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European Life Sciences Market Trends: Corporate, Collaboration, IP, Competition

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Jayne McGlynn, Mike Pierides & Omar Shah

7 October 2020

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COVID-19: Immediate Impacts

It all started at Biogen conference in Boston

Remote working becomes the new normal

Exceptions for critical infrastructure / essential workers

- Anyone in pharma supply chain, including clinical stage
- Safety measures
- Staff reductions

COVID-19: Clinical Developments

Enrolment/recruitment delays

- Worldwide geographic variations over next year
- Scepticism on the part of potential partners
- Particularly acute in certain modes of administration

Patient follow-up delays

Regulator bandwidth / protocol amendments

Delays at suppliers, pack and fill

Potentially longer term impact on development timelines and financing

COVID-19: Financing Impact

Financing needs:

- To bridge delays
- Build nest egg for potential downturn / choppy markets

Surprisingly robust capital markets throughout 2020

Substantial amounts raised in IPOs and follow-ons

Disclosures and risk factors

- Development timelines
- Financing needs
- Health system capacity

US Trends – Life Sciences in the Capital Markets

By August 2020:

- Approximately $9.4 billion in IPOs raised by US-listed biotech companies, but only $6.5 billion in the whole of 2018
- Over $32 billion raised by biotech companies in follow-ons

In Q2 2020:

- Over $17.6B in equity funding into biopharma across IPOs and follow-ons (excluding Regeneron and Royalty Pharma offerings)
- The most capital raised at biotech IPO fundraising level in one quarter

In the first half of 2020:

- Biotech comprised over 80% of all pharma and life sciences deal volumes
- 148% increase in pharma and life sciences proceeds

UK Trends – Life Sciences in the Capital Markets

In the first half of 2020:

- In 40 transactions on the Main Market and AIM, over £2 billion was raised in the highest number of deals in life sciences and healthcare since 2008
- Life sciences and healthcare constituted 21.2% of total AIM deal volume, making it the dominant sector for the second consecutive year
- Healthcare was the only sector that did not experience broad-bases losses on the FTSE All Share, down 14.5% since the start of the year

Between March and August 2020:

- Over £775 million was raised by AIM-listed companies within the healthcare sector, most of these being pharmaceutical and biotech companies


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Trends in Life Sciences M&A
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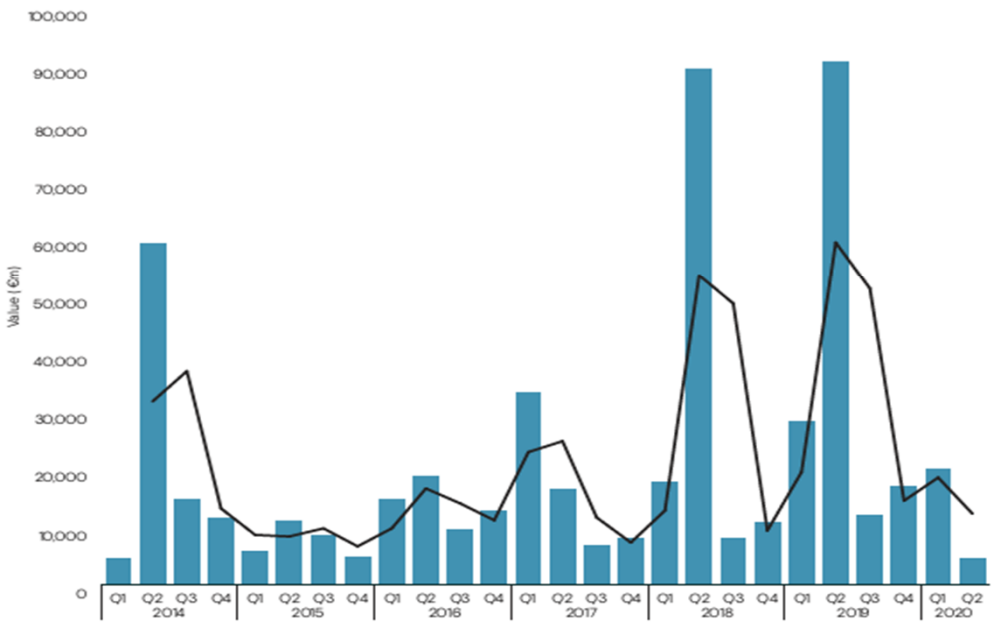
European Life Sciences M&A in H1 2020

Quarterly M&A activity
Value

Based on announced deals, excluding those that lapsed or were withdrawn, where the dominant location of the target is in Europe. Industry sector is based on the dominant industry of the target.



