

## Life Sciences Webinar Series

# Biotech and Pharmaceutical Patent Due Diligence: How to Maximize Value and Mitigate Risks from the Buy Side and Sell Side Perspectives

April 30, 2020

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# Shameless Plug . . .

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The Business of  
the Hatch-Waxman Act

May 20, 2020



Betsy Flanagan



Chad Shear

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# The Basics Of Due Diligence

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- **Checklists, checklists, and more checklists**
  - You can find them anywhere
  - Helpful to a point
  - Don't become overly reliant, may lead you astray
- **Due diligence is only partly about performing diligence**
- **Understand the diligence *before* there is a diligence**

# Understand The Diligence Before There Is A Diligence

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- **Ever diligent**
- **You're not getting a patent, you're creating an asset**
- **You're not creating an asset, you're creating a portfolio of assets**
- **Welcome the thought of litigation**

# Mindset

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- **Before the diligence**
- **During the diligence**
- **After the diligence**

# The Basics Of Due Diligence – The Value Proposition

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- Understand the asset
- Understand the value of the asset
- Understand the reason your client wishes to buy/sell the asset
- Understand the benefits and risks of any deal
- Understand the long game
  
- Only after you understand all of the above, should you begin to think about the diligence

# Understand The Asset And Its Value

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- **Is it a product?**
  - What stage of development?
    - **Is it in the safe harbor?**
      - For how long?
  - What indication?
  - New target?
  - First in class?
  - Possible growth?
  - Competitive landscape?
  - How does it fit into the buyer's portfolio?
- **Is it a platform?**
- **Is it a disruptive play?**
  - For the industry?
  - For the client?

# Why Are We Here?

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- **First and foremost, what is the business objective?**
  - Short term
  - Long term
  - Is the portfolio designed for each?
- **The business objective may shape the analysis**
- **What are the risks?**
- **What are the benefits?**

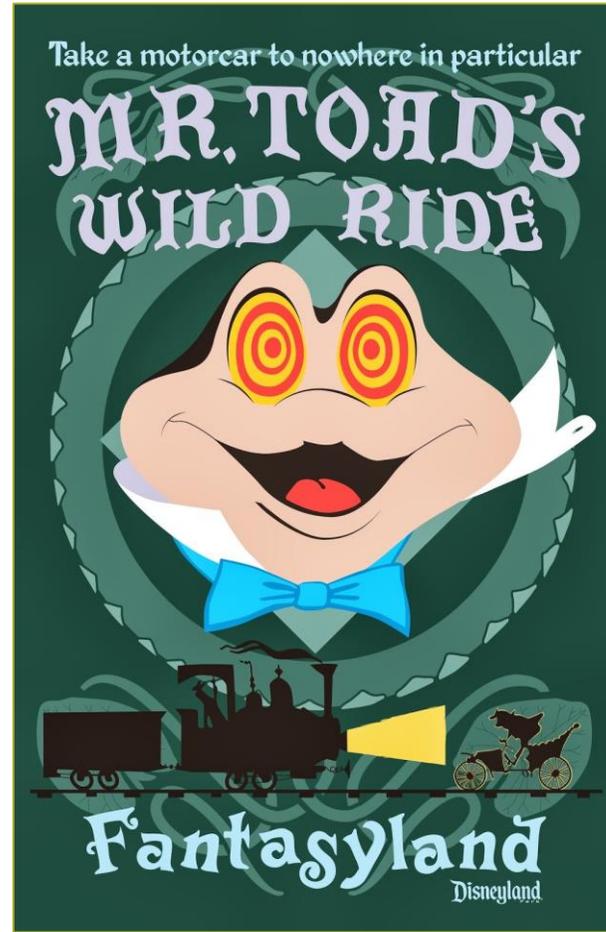
# The Structure Of The Diligence

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- **Financing vs Acquisition**
- **All-in**
- **Multi-phased/tiered**
- **Competitive/Auction**
- **One-sided (stealth/hostile)**
- **Litigation pending/imminent**
- **Hybrid of all of the above**

# The Diligence Begins . . .

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# The Diligence Begins – The Team

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- **Is the team built for speed or stamina?**
- **Pick the right team . . .**
  - Someone needs to understand the science
  - Someone needs to understand the business
  - Those someones need to be able to talk to one another (and to want to)
  - Someone needs to actually be able to assess the risk
- **Who will have access to the information?**
  - Is there a conflict?
  - Is there a potential for misuse of the shared information?
  - Is there a potential for contamination?

