IP Considerations in Business Transactions Across the Life Sciences Sector

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Alicia Russo
Partner | 212.218.2568 | arusso@venable.com

Prajakta A. Sonalker, Ph.D.
Partner | 212.503.0871 | pasonalker@venable.com

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Economic Impact of Life Sciences Deals

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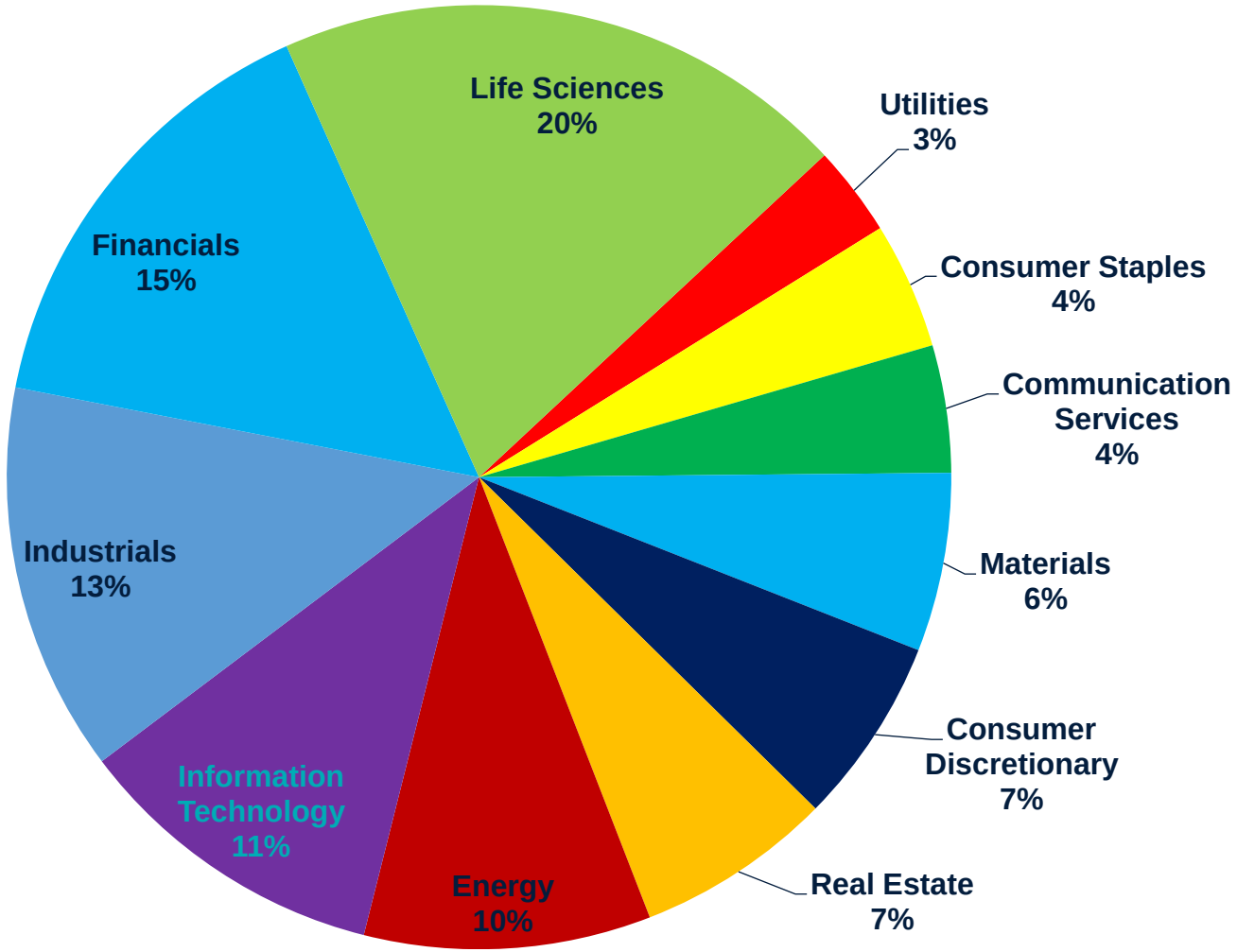
Life Sciences Deals Compared to All Deals
1H 2023 Deals by Transaction Value (Percentages)