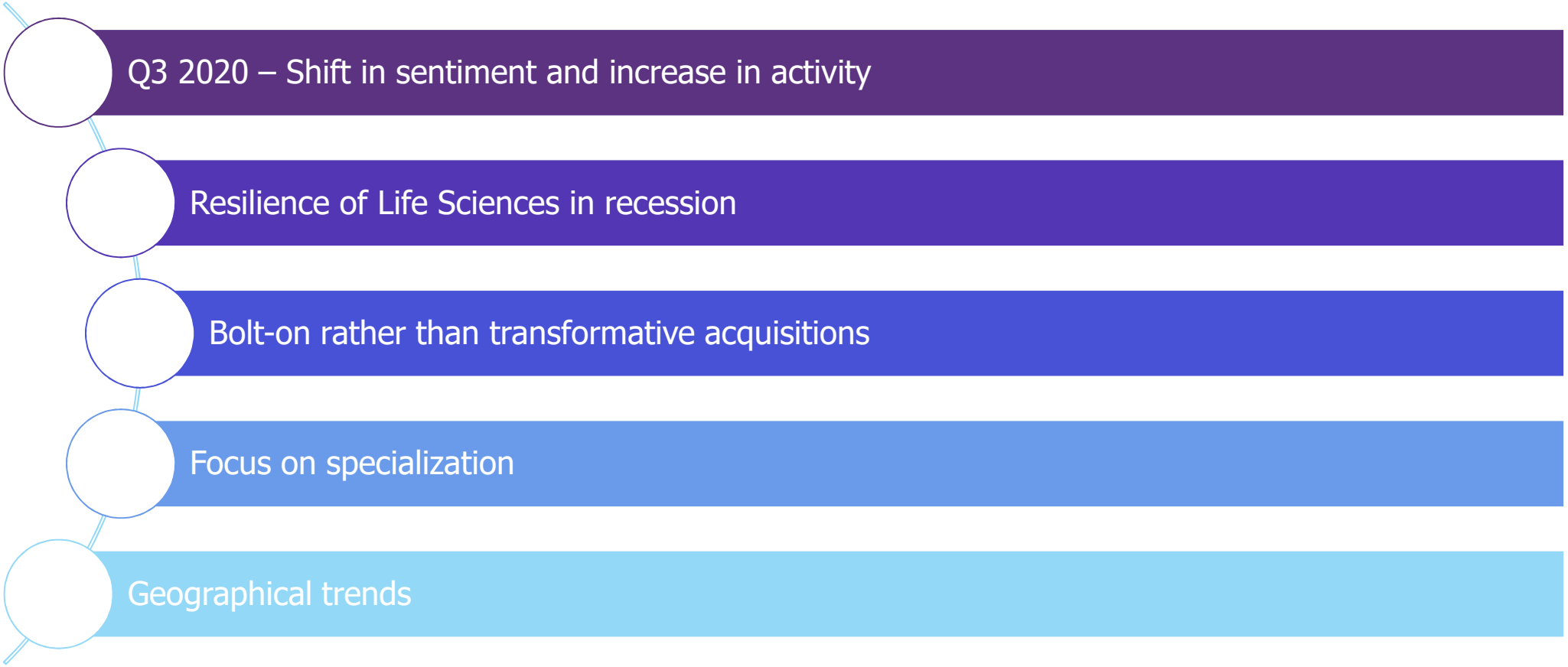
Deal value — Moving average trend line

Source: MergerMarket 2020

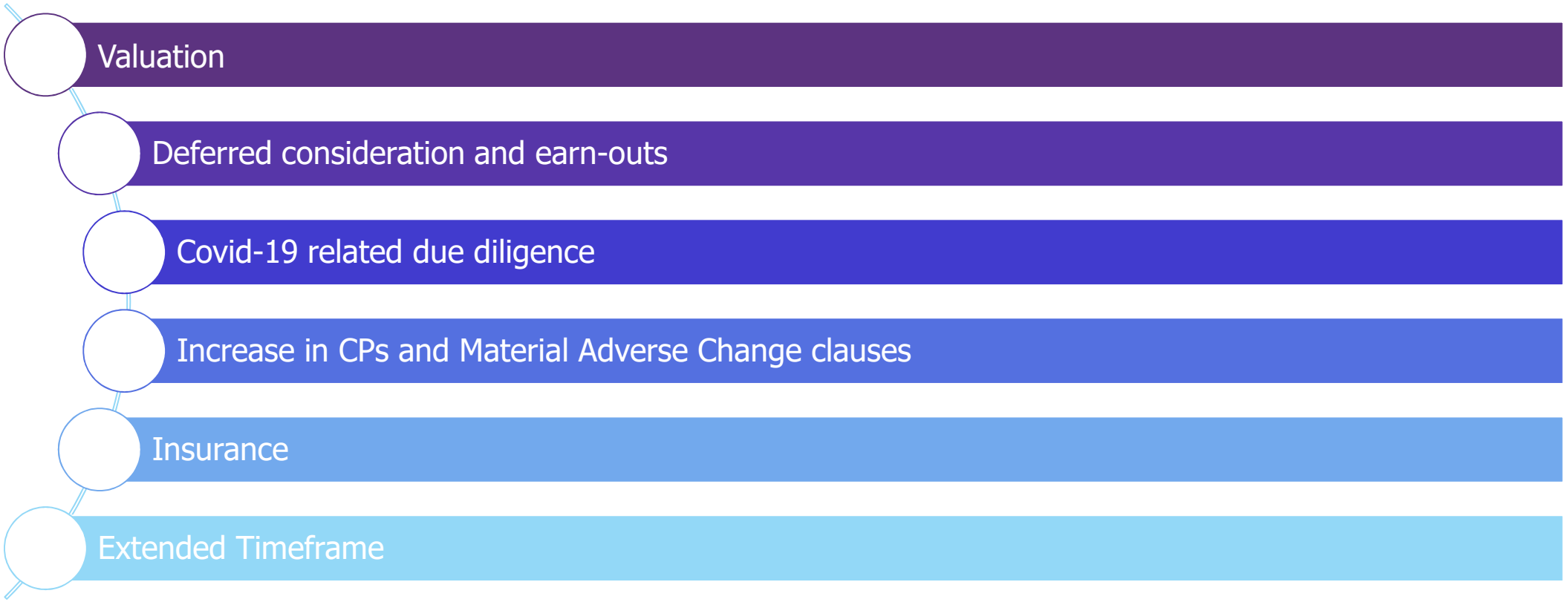
Top Announced Deals H1 2020: European Targets

