INTERGROWTH®2019 BREAKOUT SESSION

The Importance of Intellectual Property in Your Next Deal

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THE IMPORTANCE OF INTELLECTUAL PROPERTY IN YOUR NEXT DEAL

May 6, 2019

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Therapeutics MD°

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Agenda

- 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.
- I have not yet watched Season 8, Episode 4 of Game of Thrones.



Why is IP Important?



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Why is IP Important?

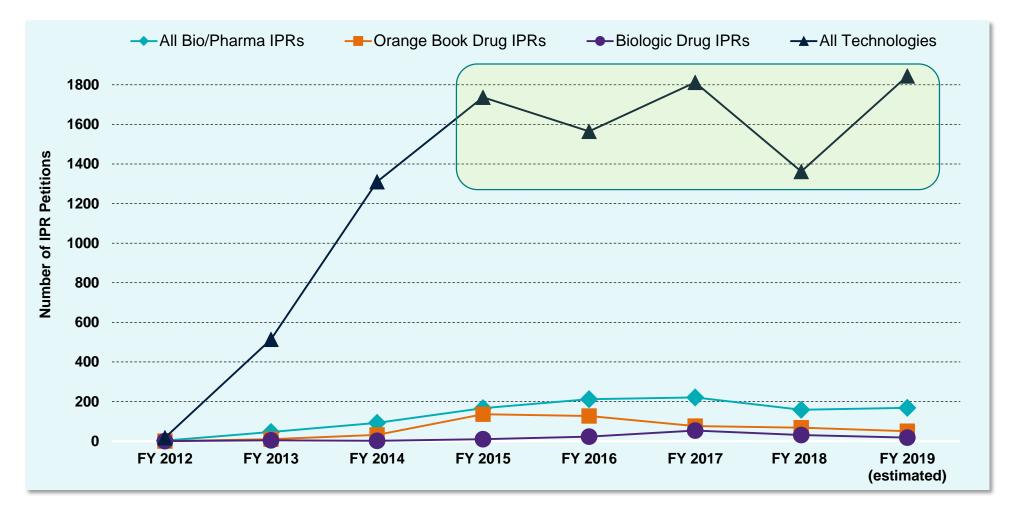
- Establish exclusivity/value
- Evaluate and support deal structure/economics
 - License/Collaboration
 - Royalty
 - -M & A
- Identify Risks
 - -Shift or mitigate risks
- Assist in Drafting and Negotiations

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- Loss of Exclusivity
- Total Portfolio
 - Types of IP
 - Patents, TM, domain names, copyrights or trade secrets/know-how
 - Breadth of coverage
 - Genus Claims vs Species Claims vs. Picture Claim
 - Timing of Expiration
 - Patent Term Adjustment & Extension
 - Regulatory Exclusivity (NCE/BLA/Pediatric/Orphan/Data)
 - Rights to Developments and Improvements

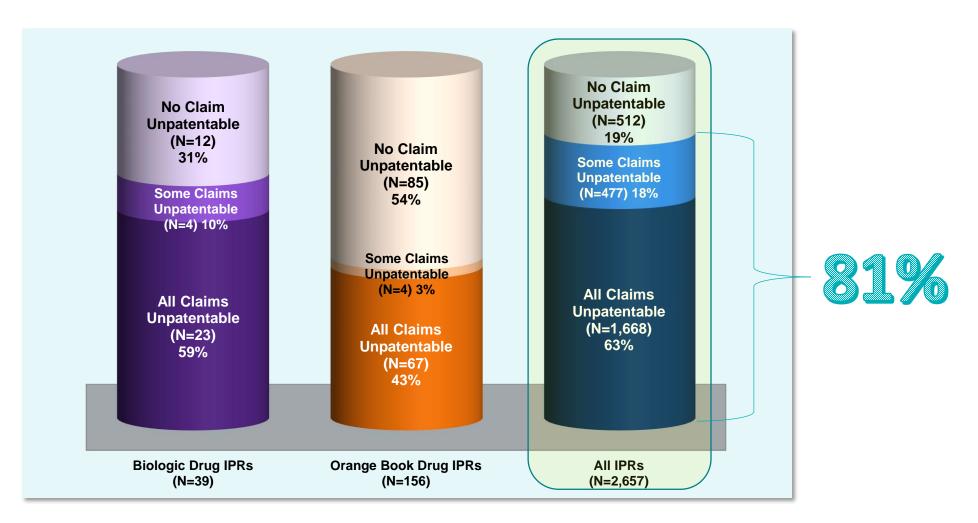
- Competitive Intelligence
 - Likelihood of Competition
 - Impact of Type of Product (pharma product vs. medical device vs. software/tech)
 - IP impacts LOE more for pharma products than software/tech due to faster product evolution in software/tech
 - Weighs into risk calculus, less for pharma and significantly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