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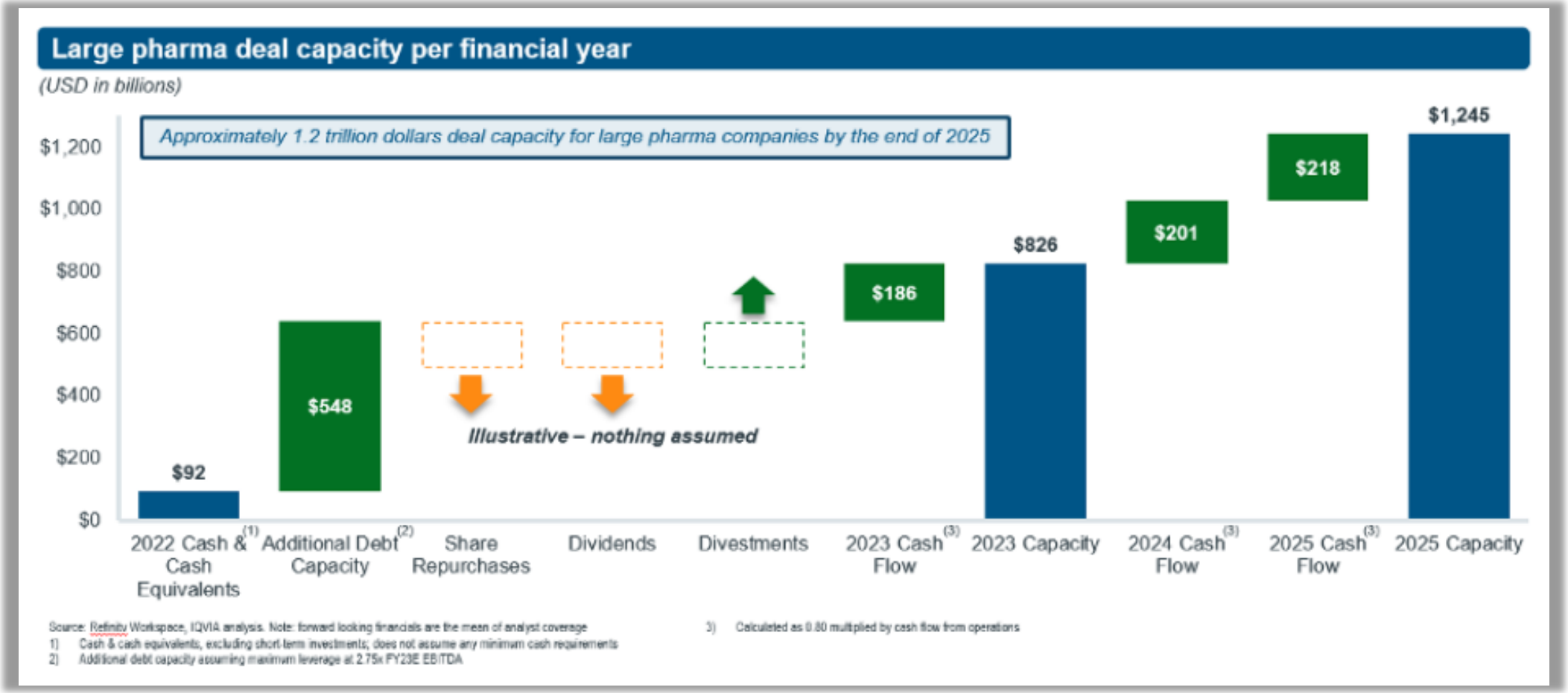
Data compiled from S&P Global Market Intelligence

Life Sciences Deal Trends through 2025

Deal capacity is growing, projected to be $1.245 trillion by 2025 for the top 15 companies



IQVIA: https://www.iqvia.com/blogs/2023/07/biopharma-m-a-momentum-returns-but-uncertainties-remain