# The Diligence Begins . . . The Data Room

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- **The data room is the tip of the iceberg**
  - DO NOT LIMIT YOURSELF TO IT
    - **The data may seem to put forth a certain message whether intentionally, through incompetence, or because of a genuine disconnect**
    - **Do not assume that the side populating the data room knows what they are doing or why**
- **Ask questions!**
  - Get organized first
  - Classify your questions
  - Be prepared to move quickly

# The Basics Of Due Diligence

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- **Be wary of the unknown/unexplained**
- **Be wary of the things that get in the way**
  - Protective Orders
  - Confidentiality Agreements
  - Attorney-Client Privilege
  - Lack of information/access to the right people
- **Be creative in coming up with a work around, with comfort-level answers**

# Ownership And Chain Of Title

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- **Corporate Structure-- flow of rights clear?**
  - Hub and Spoke companies
  - Government grants (academic/research institutions)
  - Right to Claim Priority (see also assignments)
- **Employment agreements**
  - Inventors
  - Former employees
    - **Obligation to assist?**
- **Assignments**
  - Contractors
  - Consultants
- **License agreements**
- **Collaborators, SRAs, MTAs**

# Inventorship

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- **Who?**
  - Employees
    - **Former employees**
      - Current relationship – hostile? aggressive?
      - Beware of what you are buying
  - Collaborators
  - CROs
  - Changes in inventorship
- **Where?**
  - Foreign filing licenses
    - **US and Ex-US**
    - **CRO work**
- **When/how occurred?**

# Freedom To Operate

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- **Direct Infringement**
  - Compound
  - Indications
  - Target
  - Formulation
  - Manufacturing/intermediates
  - Biomarker/diagnostic
- **Indirect Infringement**
  - Inducement/contributory
    - **Dx/Rx**
    - **Claims vs. Drug Label**

# Portfolio Overview

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- **By Product or Program**
- **Breadth of coverage**
  - Is there a clear strategy behind the filings?
    - **Genus, species, polymorphic forms, formulations, clinical results, other indications, specific patient populations, target claims, biomarkers, production/process, QC**
    - **“Patent the label”**
- **Positioning vis a vis generics, competitors**
  - Patents, clinical timing, regulatory exclusivities
- **Validity – 101, 102, 103, 112**
  - IDS, search reports
  - Prior art (public disclosures, earlier filings, scientific publications, website, SEC filings)
  - On-sale bar

# Loss Of Exclusivity

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- **Timelines, timelines, timelines**
  - If/then scenarios
- **Regulatory exclusivity analysis**
  - Intersection with patent
- **Patent Term Extension**
  - Which patent?
  - Why?
  - Intersection with PTA

# Big Picture

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- **Focus on key value drivers**
  - Products
  - Jurisdictions
- **Prioritize ownership, inventorship, LOE, FTO, contractual and validity questions**
  - Then dig in
- **Don't limit yourself to what you're being told**
- **Work closely with the business, clinical, and scientific team to understand the value proposition, risks, and competitive landscape**
  - Don't go down rabbit holes that are not important to the deal
- **Identify solutions, alternative fixes, and opportunities rather than just issues**
- **Be leery of creating problems**

# How To Deal With Unreasonable Timelines

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- **Build a team that you can trust**
  - Divide and conquer
  - Sanity checks
  - Varied expertise and experience
  - Brainstorming solutions
- **Communicate, communicate, communicate**
  - Bring everyone together if possible
- **Have an end deliverable in mind before you begin and structure accordingly**
- **Prioritize key value drivers and risks**
- **Understand what can be fixed/optimized later**
- **Make it clear what you had time to do and what you did not**
- **HAVE FUN!**



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# Thank You!

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