- Risk of Contested Proceeding/Litigation
 - Invalidity vs. Infringement (Freedom to Operate)
 - Dangers of PTAB Inter Partes Review/Post Grant Review
 - Technology dependent
 - Ex-US Markets e.g., EU Patent Oppositions
 - Reviewed to evaluate validity
- Current & 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.

Kevin M. McCabe, Chief Exclusivity Officer and Associate General Counsel, TherapeuticsMD



Andrew Chien, Senior Counsel Intellectual Property, Allergan





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

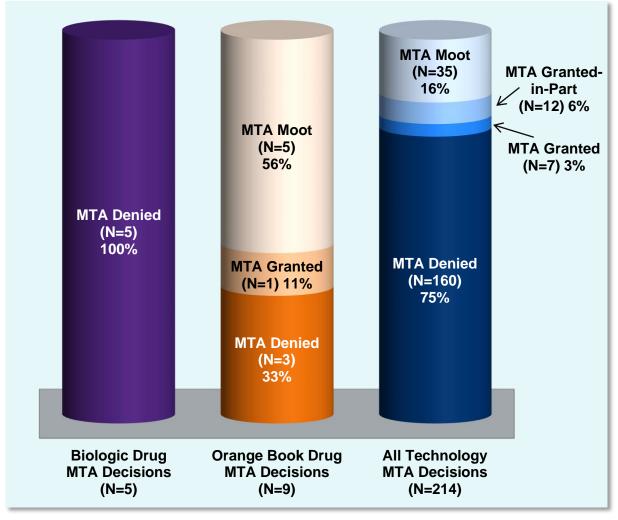


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- Open prosecution
 - Continuations and Divisionals
- Motions to Amend
- Supplemental Examination
- NDA/CDAs and Trade Secrets
 - Documenting your Trade Secret
- Typical practices
 - Involve IP group early in the process
 - CDA in place between the 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.

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Andrew Chien, Senior Counsel Intellectual Property, Allergan





Takeaways

- -Obtain Additional Patents from existing families
- -Fix Existing Patents in the PTO
- -Strengthen Confidentiality Provisions
- Don't let IP be the obstacle



- 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 claims
- Double Patenting
- Patentability
 - §101 Issues for Tech and Biologics

Rights and Obligations

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

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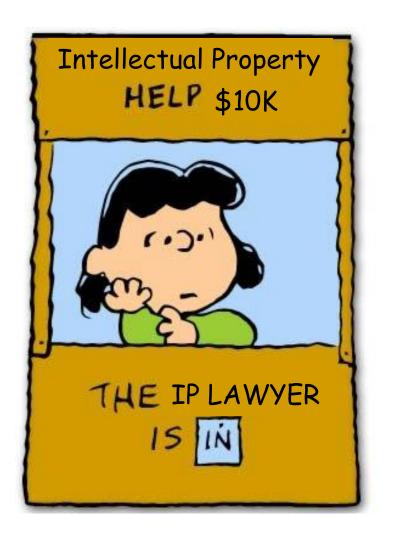
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- Takeaways
 - Know the Business Objectives
 - IP is a Value Driver, not a Deal Killer

Questions?



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