Unique Nature of Life Sciences Deals

Complex Diligence Considerations

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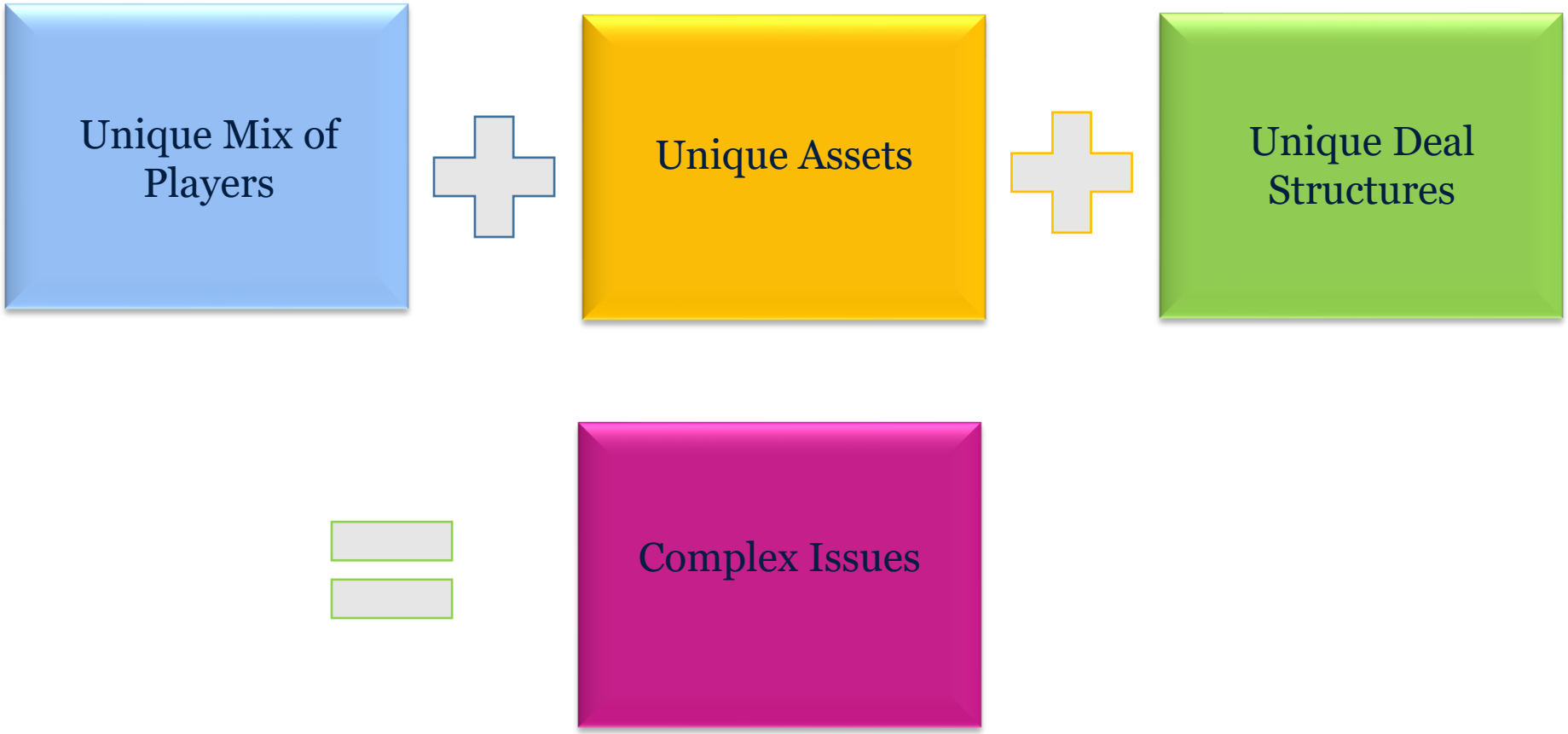
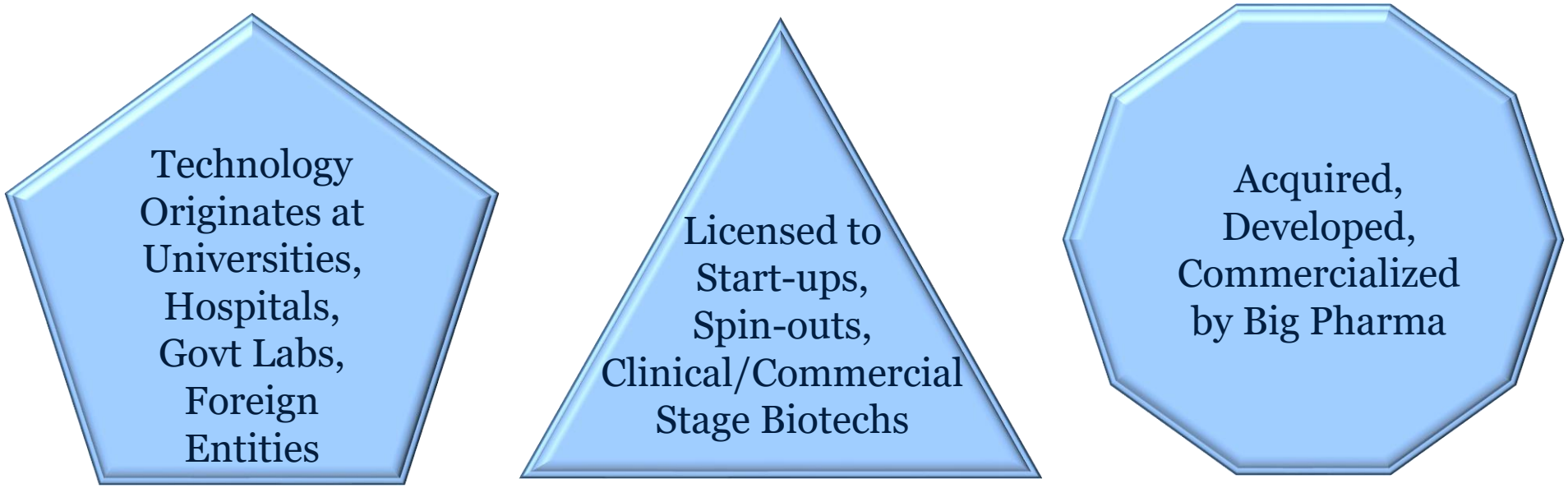
Unique Nature of Life Sciences Deals Results in Complex Diligence Considerations



