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Key Issues and Current Trends for Fund Sponsors Investing Into Biotech

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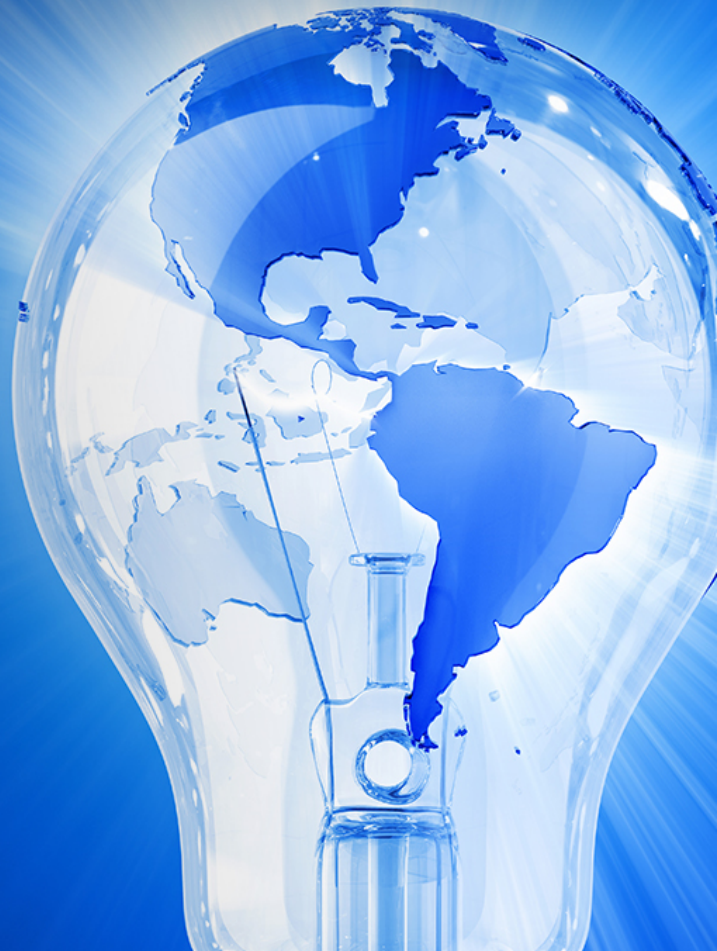

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Intellectual Property

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Intellectual Property Due Diligence

Emerging Company IP Due Diligence

- Focus on product candidates
- Chain of title for key IP covering product candidates
- Scope and duration of exclusivity position for product candidates
    - Patent, trade secret, regulatory, supply chain
    - Generic/biosimilar entry
- Freedom to operate

Established Company IP Due Diligence

- Focus existing products/revenue streams
- Review existing or imminent IP disputes
    - Access to information from litigants difficult to obtain
    - Analyst information helpful but sometimes incomplete/inaccurate
- Review key license and supply agreements

Licensing

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Licensing

1. **Key licensing considerations when investing into a "biotech"/start-up/development stage company:**
   a. Clear understanding of rights, including where rights come from and applicable limitations (e.g., chain of title, co-owners, prior licenses)
   b. Path to a commercial/revenue-generating strategy, including use of internal and external assets and understanding of contractual rights and obligations to advance development
   c. Understanding of timelines for ROI and funding heavy needs
2. **Differences between immediate licensing needs and long-term strategy:**
   a. Immediate needs are not necessarily the same as long-term needs. Licensees usually focus on immediate needs (locking-down rights; R&D) for a small company, which are different from an exit strategy and what an acquiring entity might require to advance products to commercial stage amidst a large global operation.
   b. Understanding that sacrificing in near term could hurt in the future. Certain concessions that are easier for a biotech to make, may simply be unacceptable to a big pharma (in the context of an exit) and may require going back to seek an amendment before consummating the exit. At that juncture, the original licensor will most likely look for additional consideration to enter the amendment.
   c. What does that mean? What a biotech can and is willing to deliver is different from what a big pharma/multinational may be able to, or be willing to (from a competitive and/or administrative burden/introducing possibilities for default) do.

Licensing

3. **Differences in licensing for biotech companies versus established "pharmaceutical" companies:**
    a. Experience with the various ecosystems
        i. Biotechs more nimble to work with academia/initial spin-out
        ii. Company-to-company licensing negotiation position important (e.g., desirability of asset, cash position of biotech)
    b. Administrative burdens (e.g., audit rights, reporting obligations)
        i. Biotech able to prioritize and attend to little matters
        ii. Pharma lots going on and little matters could result in "foot faults"
    c. Effects of expiration
        i. Eye on protecting downstream licensees is important for a biotech
        ii. Ensuring a clean break is important for "pharma"
4. **Issues emerging with the transition to the Biden administration:**
    a. Potential for more funding of basic research
    b. Reopening of borders/visas (COVID allowing) to access international expertise

