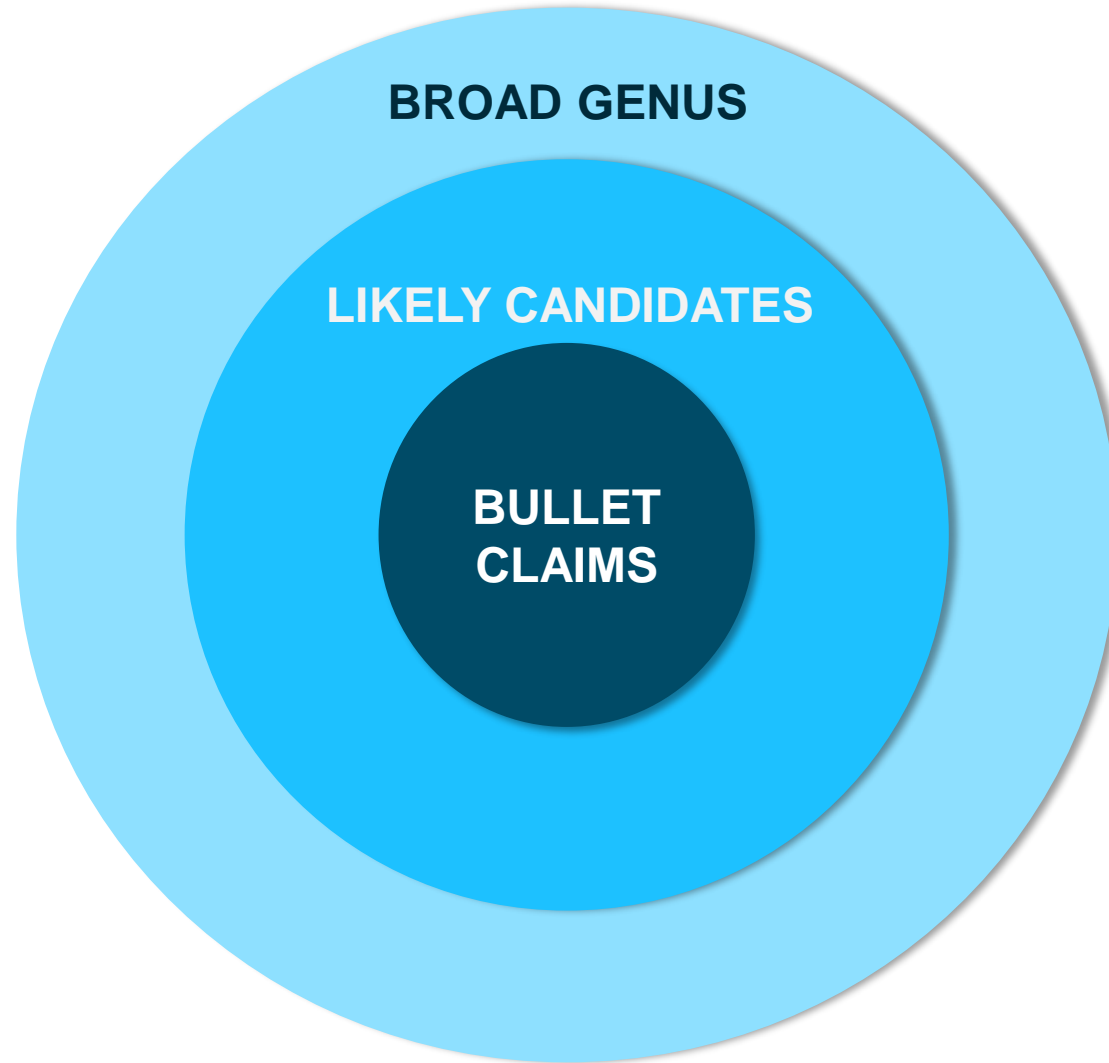
- **Robust Specifications**

- Not limited to own products
- Discloses multiple ways to solve problems

- **Multiple Jurisdictions**

- Creates global risk for defendant
- Increased chance for injunction

Vary Claim Scope



Life Sciences Claiming Strategy

- **Compound**
 - genus; species; pharmaceutically acceptable salts
- **Formulation**
 - X% active; excipients; particle size, dissolution rate, etc.
- **Method of Treatment**
 - Condition; dose; dosing regimen; PK
- **Polymorph**
 - XRPD graph; characteristic peaks
- **Devices**
 - Autoinjectors; metered dose inhalers
- **Process Patents**
 - chemical synthesis of actives
- **Intermediates**
 - chemical compound used to make active
- **Metabolites**
 - in vivo conversion product of active