Unique Mix of Players



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Challenges Raised by Unique Mix of Players

- Ownership issues
  - Trade secret considerations
  - Chain of title considerations
  - EP priority rights
- Potentially competing interests and priorities
  - Control of patents (platform vs. product vs. genus/species patents are often murky)
  - Control of development (one controlling development may have ownership of improvements)
  - Control of litigation (platform patents may be important but control by licensee is often restricted)
- Complicated agreements
  - Flow down provisions; know-how sharing; platform issues
  - IP improvement ownership issues may arise
  - Data ownership/publication rights can be complicated, particularly if dealing with a university
  - Representations/warranties may be critical to ensure value of deal but solvency/size of company may make such provisions meaningless

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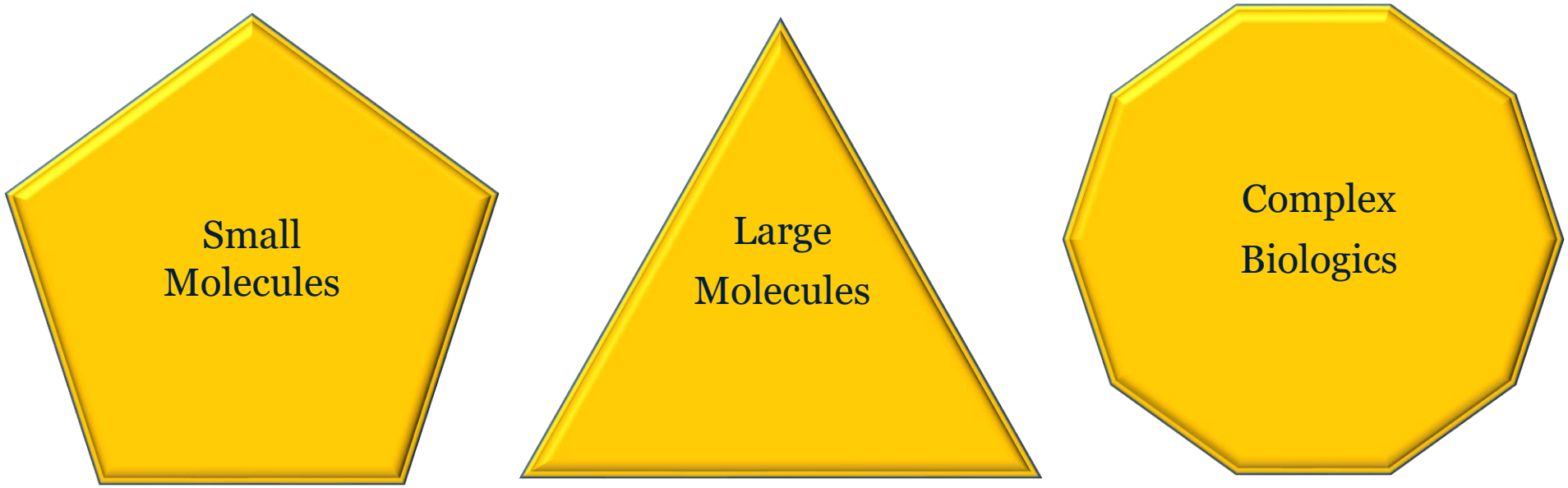
Unique Assets