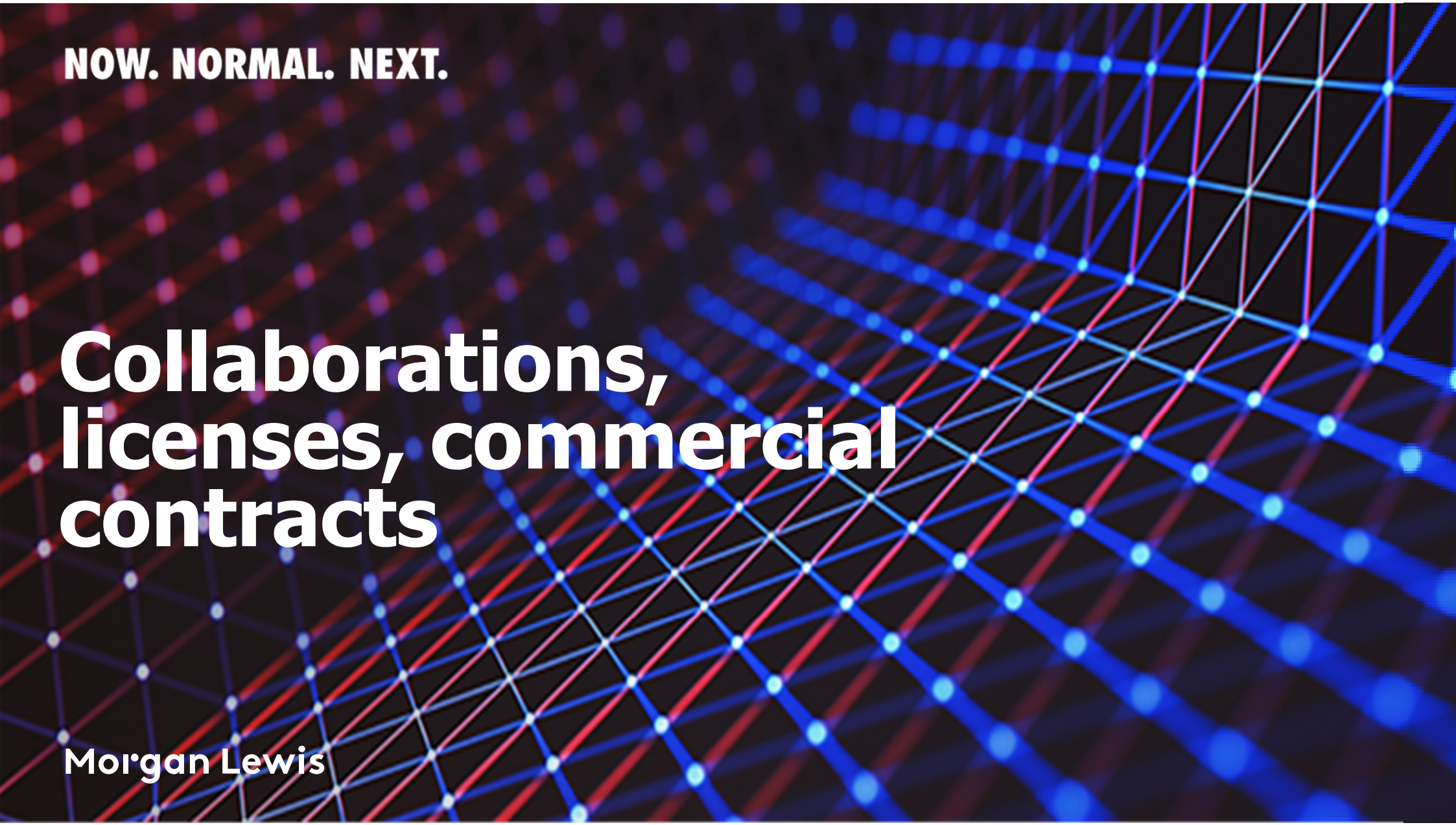
Deal Value (€m)	Bidder	Target
9,843	Thermo Fisher Scientific Inc.	QIAGEN NN
5,000	Mitsui, Temasek Holdings & others	Ceva Sante Animale SA
980	Royal DSM NV	ERBER AG
950	Ardian, UI Gestion SA, Groupe HLD	Elive SAD
765	Royal DSM NV	Glycom A/S

M&A Forecast H2 2020



2020 Deal Trends

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Collaborations, licenses, commercial contracts
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Collaboration – Thoughts for today

Focus on technology enabled collaboration

- Life sciences applications:
  - Compliance
  - Risk Management
  - Product Lifecycle Management
- Cloud services
- Computational medicine and intelligent drug discovery

General considerations

- Determining what is "complex"
- Strategies to deal with risk

Trends

Segment: Life sciences applications

- Spend of US$8.9 billion by 2022 (Deloitte)

Characteristics for the major pharma

- Siloed, specialised solutions
- Multitude of providers
- A diversity of provider types (including high proportion of SMEs)
- Different entry / procurement points into the organisation, with different stakeholders

Life sciences applications (cont.)

Contractual considerations

- Legal functions like certainty and consistency by way of contract terms and risk allocation.
- However, this is challenging to achieve in this segment, in particular with regard to:
  - Risk allocation, including liability allocation in respect of data handling issues
  - Cybersecurity risk generally
  - Ongoing responsibility for ensuring regulatory compliance
  - Cost and service certainty.
- Imposition of standard terms often not the answer: SMEs without the resources to make a transfer of liability genuine, or ineffective transfer of compliance risk.
- Prescribed but flexible approach the answer? Both in determining the appropriate terms at the outset and through the engagement process.
- We have seen a real demand from clients to build contract tools which ascertain key characteristics of the arrangement, and apply the relevant contract terms, reflective of issues such as nature of data being handled, deal value, nature of intellectual property being created etc.

Trends

Segment: Cloud Solutions

- Was already, pre-COVID-19, a major priority for life sciences and health care companies.
- Accelerated as a result of COVID.

Characteristics and contract considerations for the major pharma

- Cloud vendors are focused on the sector from a technology perspective e.g. digital innovation labs and data exchanges. Enabled by the immense compute power and skills that are available to these incredible and still in many ways young technology companies.
- Perhaps less focused from a contracting perspective. In particular from an enterprise perspective, approach is still developing by way of the protections the industry requires on issues such as data security, audit access, sub-contracting and supply chain control, and others.
- However, perceived benefits of cloud, in particular its scalability and resilience, are driving increased adoption.

Trends

Segment: Computational medicine and intelligent drug discovery

- Computational medicine and drug discovery software market - spend of US$7.87 billion by 2023 (Deloitte).
- Intelligent drug discovery (including AI) - US$3.88 billion by 2025 (from US$198.3 million in 2018) (Deloitte).

Characteristics for the major pharma

- Again, multitude and diversity of providers (including high proportion of SMEs, but also tech giants).
- Significant divergence in contract terms and risk allocation.
- Significant competition for talent and solutions, leaving to a drive for exclusivity and investment in order to create and retain competitive advantage.

Trends

Computational medicine and intelligent drug discovery (cont.)

