

The background of the slide features a dynamic, abstract design. It consists of numerous thin, parallel lines that sweep across the frame from the bottom left towards the top right. These lines are primarily in shades of deep red and vibrant blue, creating a sense of motion and energy. The lines vary in opacity and thickness, with some appearing as sharp, bright streaks and others as softer, more blended washes of color. The overall effect is reminiscent of a high-speed light trail or a stylized representation of data flow.

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M&A ACADEMY

What Makes Life Sciences Transactions Different

Tony Chan, Jacqueline Berman and Janice Logan, Ph.D.
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What Is Driving Life Sciences M&A?

- Continued volatility is expected in 2019:
 - Trade tensions between US and China continues;
 - Political pressure on drug prices in the US;
 - Generic competition and biosimilars; and
 - Patent expiries
- However opportunities remain:
 - Technology-oriented adjacencies represent an significant opportunity for both traditional players as well as technology companies;
 - Novel therapies;
 - Increasing access to health care worldwide and prescription drug spend;
 - Orphan drug market is expected to double over the next 5 years; and
 - Patent extensions and regulatory exclusivity

Source: *Deloitte 2019 Life Sciences Outlook* United States

What Are The Significant Life Sciences Market Trends?

- Pharmaceutical Drug and Disease Trends: Worldwide prescription drug spend expected to rise from USD 900 billion to 1200 billion by 2024.
- Orphan Drugs: By 2024, the orphan drugs sector expected to double and account for 20 percent of prescription sale.
- Biosimilars and Generics: The FDA is accelerating the approval process through its Biosimilars Action Plan. Through 2024, US\$251 billion in drug revenues are at risk from patent expiries, which may create opportunities for generic manufacturers.
- Personalized Medicine; Next-generation Cell and Gene Therapies: The global personalized medicine market is expected to see 11 CAGR percent through 2024. In 2019, the shift to value-based personalized health care will result in the creation of new platforms to support the patient. The CAR-T market is projected to grow at an annualized rate of over 51 percent through 2030.
- Med-tech: Projected to grow at a 5.6 percent through 2024, with the fastest growing areas anticipated to be Neurology, Diabetic Care and General and Plastic Surgery/Dental and Software-as-a-Medical Device (SaMD) expected to grow rapidly as well.
- Geopolitical Uncertainty: Disputes over US health care policies expected to continue, resulting in uncertainty for market players. Brexit has raised risks for economies and health care systems across the region.
- Pricing pressures: Predicted to continue, driven by governments, patent expiries, and increased promotion of generics and biosimilars.

Source: *Deloitte 2019 Life Sciences Outlook* United States

What Are The Significant Life Sciences Market Trends (cont.)?

- While the number of deals in 2018 decreased 9% compared to 2017, the value was more than 22% higher than 2017.
- In 2018, US deals accounted for the second highest deal value, representing \$82.2B, and the most number of deals.
- The following factors are expected to drive an active M&A market in 2019:
 - access to capital (currently on balance sheets as well as available financing);
 - capital markets normalizing for biotech companies after a year of robust valuations;
 - a need for companies to execute on their growth strategies.
- Divestitures will drive M&A in 2019 as larger companies look to divest noncore / non-strategic assets.
- The first half of 2019 is expected to be a robust period for Biotech IPOs and other fund-raising activity although there is some concern about a slow down later in the year.

Source: *PWC Pharmaceutical and Life Sciences Deals Insights Quarterly Q4 2018*

What Is Different About Life Sciences M & A?