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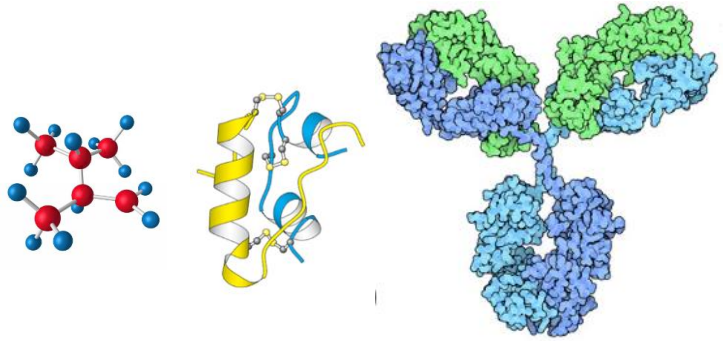
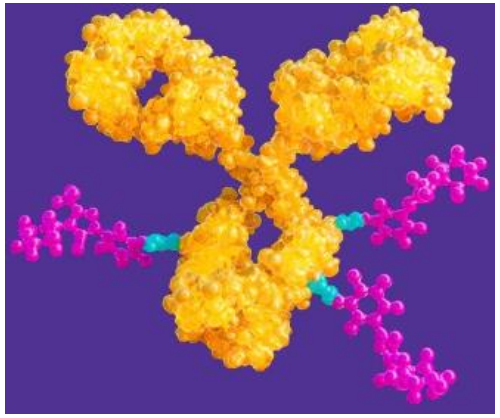
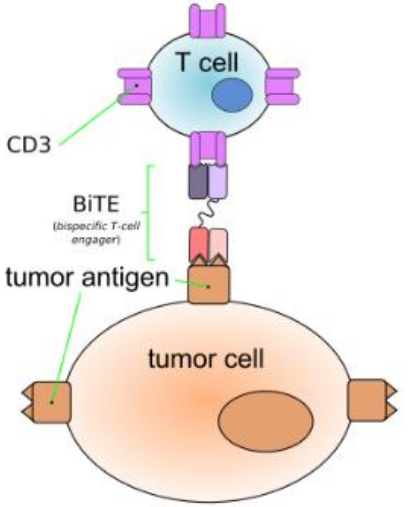
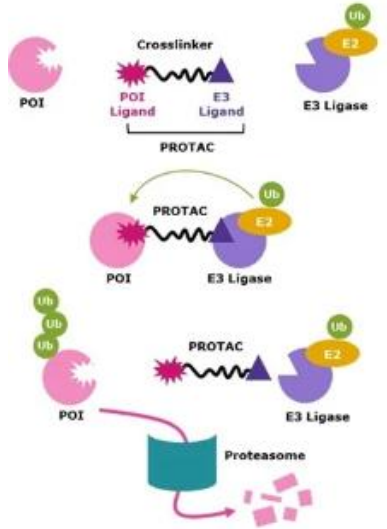
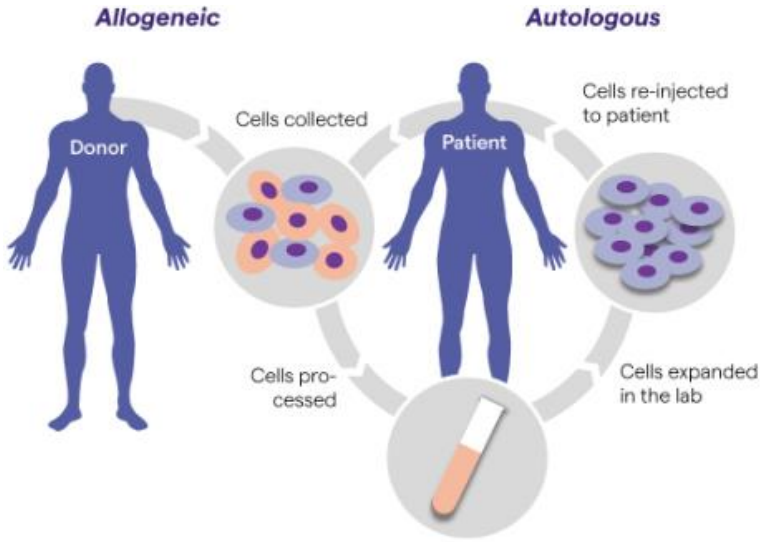
Unique Assets – Small Molecule to Gene Editing

