IMPORTANT TERMS IN YOUR NEXT PHARMA OR TECH DEAL

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Agenda

- What are the important terms?
- Why is IP important?
- What companies and investors should look for in IP when seeking to acquire a technology or life science asset
- How to best position and reinforce your IP (including patents & trade secrets) when seeking a potential M&A deal
- Where to find IP red flags in an M&A transaction that can impact the value of the deal
- Q & A Panel

Disclaimer

• None of the information or opinions discussed today are attributable to our respective organizations, they are only our personal opinions.

What are the important terms?

- IP Representations and Warranties
- Indemnification Obligations/Protection
- Restrictive Covenants
 - Confidentiality
 - Non-Competition
 - Non-Solicitation
- Common Theme: Intellectual Property
- Saved for the sequel webinar: economic terms, employment agreements, privacy and data security

Why is IP Important?



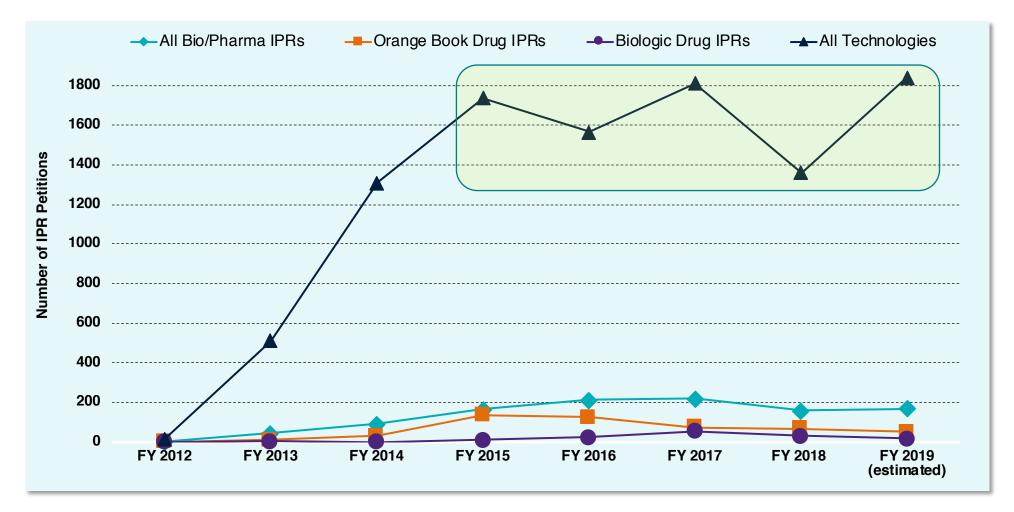
Why is IP Important?

- Establish exclusivity/value
- Evaluate and support deal structure/economics
 - License/Collaboration
 - Royalty
 - -M & A
- Identify Risks
 - -Shift or mitigate risks
- Assist in Drafting and Negotiations

- Loss of Exclusivity
 - Regulatory Exclusivity (NCE/BLA/Pediatric/Orphan/Data)
 - Patent Exclusivity
- Total Portfolio
 - Types of IP
 - Patents, TM, domain names, copyrights or trade secrets/know-how
 - Breadth and quality of coverage
 - Genus Claims vs Species Claims vs. Picture Claim
 - Timing of Expiration
 - PTA / PTE
 - Double patenting?
 - Upstream in-licenses and necessary sub-licenses
 - Rights to Developments and Improvements

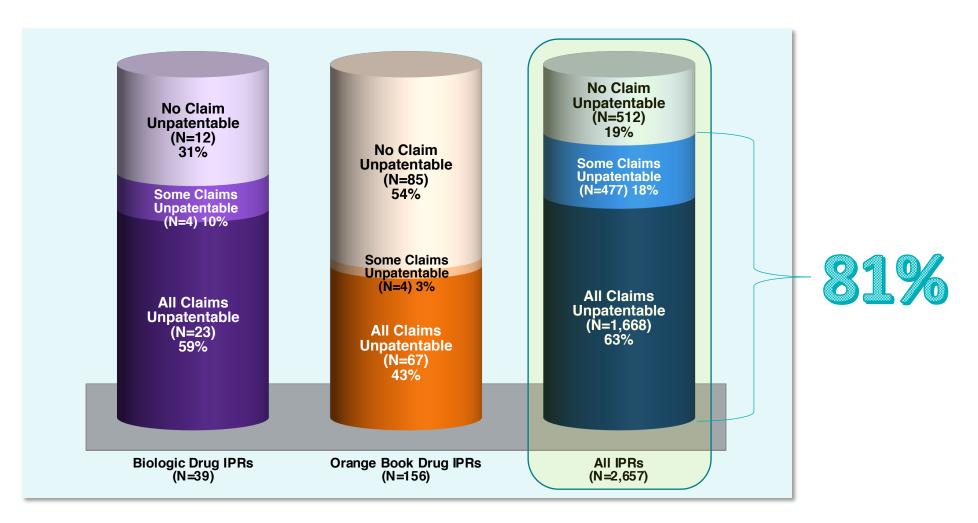
- Competitive Intelligence
 - Likelihood of Competition
 - Impact of Type of Product (pharma product vs. medical device vs. software/tech)
 - IP impacts LOE more for pharma products than software/tech due to faster product evolution in software/tech
 - Weighs into risk calculus, less for pharma and significantly more for med device and software/tech