- Specialized due diligence (IP, licensing and partnering/collaboration, government grants/rights, FDA/health regulatory and international compliance, including FCPA) depending upon the stage of development.
- Specialized representations, warranties, pre-closing covenants and indemnities (private deals) that tie into due diligence issues.
- Special conditions of closing and MAE definitions that tie into due diligence issues and/or regulatory or commercial milestones.
- Frequent use of earn-outs (private deals) or contingent value rights (public deals) tied to regulatory and commercial milestones/milestone payments to bridge valuation gaps.
- In asset or carve-out transactions (as opposed to acquisition of entire company), need for ancillary documents relating to common IP, sharing or referencing of regulatory data, clinical development material/cell banks, transition services, noncompetition.
- Employment/retention agreements for personnel are critical to the drug/product development process.
- Post-closing integration guided by specialized due diligence; corporate cultural differences (biotech vs pharma); development team and product sales force integration issues.

What Are the Key Areas of Specialized Due Diligence?

- IP
- Licensing and partnering/collaboration
- FDA
- Healthcare reimbursement and regulatory
- International compliance
- Impact of RWI

What Are the Key IP Due Diligence Issues?

- With early-stage biotechs, IP and key people may be only real assets

Ownership and right to use key platform technology



Rights to inventions of employees/consultants – confirming proper assignment (including provisional applications) and assessing IP “leakage” risk



Scope of in-licensed and out-licensed rights, definition of products, territories



Rights of US Government to IP under Bayh-Dole or other funding agreements

What Are the Key IP Due Diligence Issues?

- Strength of IP
- Availability of potential workarounds (e.g., biosimilars, generics, off-label sales)
- Evaluation of IP in relevant market jurisdictions (US, EP, Asia)
- Freedom to operate (FTO); need for third-party licenses
- Patent cliff issues and barriers to entry (e.g., regulatory exclusivity/evidence of anticompetitive conduct (e.g., “pay to delay”))
- Actual or threatened claims
 - Litigiousness of competitors
- Evaluation of IP portfolio under changing legal standards
- Impact of FDA and regulatory regimes

Changing Legal Standards

- New post-America Invents Act (AIA) changes rules about what is prior art
- AIA enacted Inter Partes Reviews (IPRs)
 - Alternative to or in addition to district court litigation to attack validity of issued patents
 - Easier to invalidate patents in an IPR
 - Evaluation of breadth of claims: remedial action or attack competitors
- “Patentable Subject Matter” § 101 issues
- “Written Description” § 112 issues



"Patentable Subject Matter" § 101 issues



- ***Mayo v. Prometheus* (2012)**
 - Diagnostic method reciting ["law of nature" + "well-known, routine, conventional"] steps is not a patent-eligible matter
 - Patentable subject matter requires **"something more"**
- ***Association for Molecular Pathology v. Myriad* (2013)**
 - Removal of introns (cDNA) represents "something more" and is patent-eligible
 - An "isolated" sequence (DNA, RNA, protein) is not necessarily patentable subject matter
- ***Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), cert denied**
 - Because the recited steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful.
- **Diagnostics, bioinformatics, methods all at risk**

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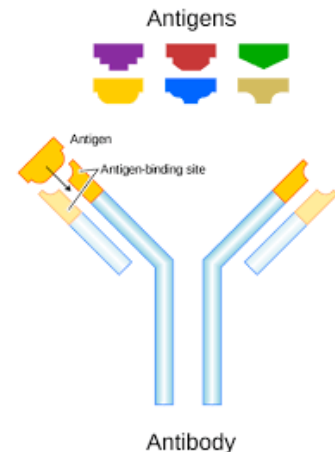


“Written Description” § 112 issues

- 35 U.S.C. § 112, paragraph 1 requires that a patent specification must contain a written description of the invention
- Written description/enablement may be raised in IPRs
 - in context of entitlement to priority date benefit
 - *Globus Medical, Inc. v. Depuy Synthes Products, LLC*, IPR2015-00099, IPR2015-00107, IPR2015-00107 (PTAB May 1, 2015): Petitions denied because petitioner did not establish entitlement to priority date of reference
 - If Petitioner, attack priority claim of challenged claims and attack written description support of proposed substitute claims in a Patent Owner’s motion to amend.
 - If Patent Owner, attack priority claim of reference and also provide written description support in original disclosure if propose substitute claims in a motion to amend.