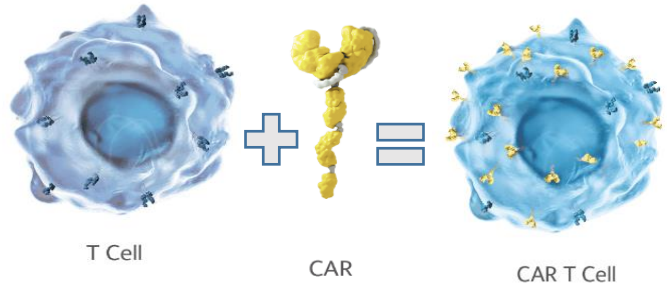


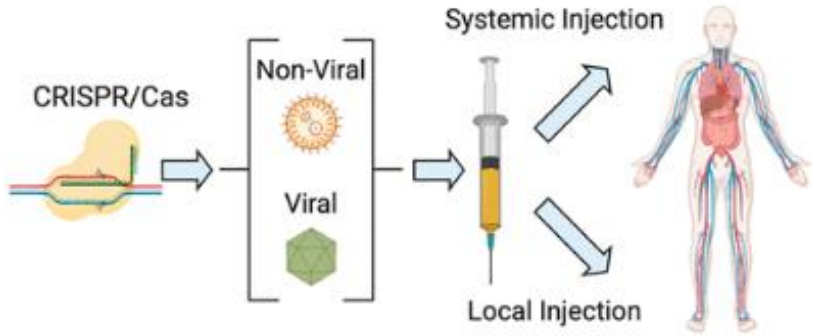












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Challenges Raised by Unique Assets

- Life Sciences assets are very complex and fundamentally different from other industries
  - Complex due diligence and upstream obligations that flow down to buyer/licensor
    - Traditional patent/IP due diligence required but may not be sufficient; Multi-tiered complex IP due diligence of every aspect of asset, including, e.g., protein modifications, manufacturing (including vectors, cell lines, cell growth conditions, etc.), gene editing technologies, research tool analysis
      - Numerous licenses may be required to practice the invention and may not exist from target company
  - Corporate due diligence of upstream agreements is critical
    - SEC filings and public company due diligence often not sufficient
      - Target companies are often not publicly traded or materiality thresholds and confidentiality mean upstream agreements often not filed or fully disclosed
      - Many licenses required/exist; many opportunities for mistakes; potential obligations to third party licensors can impact value of deal (unless licensor responsible)
      - Could have onerous obligations to share confidential information
      - Improvement IP ownership rights
      - Licensor many not renegotiate terms

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Other Asset Considerations: Phase of Assets (Discovery, Phase I, Phase II, Phase III, etc.)

- Phase of asset impacts the deal
- Earlier-stage assets likely to have lower valuations
  - Leads may not be viable
  - More risk with clinical development/commercialization efforts
- Deal valuation considerations
  - Costs: early-stage assets result in increased costs associated with development
  - Value depends heavily on patient population and indication (e.g., oncology vs. dermatology). – Phase III or Market assets = higher premiums, bigger upfronts - less risk
  - Type of modality or technology – it's critical to understand the science and the risks associated with the technology – IP diligence critical for assessing valuation
    - The risks associated with a gene editing deal vs. small molecule deal are very different

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Unique Agreement Strategies

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Nature of the Deal

- Partnerships/collaborations
  - The partner owning the technology has likely conducted diligence on the asset
    - Possible to lower diligence efforts if partner is willing to take on some risk
      - Consider infringement/ownership reps/warranties to shift risk but if partner is small startup, such reps/warranties may be irrelevant if the partner becomes insolvent
- Options
  - Options are useful ways to ensure a first right to an asset should the research prove fruitful and can avoid significant upfront payments for early-stage assets. Certain diligence efforts can be postponed, like deep dive IP diligence. However, control of asset, IP, litigation, etc. during option phase will likely not be possible
- Licenses
  - Require more diligence to ensure proper valuation but may still be able to shift some risk to licensor with reps/warranties – solvency issues still a consideration
- Asset Acquisitions and M&A: reps/warranties will be minimally useful. Diligence efforts should be fully vetted. Post-closing deal requirements may be hard to achieve – should have issues buttoned up pre-closing if possible
- Nature of the target may impact valuation – obligations to employees (particularly for foreign entities) should be considered – remuneration and other obligations can be considerable

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Recent Case Law Developments

Potential Impact on IP Diligences

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Enablement

Amgen Inc. v. Sanofi, No. 21-757 (U.S. May. 18, 2023).

