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Venture Law Meetup

During the JP Morgan Virtual Healthcare Conference 2022

Legal Developments Affecting Life Science Companies

Introductions

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Session 1: Public Policy

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Public Policy

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- Where is life science federal research and development funding going?
- Which companies are the federal government partnering with? Who will be good for investing?
- Federal budget process and how to impact it (appropriations requests, meetings, etc.)
- Focus on venture capitalism in the life science field

Session 2: Venture Capital and Private Equity

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Venture Capital Transactions – Overview

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- Stock Purchase Agreement
- Amended and Restated Certificate of Incorporation
- Investors' Rights Agreement
- Right of First Refusal and Co-Sale Agreement
- Voting Agreement

Venture Capital – Trends

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- Early-stage VC is the relatively strongest segment of the venture lifecycle as late-stage and growth investors have been backing younger companies. Valuations at this stage have more than doubled on an annualized basis
- Increased competition for most promising seed-stage startups has pushed the pre-money valuations of top-quartile companies to $15 million, creating an unprecedented spread of $10 million above bottom quartile seed-stage valuations.
- While late-stage valuations declined slightly quarter over quarter, half of all late-stage financings in the last year raised new capital at more than double their previous valuations.

Venture Capital – Key issues (Founder Rights vs Investor Protections)

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- Valuations
- Cumulative dividends
- Exempt transfers by Key Holders
- CFIUS
- Protective provisions (cryptocurrency, SPACs)
- Rights only for Major Investors (Information, ROFO)

Global M&A and PE Activity in 2021

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- "*Squire Patton Boggs – Surging Ahead: M&A Outlook 2022 and Beyond*" (published in association with Mergermarket and available online at www.squirepattonboggs.com)
- 18,736 global M&A deals with a collective value of more than US$4.2 trillion through Q3 2021, which represents an increase of 47% and 122% respectively over the prior period in 2020.
- Private equity funds deployed capital in over 6,441 deals worldwide with a collective value of approximately US$1.6 trillion through Q3 2021.
- Global transactions in the life sciences sector (health, pharma, biotech) accounted for US$156 billion across 726 deals through Q3 2021.

Global M&A and Private Equity Trends for 2022

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- Intense competition for quality assets will continue from all sources of capital – corporates, private equity sponsors, SPACs, family offices, independent sponsors, etc.
- Private equity has unprecedented levels of “dry powder” to invest and the deployment of that capital will continue to drive M&A activity in all sectors in 2022, including life sciences.
- Dislocation in the market caused by the COVID-19 pandemic will continue to create M&A opportunities, but can also create uncertainties or dampen M&A in jurisdictions where vaccination rates are lower or variants cause lock downs.
- Potential headwinds in 2022 include a rising interest rate environment, increased regulatory scrutiny (antitrust and national security), continued supply chain issues, labor shortages (the “great resignation”), and tax reform.

Types of Private Equity Transactions in Life Sciences

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- Growth Equity
- Joint Ventures
- Product Specific Development
- Carve Outs
- Buy & Build Strategy (Add-On Acquisitions)
- Mezzanine
- Buyouts

Considerations When Doing a Private Equity Transaction

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- Fortune Favors the Prepared, Not the Brave!
- Time Kills All Deals!
- Earnouts = Payouts . . . When You Pay Attention to the Details!
- Rollovers – A Second Bite of the Apple!
- R&W Insurance – A Gift That Keeps on Giving in Today's Sellers' Market

Session 3: Intellectual Property

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Assess What IP Works Best for Your Innovations

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Type	Time	Rights
Patent	20-years from filing	Gov't issued, time-limited, right to exclude others from making, using, selling, offering for sale, or importing a claimed invention.
Copyright	Life of author plus 50/70 years	Federal statutory right of authorship and expression granted to an author for a work that is expressed in a tangible medium
Trademark	Depends on use/renewals	Any word, name, symbol, design or slogan used to identify or signify a source and quality of a product
Trade secret	Indefinite if secrecy maintained	Information that derives independent economic value from not being generally known, and which is the subject of reasonable efforts to maintain its secrecy

How IP Is Valued

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- What drives value
  - Important to investors, purchasers and customers
  - Useful in negotiation of rights and can be monetized
  - Respected by competitors and other rights holders
  - Legally enforceable
- Owned by you or exclusive license to others' IP

Tip: Consider what matters most to your most important "audience" at the time of your creation/invention. This likely changes over time.

Consider the Use of Utility Patents

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- Government-issued – country by country
- Right to exclude others from making, using, selling, offering for sale, or importing
- Contrast with Freedom-to-operate (FTO) - ability to use your technology without legal liabilities to third parties (e.g., other patent holders or trade secret holders)

Tip: File in countries where you have a presence, where your competitors are, where you manufacture, size of and where your markets are.