FDA

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FDA

- COVID-19 continues to pull significant resources at FDA
  - FDA evaluated more than 400 COVID treatment proposals, 2300 EUAs
  - Issued over 600 EUAs mostly for devices
  - In 2020 FDA issued 65 industry guidances—many COVID-related
- New vaccines will be subject to different standards—comparator rather than placebo trials
- Whether and how the Biden administration invokes the Defense Production Act to address COVID and non-COVID supply chain issues is still unclear. "Buy American" policies for pharma and device products may refocus investment in US facilities and resources
- Efficiencies from COVID to non-COVID products will begin to appear but industry experts are predicting continued disruption and delay in R&D programs and product applications
- The recently issued Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan suggests FDA is turning toward use of AI and related technology tools in product development and treatments
- Drug pricing will continue to be front-and-center policy issue, along with continued emphasis on generic drugs and biosimilars

Royalties

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Royalties

- Royalty Monetization 101
- Structure
- Economics
- Diligence
- Documentation

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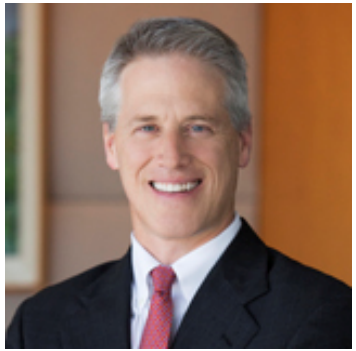
Louis W. Beardell Jr. focuses his practice on intellectual property (IP) matters in connection with patent strategies, IP due diligence, litigation, and transactions. He assists clients in developing and implementing programs that protect products and inventions including trade secrets, particularly in the life sciences, technology, and financial services fields. For US and international clients, Louis negotiates and prepares the IP aspects of licensing and purchase agreements, as well as agreements relating to product and service supply, collaboration, research, consulting, patent litigation settlement, and material transfer.

Louis counsels on all matters related to patent strategies, patent validity, patent due diligence, and freedom-to-operate opinions. His clients include an array of US and international companies in pharmaceuticals, chemicals, biotechnology, agricultural science, medical devices, and food science as well as major venture capital funds.

As companies evolve and modernize the way they operate, Louis ensures that they are able to establish exclusive positions to protect how they do business through procuring business method patents, as well as evaluating patent validity and freedom-to-operate positions for computer and business method inventions. His ability to prosecute patents and handle important trade secrets allows him to counsel clients through the creation of a diverse assortment of IP programs.

Louis frequently lecturers to academic institutions and professional organizations on a variety of IP topics. He has been hosted by US and international IP and business associations, as well as top law schools and business school IP and entrepreneur classes.

Scott D. Karchmer



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Scott D. Karchmer counsels entrepreneurs and emerging and established companies in business transactions. Representing global clients in the biotechnology, medical device, software, data analytics, financial services, fintech, and networking and storage industries, he advises companies at critical junctures in their lifecycles. Scott handles formation, raising funds from venture capitalists, initial public offerings, mergers and acquisitions (M&A), investments, divestitures, and other issues organizations confront. He also advises venture capital firms and other investors in connection with investments in private companies.

Counseling public companies on securities law, governance, and general corporate matters, Scott represents clients in capital markets transactions. He advises on private investments in public equity (PIPEs), registered direct offerings, convertible debt offerings, 144A offerings, and underwritten offerings.

Scott is the pro bono chair of Morgan Lewis's San Francisco office. He serves on the board of directors for Legal Services for Children, a San Francisco-based nonprofit organization that provides legal counsel to individuals under 18. He also volunteers for the Alameda County Food Bank.

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Andrew R. Mariniello counsels clients on a wide variety of business law matters, with an emphasis on advising public and private companies and private equity firms in domestic and cross-border mergers and acquisitions, as well as general corporate and securities law matters. Andrew has represented private equity firms, venture capital investors, and privately held companies in early stage and follow-on investments.

Andrew has helped clients navigate complex deals ranging in value from millions to billions of dollars across a wide variety of industries—including technology, life sciences, healthcare, real estate, manufacturing, and financial services. He has counseled public and private companies on corporate governance and transactional matters. In addition, Andrew has experience in the field of royalty monetizations, advising both investors and royalty holders in the structure and negotiation of a variety of royalty monetization transactions.

Before joining Morgan Lewis, Andrew was a senior corporate associate in the New York office of a major international law firm. He received his J.D. from the University of Pennsylvania Law School, before which he worked as a financial analyst in the real estate investments department of an international insurance company in New York.

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Benjamin H. Pensak counsels clients on technology transactions and related corporate matters, primarily in the life sciences industry. Ben represents international and US-based public and private companies and institutions, and his clients include biotechnology, pharmaceuticals, medical device, diagnostics, and medical informatics companies. Ben advises clients regarding negotiating and structuring acquisitions, divestitures, joint ventures, corporate partnering, licensing, and other complex collaborations. He also drafts and negotiates day-to-day technical contractual arrangements. He is the deputy leader of the firm's life sciences transactions practice. Ben is admitted in California and Pennsylvania only, and his practice is supervised by Illinois Bar members.

In his transactional work, Ben handles arrangements related to discovery, development, manufacture and supply, marketing, and outsourcing for life sciences companies and other innovative and developed technology companies. He also works with research organizations and institutions. Recognized by *Chambers USA*, Ben is hailed as having "an extremely high legal and life sciences IQ . . . . He is quick on his feet and is an excellent technical drafter."