Contractual considerations

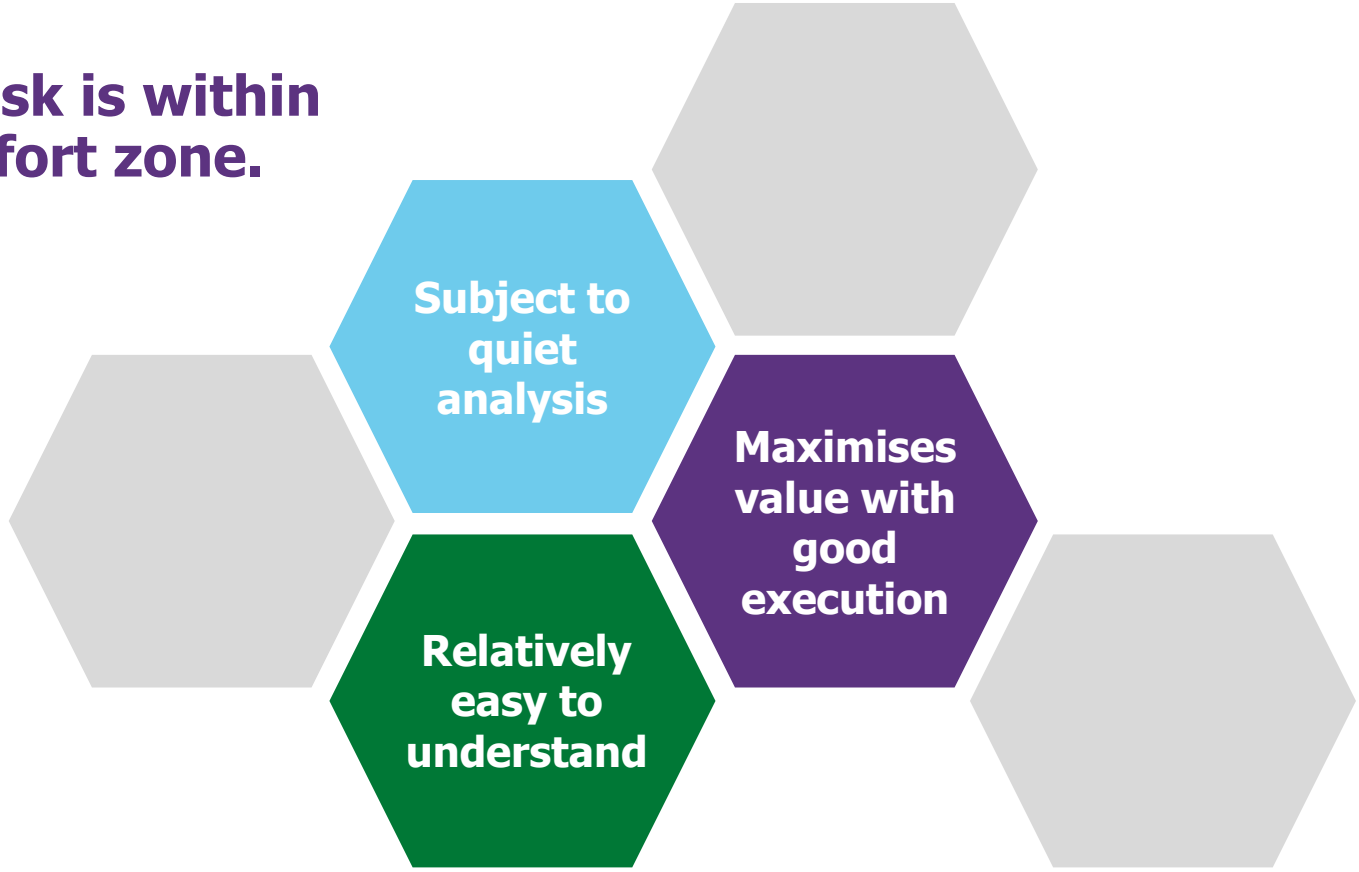
- Tech companies: may be viewed as a competitive threat by traditional health sector companies – and rightly so.
- This will play out over a long period of time. The large tech companies bring immense computing power, manufacturing analytics, and advanced supply chain control towers.
- Regulated industry with some insulation for the traditional players, but this will change and there is no doubt that collaborations and partnerships will bring significant downside risks.
- From a contracting perspective what does this mean: obviously scenario dependent, however it is important to establish rules and principles which are contractually memorialised. In particular, think about how to protect your corporate e.g. (i) who owns data / research outcomes (ii) how innocuous is a licence back for a broad "use" (iii) what does it mean if you have to rely on a licence to use (e.g. how "inviolable" will that licence be in practice) (iv) exclusivity of arrangements.
- Bet the company type arrangements – or thereabouts.

Nature of the contractual relationship

Relates to the complexity of the relationship, and the product	
Noncomplex	• Completely describable in a contract • Supplier agnostic • Inverse relationship between price and value
Complex Product	• Complex business need to specification connection • Requirements can be elusive and difficult to fully describe • May be sticky • The relationship between price and value may not be inverse (complex relationship below) • May require entering into a complex relationship to fully realise value
Complex Relationship	• Parties are very interdependent • Neither can be truly successful without the input, support, and cooperation of the other • Economic rents may be involved • The relationship between price and value may not be inverse

Static Risk

Static Risk is within our comfort zone.