- Expect a shift in investment, transactions, patent prosecution and litigation strategies in life sciences industry
- Expect more enablement challenges as parties debate what is covered within "the full scope of the invention"
- Broad functional patents susceptible to challenge, potentially impacting how life sciences companies/investors value patents and interpret freedom-to-operate hurdles posed by those patents
- Expect life sciences companies to fast-track existing programs or to develop new competing products and de-risk patents from FTO standpoint (especially those covering foundational technologies)
- Expect impact on generic and biosimilars filers that are developing their pre-litigation strategies for challenging innovator patents
- Expect increased scrutiny in life sciences transactions as parties attempt to resolve how much experimentation is considered "reasonable degree of experimentation" under *Amgen v. Sanofi*
- Consider potential impact on in-licensed and out-licensed technologies
  - Monetization of IP
  - 112 challenges to licensed patents

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Obviousness-Type Double Patenting (OTDP)

In re Cellect, No. 2022-1293 (Fed. Cir. Aug. 28, 2023).

- Expect life science companies to:
  - Audit existing patent portfolios for potential OTDP, including whether to file terminal disclaimers for "patentably indistinct" claims across patents
  - Carefully build future patent portfolios by seeking counsel from attorneys with both transaction and litigation expertise
  - Several considerations play a key role:
    - Potential impact of patent portfolios/multiple patents on LOE, including PTE
    - Whether terminal disclaimers for patent families are an adequate recourse, and if so timing
    - Strategically drafting claims to benefit from safe harbor provisions of 35 U.S.C. § 121
  - Scrutinize third-party patent portfolios (whether assessing target IP or potential FTO) by conducting thorough OTDP analyses
  - Adopt a wait-and-see approach
    - *In re Cellect* not yet settled law – expect rehearing or further appeals to Supreme Court

Assignor Estoppel

Minerva Surgical, Inc. v. Hologic, Inc., 141 S. Ct. 2298 (2021)

- Supreme Court's decision limits application of assignor estoppel, which bars inventors-assignors of patents from challenging validity of the patents they previously assigned
  - E.g., serial entrepreneurs/improvements by inventors-assignors
- Assignor estoppel does not apply if:
  - Assignment occurs before inventor can make a warranty of validity as to specific patent claims, e.g., employment agreements that include present grant of rights in future inventions
  - Later legal developments render warranty given at time of assignment irrelevant, e.g., 101, 112, etc.
  - Assignee enlarges patent claim scope such that claims are "materially broader" than claims of previously assigned patents
- Assignees need to be aware that adding or amending claims to make them materially broader than what was originally assigned could result in later patent being susceptible to invalidity challenges by inventors-assignors
- Parties that assign or acquire patents may need to review agreements, reconsider blanket assignments covering multiple patents and revise assignment language to make them explicit and narrowly tailored to each patent
- Consider including express provisions in employment agreements preventing inventors from later challenging validity of assigned patents
- Non-compete agreements

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Artificial Intelligence (AI) in Life Sciences

- Increasing use of AI systems from drug discovery and development ranging from identifying targets, designing drugs or biologics, precision diagnostics to design and support of clinical trials
- At least in US copyright law, DC District Court recently (Aug. 18, 2023) held that AI-generated work "absent any guiding human hand" is not protected by copyright, reasoning that "[h]uman authorship is a bedrock requirement of copyright." *Thaler v. Perlmutter*, No. 1:22-cv-01564, (D.D.C. 2022)
- Patent legal landscape remains unclear
  - AI systems typically not considered "inventors" in U.S. (35 U.S.C. § 100)
    - Mar. 17, 2023: Stephen Thaler petitioned Supreme Court to review whether patents can only be issued to human inventors or whether his AI system can be the legal creator of inventions it generated. SCOTUS refused to weigh in on the issue. *Thaler v. Vidal*, No. 2021-2347 (U.S. Aug. 5, 2022); *Thaler v. Vidal*, 43 F.4th 1207 (Fed. Cir. 2022)
  - Some jurisdictions (e.g., Australia, South Africa) have held that AI systems can be named as an inventor, while other jurisdictions (e.g., European Union, UK) have held otherwise
  - Query whether inventions made by humans "with the assistance of AI" would be patent eligible
- For deals involving AI, consider additional issues such as data, cybersecurity, privacy and IP rights
  - Reps and warranties
- Policy changes

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Questions?

Meet Our Speakers

Alicia A. Russo
Partner
+1 212.218.2568
arusso@Venable.com

Alicia Russo is a co-chair of Venable's Intellectual Property Transactions Group. Alicia has significant experience in IP due diligence and licensing associated with high-profile acquisitions. She has represented clients in complex patent litigation and contested proceedings before the United States Patent and Trademark Office (USPTO), and has secured patents for clients in numerous technical fields. She focuses on biologics and small-molecule pharmaceuticals, informed by her prior work in medical research. Alicia also advises clients on matters related to energy, fiber technology, building materials, biotechnology, and bioinformatics.