Amgen v. Sanofi, 872 F. 3d 1367 (Fed. Cir. 2017), cert denied

- Claimed antibody is defined by antigen.
- Claims are invalidated because the specification did not disclose "a representative number of species falling within the scope of the genus *or* structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus."



FDA Due Diligence: Issues to Consider – Determining the Scope

- What is being acquired?
 - Specific products or the entire company
- What is material to the transaction?
 - Will dictate where to focus
- What stage are the products?
 - Pre-market
 - Post-market
- Following closing, how will the company be operated?

FDA Due Diligence: Issues to Consider – Cross Cutting Issues

- Regulatory Correspondence (*e.g.*, meetings, letters, submission, summaries)
- Enforcement Actions (*e.g.*, warning and untitled letters, import alerts)
- Manufacturing (*e.g.*, cGMP compliance, recalls)
- Product Life Cycle (*e.g.*, exclusivity, additional uses/indications)
- Competition (*e.g.*, similar products, blocking products, follow-on products)
- Contractual Agreements (*e.g.*, partners, licensees, licensors, contractors/service providers)
- Overall regulatory landscape

FDA Due Diligence: Issues to Consider – Premarket Products

- Do the company's strategy and timeline align with FDA's?
- Scientific Assessment-Preclinical and Clinical Trials
 - Safety and efficacy results (*e.g.*, AEs/toxicities, preclinical indicators, clinical endpoints)
 - Study design (*e.g.*, scientific validity, consistency with FDA expectations)
 - Third-party reviewer comments (*e.g.*, IRBs, DSMBs)
- Regulatory Compliance (*e.g.*, GCPs/GLPs, clinicaltrials.gov)
- Application strategies
 - Application, specialized, and expedited pathways
 - Device strategies (*e.g.*, drug-device combinations, IVDs)
 - Application impediments (*e.g.*, patent certifications, citizen petitions)
 - Controlled substance scheduling designations
- Voucher opportunities

FDA Due Diligence: Issues to Consider – Marketed Products

- Basis for marketing
- Labeling (*e.g.*, restrictions, off-label risks)
- Safety/Efficacy
 - Robust pharmacovigilance system
 - Identified serious issues
- Promotional practices
- Post-approval Obligations (*e.g.*, REMS, Phase IV studies, controlled substances)
- Licensing/Registration Requirements
 - FDA, DEA, State licenses/registrations
 - License transfers

What Are The Specialized Representation, Warranty and Pre-closing Covenants and Indemnities?

- The acquisition agreement will contain detailed representations and warranties covering the key due diligence areas discussed above, which serves two purposes: (1) creates legal protection through conditions to closing (public deals) or indemnities for breach that survive closing (private deals) and (2) requires disclosure that helps with post-closing integration.
- Many deals are subject to two steps: (1) signing and public announcement (public company deals) and (2) closing following receipt of required regulatory approvals (e.g. HSR, SEC) and the gap between the two can in certain cases last 3 months or longer.
- Special conditions of closing or material adverse change clauses may be included to address potential issues between signing and closing, such as failure of clinical trials, product recalls, or termination of material license or collaboration agreements.
- Special pre-closing covenants will regulate ongoing regulatory, clinical, product development and other activities that could materially affect the business.
- To bridge valuation gaps with respect to products in development, earn-outs in private deals or contingent value rights in public deals are often included to compensate sellers for subsequent successful regulatory and commercial milestones; significant value can be deferred, and in private deals earn-outs are a large source of disputes.

What are the Common Contingent Consideration Structures?