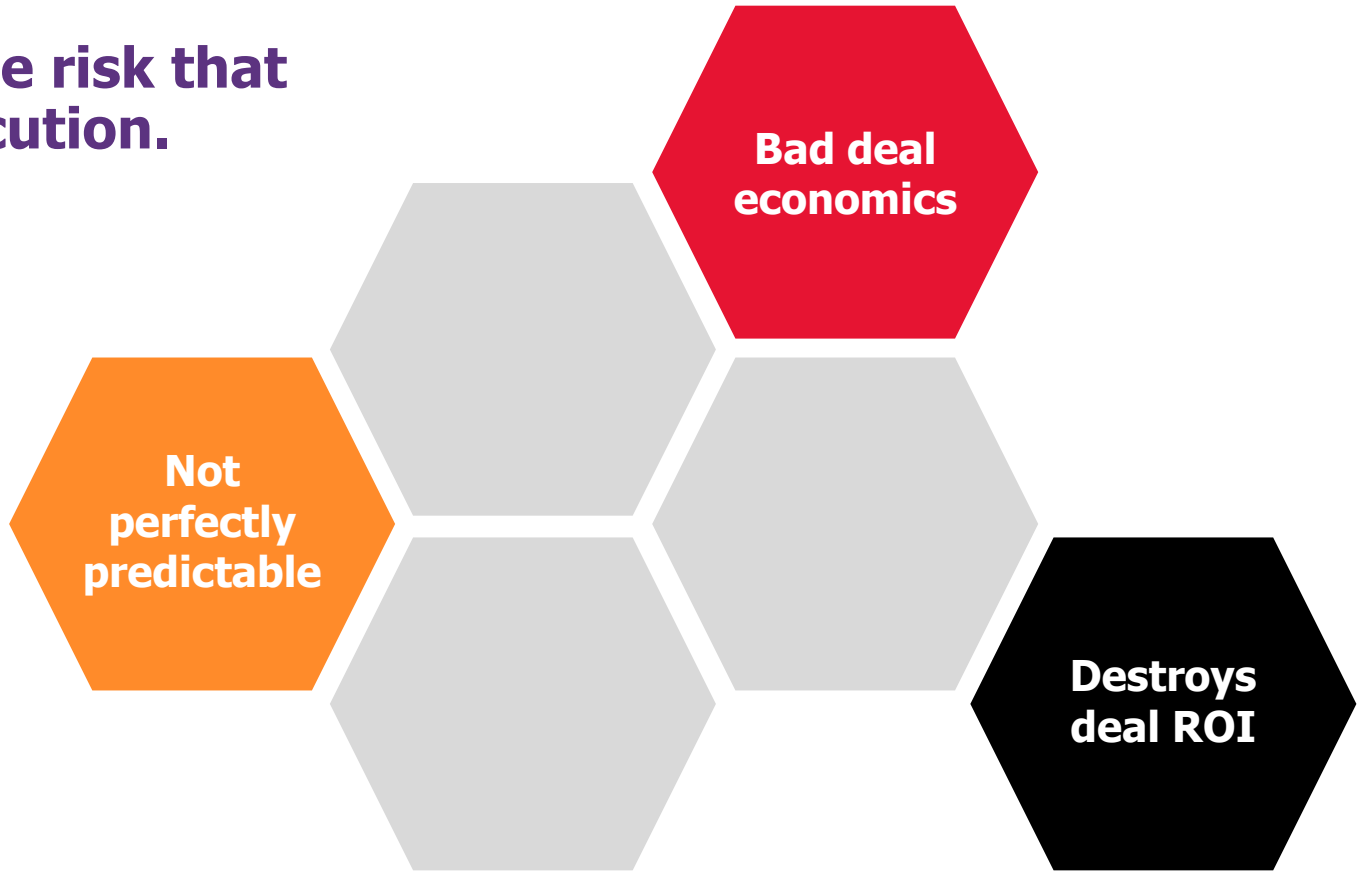


Static Risk Examples

Example	Potential outcomes
Liability caps below market	If there is ever litigation, lower recovery?
Change of law cost allocation below market	Cost gets passed to customer in different ways?
Service credit at risk amount below market	Supplier less incentivised to achieve SLAs?
Heads of recoverable loss below market	If there is ever litigation, lower recovery?
Indemnified losses below market	If there is ever litigation, lower recovery?

Dynamic Risk

This is the risk that kills execution.



Dynamic Risk Examples

Example	Potential outcomes
Down-selecting out the right partner	Cultural or capability mismatches, resulting in overreliance on a contract
Inappropriate timing of buy process	Poor partner match; ill-defined deal; poor transitions
Failed transition	Cost of delay, wasted resources, customer impact
Insufficient change management	Poor operational alignment, employee attrition, failure to achieve buy-in to solution
Inappropriate pricing	Too high or too low; use a pricing model and a rate card to stay aligned
Over-leveraged buy process	Over commitment from vendor leading to a death spiral early in the deal
Misaligned SLAs or business outcomes	Increased probability of a hostile environment, which will drive up transaction costs

Risk: Allocation or Mitigation?

Risk Allocation…

- Shifts risk to the other party
- Not a great strategy for complex deals
- Is largely market driven

Risk Mitigation…

- Lowers the amount of overall risk
- Offers better results for both parties

Some Relevant Terms (Examples)

Risk Allocation	Risk Mitigation
Limitation of Liabilities	Objectives
Indemnities	Service Levels
Compliance with Laws	Pricing Model
Privacy/Data Protection	Certain Personnel Provisions
Certain IP Provisions	Staffing Plan
Certain Warranties	Certain Warranties
Others?	Others?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Impact of Brexit on UK/EP Intellectual Property for Life Sciences
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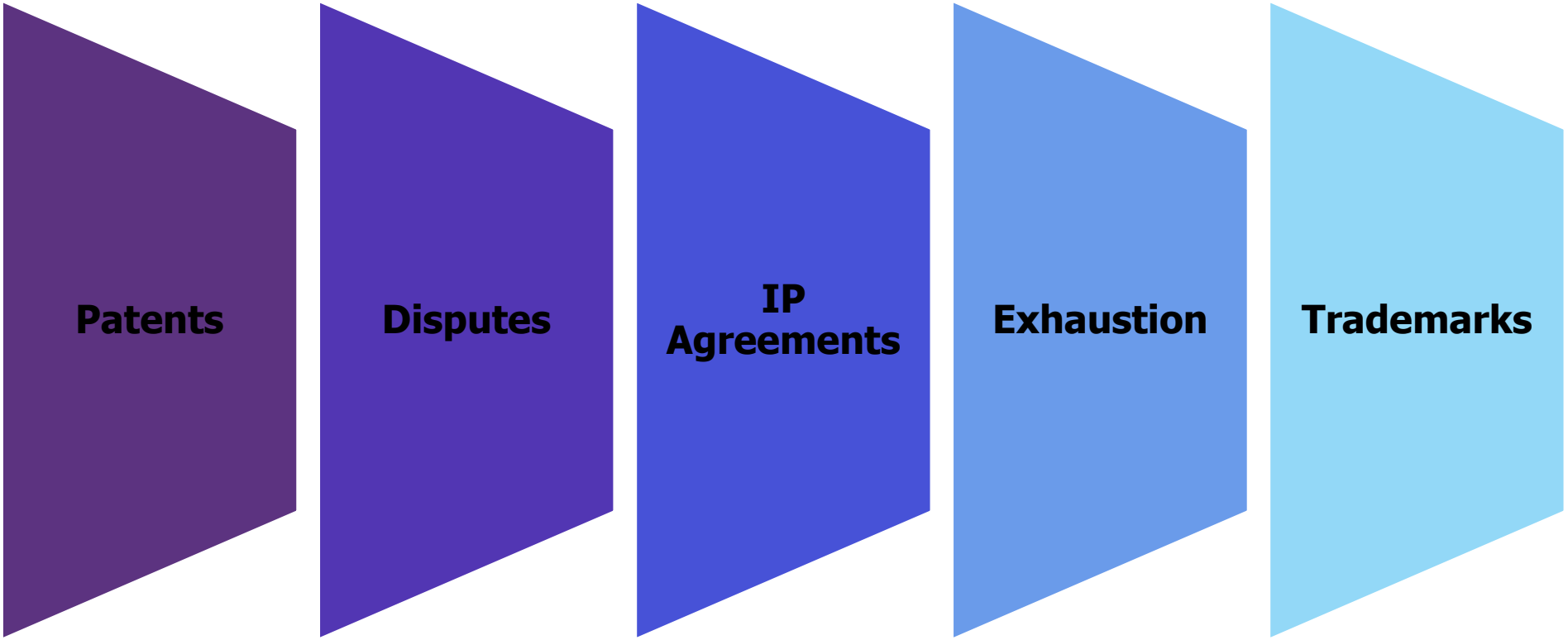
Likely Impact