Prajakta A. Sonalker, Ph.D.
Partner
+1 212.503.0871
psonalker@Venable.com

Prajakta Sonalker focuses her practice on complex intellectual property litigation, including patent and trade secret disputes, with an emphasis on biotechnology and pharmaceuticals. Prajakta has experience in all stages of litigation, from pre-suit investigations through trial and appeals, and proceedings before the Patent Trial and Appeal Board (PTAB). She counsels clients on a variety of technologies, including cell and gene therapies, vaccines, antisense oligonucleotides, RNA interference, biologics, small molecules, pharmaceuticals, and medical devices. Prajakta also advises clients on patent licensing and due diligence, and assists clients in multijurisdictional and parallel proceedings outside the U.S.

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Appendix

General IP Diligence Considerations

Key Points to Address in IP Diligence

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Goals for Diligence

- Review all owned and/or licensed patents and applications by product, including foreign counterparts, and their status
- Assess validity/enforceability of key patent families for assets of interest
- Ensure target owns the patents or has licensed rights
- Conduct freedom-to-operate on the key assets
  - Is there any third-party IP that may be infringed (freedom-to-operate)?
    - Has the target received a notice from a third party regarding infringement?
- Assess whether the target has been involved in any disputes (including ownership/infringement/validity of target's IP)
  - Does the target anticipate any such disputes?
- Determine whether there have been any patent office proceedings relating to the patent families of interest

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Review of Target's IP

- **Patents – high-level review**
  - Patents valid and in force – maintenance fees paid, pending cases, breath/pendency of foreign filings
  - Gaps in patent coverage for products? Future IP planned? Does IP cover indications/formulations/etc.?
  - Issues with priority rights (EP considerations - Applicant consistent for priority application)
- **Patents – Ownership**
  - Issued patents have clear chain of title – check assignments – are patents assigned to current contracting entity? Assess employment agreements, which usually govern the assignment of the inventions
  - Are there any third party inventorship interests or inventorship disputes? Research prior employment of inventors and whether there are any potential ties to prior employers (research on similar subject matter? Close in time for leaving prior employer and filing patent applications?)
  - Are there any liens, security interests or other third-party rights in patents/applications?

LOE Assessment

- Double-check expiration of patents
- Impact of regulatory exclusivities and extensions (e.g., ODE/PTE)
  - Does regulatory exclusivity govern or patent exclusivity?
- Double patenting issues
  - PTA may no longer be available – impact on PTE determination?
- Consider potential future protection (e.g., new indications for patenting, pediatric studies)
- Assessment of LOE for key foreign jurisdictions – EP, JP, CN
  - Consider new EP legislation which shortens regulatory exclusivities

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Review of Target's IP-related Agreements

- Research & Development Agreements
- Material Transfer Agreements
- Funding Arrangements or Agreements
- Government & University Sponsorship/Agreements
  - CRADAs, grants, etc.
- Licenses or Rights Granted to Third Parties
- Covenants Not to Sue, Supply and Indemnification Agreements
- Audits
- Non-Disclosure Agreements
- Executive/employment agreements
  - Obligations to assign/confidentiality provisions/obligations to participate in ongoing prosecution/litigation
  - Consider remuneration provisions for foreign entities

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Patentability Assessment

- Prior Art Searches and Considered References
- Publications Related to the Product
- Correspondence with Third Party Challenging Product
- Laboratory Notebooks or Other Materials Supporting Patent Application
- Laboratory Notebooks or Other Materials Supporting Any Declarations
- Request Invention Story
- Avoid Privileged Information to Preserve Privilege

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Contested Proceedings

- Past or Ongoing Litigations Relating to the Product
- Distinguish US or Foreign Decisions That May Impact the Product
- Assess Past or Current US or Foreign Patent Office Proceedings Relating to the Product
  - Any potential worldwide impacts
  - Any declarations/admissions in foreign jurisdictions/inconsistent positions?
- Contemplated Assertion Against Third Parties
- Paragraph IV Notice Letters
- Cease and Desist Letters
- Notice Letters Received from Third Parties
- Settlement Agreements and Releases

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Review of Target's IP-related FDA Documents

- Sections relating to manufacture/formulation/etc.
  - Obtain information for freedom-to-operate analyses
- Dates for IND/NDA for LOE assessment
- Draft label documents
- Who filed IND/NDA?
  - Relationship to target company

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