While earning his undergraduate degree in religion, Ben conducted a range of microbiology research focused primarily on gene therapy.

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Kathleen M. Sanzo centers her practice on regulatory and compliance issues connected to products regulated by the US Food and Drug Administration (FDA). She leads and counsels clients on matters relating to prescription, OTC drug, and biotechnology products clinical testing; food, dietary supplement, and cosmetic product manufacture, approval, marketing, and distribution; device promotion and labeling issues; food, drug, and device compliance matters; and all consumer product issues regulated by the US Consumer Product Safety Commission (CPSC) and state enforcement agencies.

As the FDA practice leader, Kathleen represents clients in the pharmaceuticals and biotechnology, food and dietary supplements, consumer products, consumer protection safety, advertising, cosmetics, drugs, and medical industries.

Kathleen advises companies on regulatory pathway strategies, appropriate responses to FDA protocols and complete response letters, dispute resolution, responding to Current Good Manufacturing Practice (cGMP) issues, including 483s and Warning Letters, as well as day to day counseling on marketing and promotion launch and other communications, including responses to FDA Untitled and Warning Letters; and similar advice and counsel on food, dietary supplements, and cosmetic products, including various notices and registrations to FDA; recalls and other crisis management; and counseling on product testing, Section 15(b) notices and penalty investigations, as well as product recalls.

A frequent author and co-author on publications related to FDA matters, Kathleen regularly speaks on these issues at industry events. Industry and legal groups have praised her work: Legal Media Group Life Sciences named her the "US Regulatory Attorney of the Year," "FDA Pharmaceutical Industry Lawyer of the Year," and a "Life Sciences Star." *Chambers USA* have listed her in "America's Leading Lawyers for Business."

Kathleen serves as vice-chair of the Consumer Product Regulation Committee of the American Bar Association Section of Administrative Law and Regulatory Practice.

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Julio Vega represents public and private companies in a broad range of industries, including biotechnology, medical devices, nanotechnology, advanced materials, software, networking, e-commerce, and fintech. Julio has experience counseling clients on venture capital and other private equity financing transactions, public offerings, mergers and acquisitions, joint ventures, strategic alliances, licensing, and corporate partnering transactions. He regularly counsels clients on general corporate, employee compensation, and corporate governance matters. Julio is also very active in the representation of startup and emerging growth companies in the life sciences and technology industries.

Julio also has experience advising on international transactions and is fluent in Spanish.

Prior to joining Morgan Lewis, Julio was a partner in the emerging company, venture capital, mergers and acquisitions and securities practice of another international firm.

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Jedd H. Wider focuses on global private investment funds and managed accounts, particularly global hedge, private equity, secondary, and venture capital funds. As co-leader of the global private funds practice, he represents leading financial institutions, fund managers, and institutional investors in their roles as fund sponsors, placement agents, and investment entities. He assists clients through all stages of product development and capital raising as well as customized arrangements, seed and lead investor arrangements, and joint ventures. He specializes in all aspects of secondary transactions, and complex financial structurings.

Jedd concentrates on all aspects of bespoke fund products and arrangements including funds of one and managed accounts and regularly advises clients on all aspects of regulatory compliance.

Members of the international media often seek out Jedd for his views on the hedge fund and private equity fund industries and capital markets. His analysis can be found in US and international publications, including *The Wall Street Journal, The Economist*, and *Financial Times,* as well as on television networks such as Bloomberg and CNN.

Jedd lectures and serves as a panelist on private investment fund topics for trade programs and organizations around the world. He has delivered speeches and presentations to numerous private fund conferences such as the Hedge Fund Institutional Forum, Dow Jones Private Equity Analyst Limited Partners Summit, Endowments & Foundations Roundtable, Association of Life Insurance Counsel, National Association of Public Pension Fund Attorneys (NAPPA), West Legalworks, InfoVest21 Hedge Fund Conference, the Annual Euromoney Summit of European Hedge Funds in London, Capital Roundtable Fund Conferences, the Annual International Conference on Private Investment Funds in London, the Wharton Private Equity and Venture Capital Conference, the On Point Investors and Hedge Fund Risk Summit, and the Lazard Capital Markets Hedge Fund Conference.

Jedd is listed in *The US Legal 500*, *Chambers Global: The World's Leading Lawyers*, and *Chambers USA: America's Leading Lawyers for Business*.

He serves as an editorial board member of *The Journal of Investment Compliance* and as an editor of the *Morgan Lewis Hedge Fund Deskbook: Legal and Practical Guide for a New Era* published by Thomson Reuters/West. He regularly publishes articles on current hedge fund and private equity fund topics. He co-chairs the Annual Morgan Lewis Advanced Topics in Hedge Fund Practices Conference and chairs Morgan Lewis's Hedge Fund University Web Series.

Jedd clerked for Judge Nicholas Politan of the US District Court for the District of New Jersey and for US Attorney Rudolph Giuliani of the Southern District of New York.

THANK YOU