*****Keep in mind regulatory requirements, e.g., expected contents of ANDA**

Claiming Strategy

- **Joint/Divided Infringement**

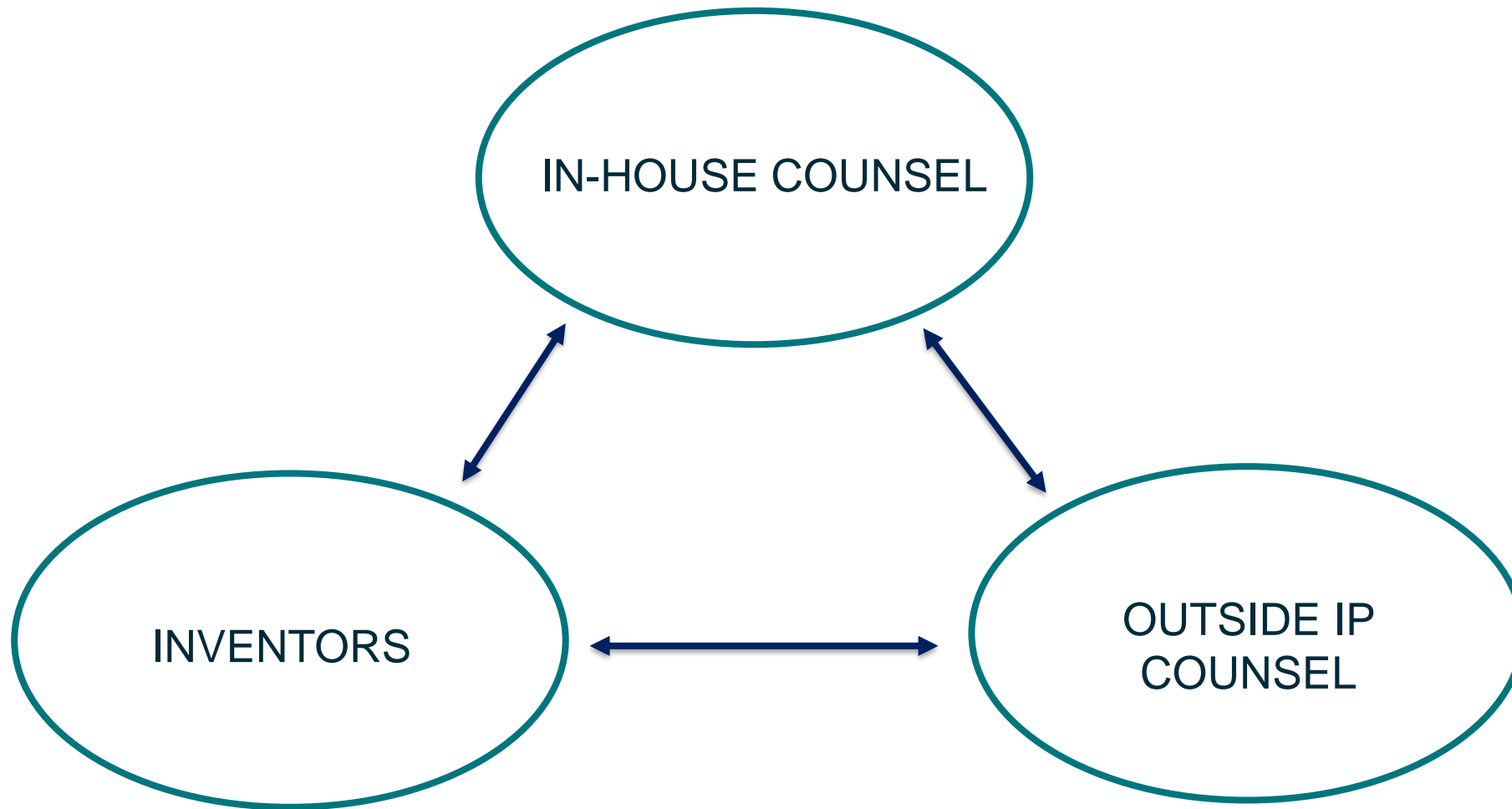
- Multiple actors perform all the steps of a method claim (or use disparate elements of a system) such that no one party directly infringes a patent under 35 U.S.C. §271(a)
- If the alleged infringer conditions participation in an activity, or the receipt of a benefit, upon performance of a method step, and establishes the manner/timing of that performance, alleged infringer can be liable.
 - Service provider – customer relationship
 - Physician – patient relationship
 - Partnership-like relationship