- Risk of Contested Proceeding/Litigation
 - Invalidity vs. Infringement (Freedom to Operate)
 - Dangers of PTAB IPR/PGR re Invalidity
 - Technology dependent
 - Freedom to Operate risk also technology dependent
 - Pace of innovation and development; changes in patent law
 - Ex-US Markets e.g., EU Patent Oppositions
 - Reviewed to evaluate validity
- Current and Settled Litigations
 - Settlement agreements
 - Positions taken during span of litigations
 - Outside counsel eyes only





All Bio/Pharma and All Technologies filings from USPTO statistics as of Mar. 31, 2019; Orange Book and Biologic Drug filings from Venable Fitzpatrick proprietary database as of Mar. 31, 2019.





All IPR filings from USPTO statistics as of Mar. 31, 2019; Orange Book and Biologic Drug filings from Venable Fitzpatrick proprietary database as of Mar. 31, 2019.

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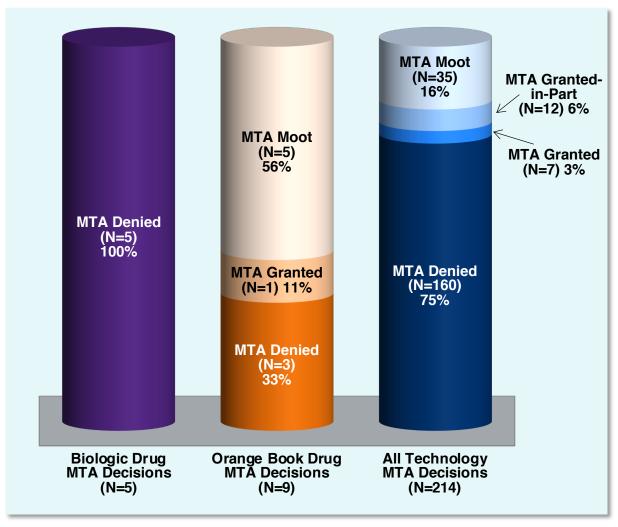
Takeaways

- Determine Loss of Exclusivity
- Examine Vulnerability of Patents
- Identify Breadth and Scope of IP
- Clear Freedom to Operate
- Avoid "Buying a Lawsuit"
- Determine the Likelihood of acquiring IP
- Consider the Ability to Enforce IP
- Confirm structure and economics make sense in light of IP realities



- Open prosecution
 - Continuations and Divisionals
- Motions to Amend
- Supplemental Examination
- NDA/CDAs and Trade Secrets
 - Documenting your Trade Secret
- Typical practices
 - Involve IP group early in the process
 - CDA in place between the parties
 - Access to confidential information
 - IP opinions
 - Non-binding term sheets

- The PTAB started a pilot program for MTA practice on March 15, 2019
 - Provides patent owners the option to receive preliminary guidance from the Board on its MTA
 - Allows patent owners to revise MTA after receiving petitioner's opposition and/or after receiving PTAB's preliminary guidance





All IPR filings from USPTO Motion to Amend study published Mar. 2019 with decisions as of Sep. 30, 2018; Orange Book and Biologic Drug MTAs from Venable Fitzpatrick proprietary database as of Apr. 30, 2019.

- If the transaction is already proceeding, get your (black) ducks in a row:
 - -Anticipate diligence requests
 - Know your FTO landscape
 - -Confirm inventions assignments and NDAs
 - -Review accuracy of representations and warranties
 - -Prioritize key IP, but identify additional IP as well
 - -Negotiate material contract thresholds

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Takeaways

- -Obtain Additional Patents from existing families
- Fix Existing Patents in the PTO
- -Strengthen Confidentiality Provisions
- Don't let IP be the obstacle
- Know what you have, Know what you are representing





Reps & Warranties

- IP Rep, underqualified and overreaching
- Title to Assets (aka Assets and Properties) Rep

Indemnification

Piece-meal negotiation

Between signing and closing

- Overly-restrictive covenants
- Consequences of disclosure schedule updates

Restrictive Covenants

- "Business" definition

- Inventorship
 - -Title, assignability and ability to control the IP exclusively
- Undisclosed Prior Art
- Claim Scope
 - Lack of Picture Claim
 - Lack of Genus Claim
 - White space for offensive development or defensive coverage

Vulnerabilities

- Method of Treatment and formulation claims
- Double Patenting
- Patentability
 - §101 Issues for Tech and Biologics
- Bahy-Dole Compliance

Rights and Obligations

- In-licensed and Out-licensed obligations
- Third party IP
- Importance of FTO

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Takeaways

- -Mind your "Business" definition
- Don't let specifically-negotiated provisions be undercut
- Know the Business Objectives
- IP is a Value Driver, not a Deal Killer

Questions?



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