Tip: Be able to articulate your patentability and FTO positions and the difference between the two.

When to File

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- Basic requirements for filing: patentable subject matter, useful, novel, inventive (i.e., nonobvious), adequate disclosed and supported, clear
- Ideal: File as soon as your ideas are fully formed, sufficiently described, and enabled
  - Worldwide: Patents are awarded to the first (inventor) to file
  - (Public) disclosure before you have filed starts the clock for filing a US patent application, and may bar filings outside of the US

Tip: Have an on-going conversation with your patent attorney about whether you meet these requirements for filing.

Alternatives to the Ideal

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- Rely on other types of protections.
  - Use Non-Disclosure Agreements if you must share
  - Use joint development agreements for work done with partners
- Consider filing before you are completely ready, using one or more provisional applications, updating with new information as you go; abandon at one year conversion deadline.

SPOTLIGHT: Support Requirements for Antibodies

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Amgen *v.* *Sanofi*

Repatha (evolocumab) injection 140 mg/mL

Praluent (alirocumab) Injection 75mg/mL 150mg/mL

- U.S. Court of Appeals for the Federal Circuit held several patents on Repatha® invalid for lack of enablement on the grounds that they covered thousands of antibodies and the skilled artisan could not recreate them
- The CAFC struck down the "newly characterized antigen test" that had formed the basis for explicit USPTO guidance and corresponding applicant claim strategies **for more than twenty years**
- A similar line of reasoning was recently used to invalidate patent claims for Juno Therapeutics and Memorial Sloan-Kettering on CAR-T cell therapy, on the basis that their exemplary CD19 binders were not adequately disclosed

Antibody Genus Claims: Why do they matter?

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- Genus claims are a central feature of patent law in the chemical, biotechnology, and pharmaceutical industries
- Potentially devastating to R&D incentives for future antibody development
- Upending decades of well-settled law and long-standing applicant expectations and practice
- Growing disparities between U.S. patent law on antibody claiming and other major jurisdictions
- Beware the slippery slope!

Session 4: SPACs

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SPAC Introduction

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- **What is a SPAC?**
  - Special purpose acquisition company formed for the purpose of effecting an acquisition or business combination of a traditional operating company or companies.

- **The Life Cycle of SPACs**
  - Set up the Entity
  - SPAC IPO
  - Identify a Target
  - De-SPAC transaction

De-SPAC Process Overview

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The First Step
SPAC and Target Negotiation
1. Identify SPACs 2. Sign letter of intent 3. Conduct Due Diligence 4. Negotiation 5. SPAC may arrange committed debt or equity financing. For example, a private investment in public equity ("PIPE") commitment 6. Prepare proxy statement/S-4/F-4 7. Sign merger agreement

De-SPAC Process Overview

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The Second Step
SPAC Shareholder Approval and Closing
1. Announce transaction 2. File proxy statement/S-4/F-4 with the SEC 3. The SPAC obtains approval from its shareholders for the merger transaction 4. Public shareholders who choose to redeem their shares redeem their shares 5. Complete the merger transaction 6. File the Super 8-K form with the SEC

De-SPAC Merger vs. Traditional IPO

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	De-SPAC Merger	Traditional IPO
Timing	Typically 3-4 months after the LOI is signed	Generally 4-6 months
Costs	Legal, accounting and other costs are high, maybe comparable to, or even higher than a traditional IPO	Legal, accounting, underwriting and other fees are high.
Pricing and Valuation	Negotiated value and pricing; more certainty	Valued through market-based pricing discovery. Volatile
Financial Statements Requirements	• Emerging Growth Company (EGC) benefits • Target will be required to have the same types of f/s required in connection with an IPO • Target may have to provide pro formas and restate f/s following completion of the merger	Emerging Growth Company (EGC) benefits
Forecasts	• Projections for the Target are included in the proxy/prospectus • These projections are also shared with potential PIPE investors	Forecasts/Projections are not allowed
Rule 144	Will not be available for one year following filing the super 8-K with Form 10 information.	Available to stockholders subject to compliance with applicable conditions.

De-SPAC Merger v. Traditional IPO

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	De-SPAC Merger	Traditional IPO
Road Show	• Target will be required to engage in presentations to the SPAC sponsors • Target will usually hold investor meetings for potential PIPE investors • SPACs cannot rely on the communications safe harbors available to targets. SPACs cannot use FWPs or rely on the taped road shows • SPACs can use Rules 165 and 425 to do taped meetings, as long as the materials and script are filed with the SEC	• Road show presentations • A taped road show • provide useful feedback from institutional investors
Corporate Approvals	• Target may need to get its existing shareholders' approval for the de-SPAC merger • The SPAC must obtain its shareholders' approval	Generally, companies will have addressed the mechanics for preferred stock conversion upon occurrence of a qualifying IPO.
Committee on Foreign Investment in the United States (CFIUS) Consideration**	• The ownership and governance rights of all prospective **foreign investors,** including SPAC sponsors, PIPE investors and warrant holders • Both the SPAC sponsor and target must understand whether the target business raises CFIUS considerations, particularly as they relate to mandatory filings • **CFIUS is a U.S. government interagency committee charged with (1) reviewing foreign acquisitions of, or investments in, U.S. businesses and (2) identifying and mitigating any risks to national security raised by those transactions	Typically a traditional IPO has no CFIUS considerations.