Capturing Inventions and the Stories Behind Them

What makes a very good patent

- **Filed at the right time**
 - The invention is ripe for patenting
 - The prior art is manageable
- **Contains the right information**
 - In many fields data really matters
- **Provides value by covering a product**
 - Focus is products, not on industry domination
- **Tells an interesting story**
 - When a patent is valuable, it will likely be enforced
 - When a patent is enforced, the judge/jury needs to understand that you faced challenges to do something wonderful – tell the story



Capturing Inventions

Educate management about patents and the value of a strong patent portfolio. Educate employees about patents and how to incorporate “patent thinking” into their day-to-day activities.

Cultivate a pervasive company-wide attitude that patents are vital to company’s future.

Harvest ideas via internal invention disclosure processes (organic) and regular harvesting meetings (focused).

Select the best/right ideas for investing in the patenting process.

Reward the inventors with payment and recognition.

Capturing Stories

Stories Win at Trial

- **Lab notebooks**
 - Engineer / scientist perspective
- **Meeting Minutes**
 - Project perspective
- **Memos**
 - Management perspective
- **Invention Disclosures**
 - Should broadly disclose the problem and solution
 - Avoid narrowing language that could be used to limit the invention story

Capturing Stories

Stories Win at Trial

- **Buzzwords for documents**
 - Unexpected results
 - Surprising results
 - New way
- **Document retention balance**
 - Invention and project documents should be retained
 - Emails can (likely) go
 - Caveat: Anticipated litigation should implicate legal hold



Avoiding Bad Documents

The Role of Documents In Litigation

- **Trial Themes**
 - The American dream
 - David vs. Goliath
 - Our mission
 - You stole our work instead of doing your own (home)work
 - We did it first

- **Written Words vs. Memories**

Education



Education

- **Sarcasm**
- **Jokes**
- **Emotion**
- **Criticizing Existing Products**
- **Express Greed / Monetary Motivation**
- **Discuss Infringement / Validity Without Counsel**

Education



Education - Privilege

- **Communication**
- **Between counsel and client**
- **In confidence**
- **For the purpose of seeking, obtaining, or providing legal assistance to the client**
 - Includes non-lawyer actions at the direction of counsel, or to gather information to provide to counsel
- **Best Practices**
 - Limit scope of employees involved in legal advice
 - Limit written commentary
 - Identify the counsel by name in written communications
 - Be aware of line between legal and business advice



Keeping an Eye on the Competition

Competitive Intelligence

Legal can add value to business

- **Track what your competitors are filing**
 - Indicates future product direction
 - Are the filings in your focus areas?
 - Do they create FTO issues?
 - Can you file IP in their focus areas?
- **Where is the white space?**
 - Might be a business opportunity

Competitive Intelligence

Places to look

- **Track what your competitors are filing**
 - Patent / Trademark filings
 - Litigation reports
 - Competitors
 - NPEs
 - SEC reports
 - Product portfolios
- **Life Sciences specific**
 - NDA filings
 - DMF filings
 - Emerging Generics

Competitive Intelligence

Who does it?

- **Competitive patent analysis is a legal function**
 - Not for engineers unless specifically directed by legal
 - Must maintain privilege



Guarding Against Willfulness

What Is Willfulness?