Patents

Minimal effect on patents in the UK as the UK is part of the European Patent Office (EPO), which is a separate entity to the EU

- Existing European patents (including those covering the UK) are unaffected
- The UK's participation in the International (PCT) patent system will be unaffected
- European Patent Attorneys based in the UK will continue to represent their domestic and overseas clients before the EPO, and the UK can continue to be designated in European patent applications

The UK government has now withdrawn its ratification of the UPCA

- Will not be taking part in the Unified Patent Court and Unitary Patent system

Supplementary Protection Certificates (SPCs) for pharmaceutical and plant protection products granted prior to January 1, 2021, will be unaffected

- Applications for SPCs pending at the UK Intellectual Property Office will be treated as before with no need to refile

IP Agreements

Licenses and consents which cover the UK prior to Brexit will be treated as covering the UK after January 1, 2021, and references to EUTMs and community-registered designs will be treated as also referencing any comparable UK rights that are created post-Brexit

- Only apply to agreements existing before January 1, 2021
- Licenses and other agreements being negotiated should include explicit terms as to whether or not it is intended to cover the UK and any future UK comparable rights

Trademarks

Territorial coverage of EUTMs will no longer include the UK

On January 1, 2021, the UKIPO will create a "comparable" UKTM for every registered EUTM

- Comparable UKTMs will have the same filing date, priority, and UK seniority as the EUTMs, and will be subject to any license or security interest registered against the EUTMs

Owners of pending EUTM applications that have not proceeded to registration by January 1, 2021, will have nine months to apply for comparable UKTMs

Disputes

After December 31, 2020, UK courts will no longer be able to

- Adjudicate on EUTMs or designs (except in certain proceedings that are already under way) and will not be able to issue EU-wide injunctions
  - Pan-EU injunctions granted by EU courts in post-transition period proceedings will not apply to the UK
- Make references to the Court of Justice of the European Union (CJEU) for interpretation of IP legislation and other EU law that is retained in UK legislation

Cases relating to EU-registered trademarks or designs ongoing in the UK courts on January 1, 2021, will continue to be heard as if the UK were still an EU member state

- Remedies granted by the court will apply to the comparable/re-registered UK rights only

Exhaustion

IP rights that are exhausted both in the UK and EU (and EEA EFTA states) on January 1, 2021, shall remain exhausted

- Therefore it will still be possible to import goods into any EU member state if they have already been placed on the market in the UK before the end of the transition period (and vice versa)

Starting from January 1, 2021, no further lawful parallel import to the EU/EEA from the UK

- BUT trademark rights exhausted when goods placed on the marketed in EU/EEA – such goods are importable into the UK

Not clear in the long term if UK will opt for;

- National exhaustion (to prevent parallel imports from all other countries); or
- International exhaustion (to permit such parallel imports)

If You Haven't Done So Already...

1. Keep an eye out for the UKIPO's unofficial consolidations of the Patents Act and the Patents Rules as they will be updated with the relevant changes in time for the end of the transition period
2. Review important IP agreements in case these may need clarifying or may not provide the necessary rights post-transition period
3. Consider filing UKTM applications and claiming priority for pending EUTM applications
4. Consider assessing whether you will be able to obtain your desired remedies through existing proceedings if you have an ongoing litigation
5. Check whether you currently export IP-protected goods to the EEA that have already been placed on the UK market and where the rights holder's permission to export those goods is not currently required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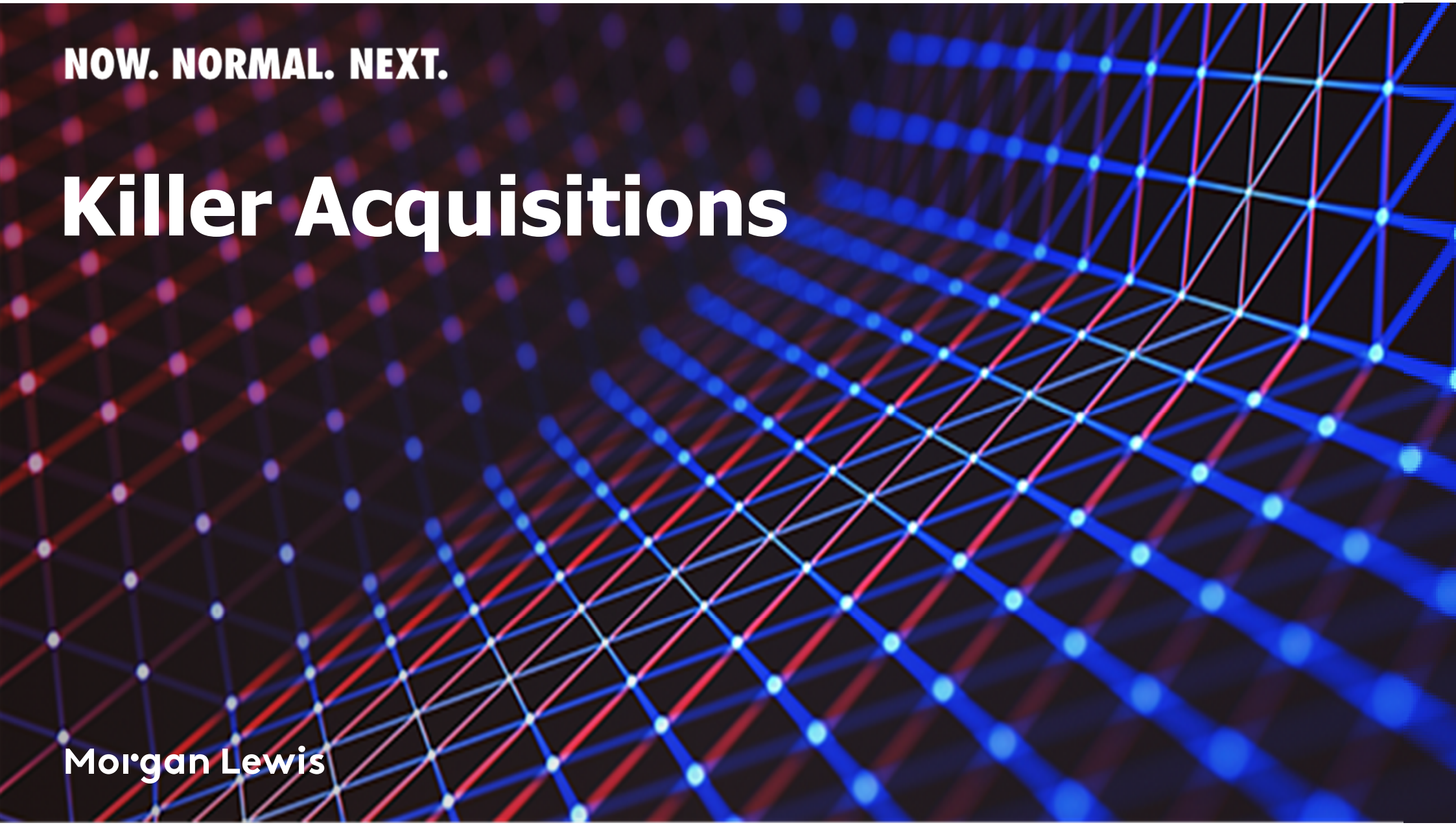
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Killer Acquisitions
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What is a "Killer Acquisition"?