The Future of SPACs

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- **The Future of SPACs**
  - Deal volumes over the last two years
  - Market performance post-de-SPACs
  - SEC's concerns and potential rulemakings
    - Conflict of interest
    - Projection
- **Are SPACs a Good Choice for Life Sciences Companies?**
- **SPACs and de-SPACs from an International Perspective**
  - Options in Europe, Hong Kong, Singapore versus the US
  - Opportunities for European/Asian Companies in the US
  - Tax and structural considerations for foreign companies doing a De-SPAC


Questions &
Answers
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- A seamlessly connected service that operates on any scale – locally or globally
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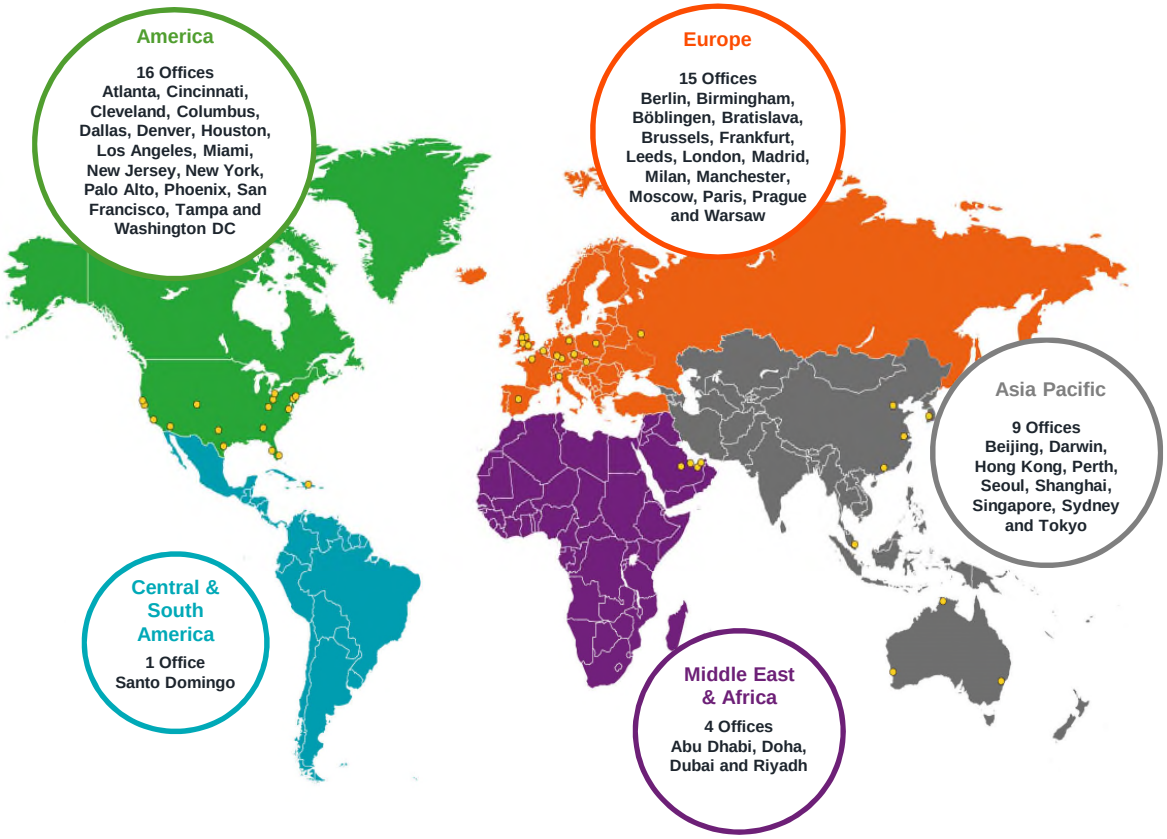
- Selected as a “go-to law” firm by in-house law departments at Fortune 500 companies
- Advise a diverse mix of clients, from long-established FTSE 100/Fortune 500 corporations to emerging businesses, start-ups and sovereign nations
- Recognising the impact of regulation/politics on business, we have a unique mix of highly experienced lobbying/political capabilities in the US, Europe and beyond

Regional Desks & Alliances
Africa
Brazil
Caribbean/Central America
India
Israel
Mexico
Turkey
Ukraine



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