Willfulness is a factual finding that the infringer deliberately and intentionally infringed, with knowledge of the patent

- **Evidentiary standard was “clear and convincing evidence,” but reduced to “preponderance of the evidence” in 2016**
 - Makes it easier to find willfulness
- **The current test is really no test at all:**
 - “The subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless.” *Halo*, 136 S. Ct. at 1933.

What Is the Impact of a Willfulness?

DAMAGES x3

Attorneys' Fees

Jury Impact

35 U.S.C § 284 (increased damages and fees are at the discretion of the Judge)

What Is Willfulness?

- **Must focus on infringer's understanding *at the time of infringement***
 - *What was the subjective belief at the time of product launch?*
- **Intentional or reckless disregard of a plaintiff's patent rights could give rise to willfulness finding even if there is a good trial defense**
- **Lack of opinion of counsel does not automatically give rise to an adverse inference**
- **Opinions of counsel can help tell a compelling exculpatory story**
 - *Highly probative evidence if relied upon by decision makers*
- **Preponderance of the evidence standard (trial court); abuse of discretion (appeal)**

Minimizing Risk of Willfulness Finding

Suggestions to Minimize Risk

- **Assess internal company policy**
 - If none, consider one
- **Show behaved in good-faith**
- **Perform internal investigations**
 - IP Department, Engineering, Other
 - Document investigations (e.g., claim charts)
- **Be prompt**
- **Respond substantively to cease & desists**

Minimizing Risk of Willfulness Finding

Suggestions to Minimize Risk

- **Consider external investigations, especially for high-risk circumstances**
- **Consider privilege issues to minimize waiver**
- **Review internal document retention policy**
 - Provide in-house training
- **Minimize the patent enthusiast**
- **Maintain independent development evidence**
- **Follow the policy**

Minimizing Risk of Willfulness Finding

Opinions of Counsel

- **No obligation, but could help on both willfulness and enhancement**
 - Some jury instructions reference opinions of counsel
 - “whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed”
- **If a jury instruction states that Defendant was not obligated, but an opinion was procured, may lean the jury towards Defendant**

Minimizing Risk of Willfulness Finding

Opinions of Counsel Alternatives

- **Non-Attorney Evidence of Good Faith Beliefs**
 - Business roles of those involved
 - Competence of the analysis
- **Decision-Maker Must Know About Beliefs**
- **Role of IPRs**

Minimizing Risk of Willfulness Finding

Privilege Considerations

- **Opinions are privileged until waived**
- **Better to have discrete opinions rather than omnibus so that scope of waiver is limited**
 - One invalidity opinion for each prior art reference for the major prior art
 - One opinion for non-infringement
- **Opinions should be drafted with an eye towards waiver**
- **Best if story can be told that shows company reliance on opinion**
 - Internal memos



Betsy Flanagan
Principal
betsy.flanagan@fr.com



Matthew Colvin
Principal
colvin@fr.com

Thank You!

Please send your NY/NJ CLE forms to mcleteam@fr.com

Any questions about the webinar, contact Michelle Zazzero at zazzero@fr.com

A replay of the webinar will be available for viewing at <http://www.fr.com/webinars>

© Copyright 2022 Fish & Richardson P.C. The opinions expressed are those of the authors and do not necessarily reflect the views of Fish & Richardson P.C., any other of its lawyers, its clients, or any of its or their respective affiliates. This presentation is for general information purposes and is not intended to be and should not be taken as legal advice and does not establish an attorney-client relationship.

These materials may be considered advertising for legal services under the laws and rules of professional conduct of the jurisdictions in which we practice.. Legal advice of any nature should be sought from legal counsel. Unsolicited e-mails and information sent to Fish & Richardson P.C. will not be considered confidential and do not create an attorney-client relationship with Fish & Richardson P.C. or any of our attorneys. Furthermore, these communications and materials may be disclosed to others and may not receive a response. If you are not already a client of Fish & Richardson P.C., do not include any confidential information in this message. For more information about Fish & Richardson P.C. and our practices, please visit www.fr.com.

FISH.
FISH & RICHARDSON