Important antitrust concept in Europe and in the US.

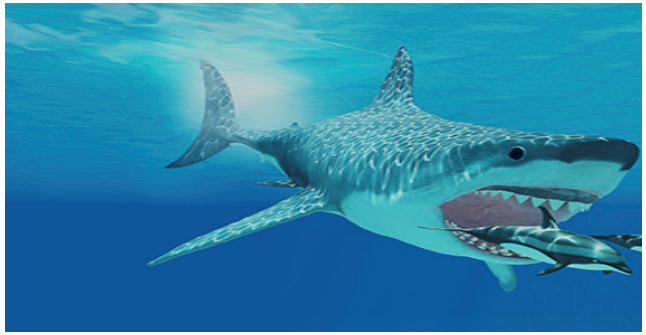
Acquisition of nascent or potential competitor, typically by a big or dominant firm.

Killer acquisitions typically occur in the tech, pharmaceutical, and life sciences industries; cf. *Colleen Cunningham, Florian Ederer and Song Ma, "Killer Acquisitions" (28 August 2018) .*

Killer acquisition can take several forms.

Potential Killer Acquisitions Can Take Several Forms

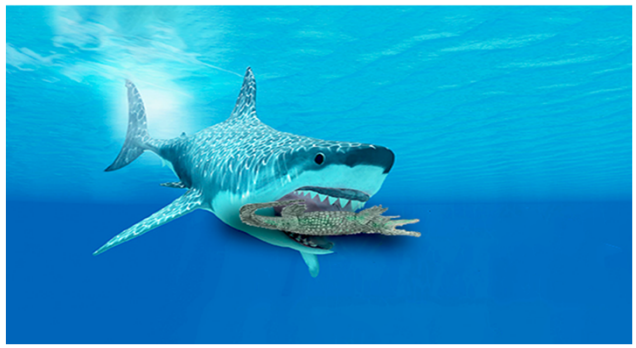
- Dominant company acquires nascent company offering the same or a similar, potentially competing product/service: e.g. pharma company with blockbuster pill acquires developer of competing pill.



- Dominant company acquires multiple nascent competitors: e.g. pharma company acquires several potential rivals over a span of time, under merger control thresholds.

Potential Killer Acquisitions Can Take Several Forms

- Dominant company acquires developer of (potentially) competing product/service: e.g. pharma company with blockbuster pill acquires developer of biological that will treat same disease as pill.



- Dominant company acquires nascent upstream or downstream company or data: e.g. big tech company acquires other tech company with unique and rich data set.

Roche/Spark (2019)

Federal Trade Commission

- A key question in the investigation was whether Roche would have the incentive to delay or discontinue Spark's developmental gene therapy for Hemophilia A. Spark's developmental gene therapy would compete with, and potentially eliminate the need for Hemlibra, a therapy marketed by Roche.
- FTC concluded that other companies develop gene therapy treatments, so that Roche would have incentive to accelerate, rather than decelerate, Spark's therapy.
- "The Commission will continue to closely scrutinize acquisitions by incumbents of emerging competitors and will not hesitate to bring enforcement actions against them where the facts support such action."

CMA

- Found jurisdiction on the basis of (i) the number of UK-based employees engaged in "activities" relating to the treatment of Hemophilia A; and/or (ii) the number of UK patents procured from an administrative patent authority in relation to the treatment of Hemophilia A.
- CMA reviewed whether Roche's internal documents relating to its valuation of Spark were consistent with the pro-competitive rationale for transaction.
- CMA cleared the acquisition after finding that several other suppliers were developing a gene therapy treatment that could be a viable alternative to the therapies marketed by Roche and Spark.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Excessive Pricing
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Excessive Pricing

Excessive pricing: practice of fixing prices at a significantly higher level than competitive on the basis of a dominant market position.

Excessive pricing is prohibited under UK and EU competition law. Historically, the CMA and the European Commission have avoided pursuing excessive pricing cases.

Recently, a number of competition enforcement actions for excessive pricing against pharmaceutical companies have taken place.

Under the *United Brands* test, excessive pricing is assessed based on a two-stage test:

- Is the price excessive?
- Is the price unfair (i) in itself or (ii) when compared to competing products?

Pfizer/Phenytoin (2020)

In December 2016, the CMA held that Pfizer and Flynn had set unfairly high prices for phenytoin sodium capsules, in breach of competition law.

It imposed fines totalling £90 million.

The decision was appealed to the Competition Appeal Tribunal ("**CAT**"), who ruled against the CMA's finding of abuse.

In March 2020, following an appeal from the CMA, the Court of Appeal dismissed Flynn's case entirely and found that a number of legal errors had been made by the CAT.

The CAT should not have required the CMA to go beyond a cost plus calculation to determine whether prices set were excessive.

Update - Current Excessive Pricing Investigations

Liothyronine tablets: suspected excessive and unfair pricing

- The CMA is currently investigating a large pharmaceutical company for the alleged excessive and unfair price fixing of Liothyronine, an ingredient used in hypothyroid drugs.
- The CMA provisionally found that the pharmaceutical company held a dominant market position and had abused that position.
- In July 2020, the CMA issued a supplementary statement of objections addressing issues arising out of the Pfizer/Phenytoin case.