- Escrows
- Deferred Purchase Price
- Earn-Outs
- Royalties
- Regulatory Milestones
- Sales Milestones
- Contingent M&A
- Commercially Reasonable Efforts
- Acceleration and Liquidated Damages

15. What Are Special Considerations for Asset or Carve-Out Transactions?

- In asset or carve-out transactions (as opposed to acquisitions of the entire company), there is often a need for ancillary agreements relating to the following:
 - Common IP – which may require cross-licensing within a defined field.
 - Sharing or referencing of clinical data or clinical material/cell banks with respect to separate development activities.
 - Transition services for supply, manufacturing, laboratory, personnel, accounting, and other back-office functions and other nontransferred resources.
 - Noncompetition agreements to define the respective fields of development and commercialization.

Biography



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Jacqueline R. Berman advises companies on US Food and Drug Administration (FDA) regulatory, compliance, and enforcement issues, as well as clinical trials and FDA-regulated product development programs. She also counsels clients on the safety, labeling, and reporting requirements for consumer products under the laws enforced by the US Consumer Product Safety Commission (CPSC), the Federal Trade Commission (FTC), and related state enforcement agencies. Jacqueline's clients include pharmaceutical, device, biologic, dietary supplement, and food/food additive manufacturers.



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Tony Chan has more than 15 years of experience advising companies on mergers and acquisitions (M&A), private equity, growth equity, and venture capital transactions, as well as on corporate governance, emerging company representation, and corporate finance. Tony's clients include strategic buyers and sellers as well as financial sponsors and their portfolio companies in the life sciences, investment management, technology, and video game sectors. He also regularly advises on complex international and cross-border matters.



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Janice Logan brings an extensive science and engineering background to her intellectual property law practice, focusing primarily on biotechnology, chemistry, and materials engineering matters. She guides clients through complex patent procurement and patent litigation matters, and handles patent portfolio management and development. She also manages due diligence for intellectual property asset transactions. Janice is fluent in Korean and Japanese.

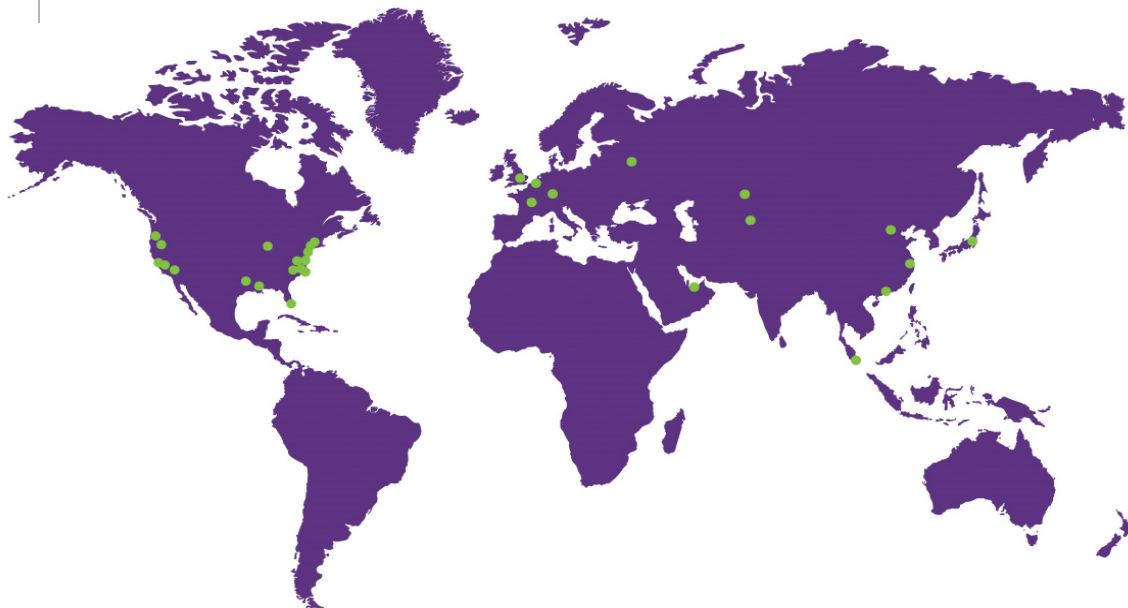


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