Cancer medication: suspected excessive and unfair pricing

- In 2017, an investigation was launched by the European Commission for the alleged excessive pricing of cancer drugs by a large pharmaceutical company.
- The European Commission's preliminary review found that the pharmaceutical company had regularly earned high profits from the sale of these cancer drugs.
- In July 2020, the European Commission invited comments on commitments offered by the pharmaceutical company.


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Pay-for-delay Agreements
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Pay-for-delay Agreements

Pay-for-delay agreements: form of settlement agreement for patent disputes.

They typically involve a generic manufacturer agreeing to delay launching a new generic product into a market in return for payments by a holder of product rights in that product.

They involve value transfers between potential competitors.

Pay-for-delay agreements can breach rules on the abuse of a dominant market position and on restrictive agreements.

The European Commission has been monitoring pay-for-delay agreements, and has imposed a number of fines in recent years.

The European Court of Justice has said that pay-for-delay agreements do not necessarily constitute barriers to competition, but if such agreements prevent consumers from future benefits, they could be deemed anti-competitive (*Case C-307/18 Generics (UK) Ltd and Others v Competition and Markets Authority*).

GlaxoSmithKline/Paroxetine (2020)

In January 2020, the European Court of Justice ("**ECJ**") endorsed the CMA's 2016 ruling against GlaxoSmithKline ("**GSK**") for breaches of competition law.

The CMA investigated GSK over certain pay-for-delay agreements entered into by GSK with other generic manufacturers of paroxetine.

It found that GSK had infringed the prohibition on restrictive agreements by entering into these pay-for-delay agreements.

It further found that the pay-for-delay arrangements had deprived the NHS of price reductions and imposed fines on GSK of around £38 million.

The ECJ's ruling provided important guidance for the assessment of pay-for-delay agreements, clarifying in particular that "it is necessary to determine how the market will probably operate and be structured in the absence of the concerted practice".

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Questions & Answers

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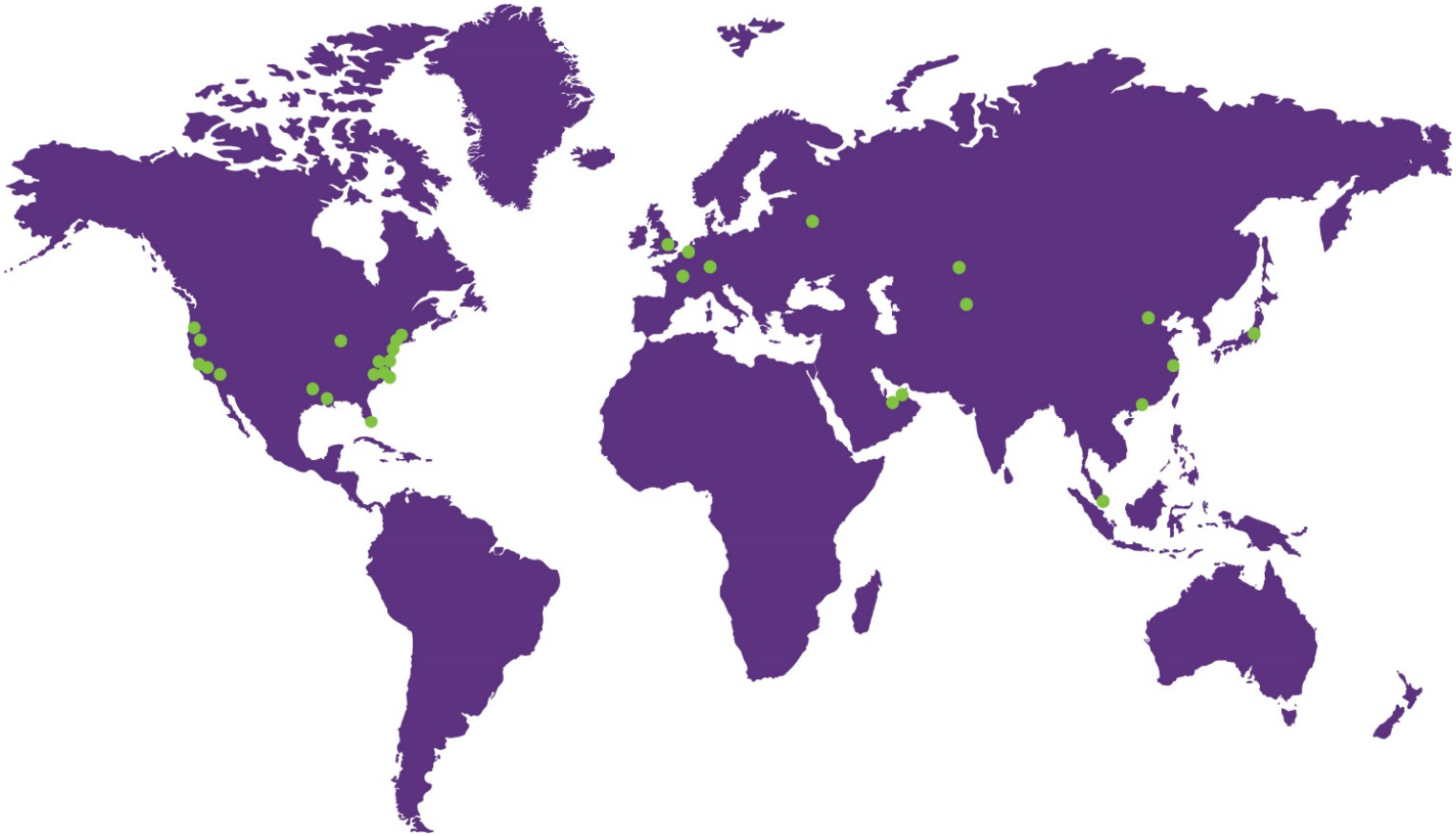

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Biography

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Louis W. Beardell Jr. focuses his practice on intellectual property 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.

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With more than 20 years of international experience, Tim Corbett advises clients on complex cross-border corporate transactions, including public and private equity and debt offerings, mergers and acquisitions (M&A), joint ventures (JVs), and venture capital financings, including representations of both companies and investors. Tim also assists public and private clients with day-to-day corporate matters, including governance, securities law compliance, and disclosure requirements and practices.

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Dr. Joachim Heine advises clients on public and private mergers and acquisitions, joint ventures, and venture capital financings with an emphasis on cross-border transactions. Joachim represents corporates and funds in the fields of pharmaceuticals, medical devices, technology, media and communication, and financial services. He is a regular speaker at conferences on mergers and acquisitions and life sciences.

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Jayne McGlynn's finance and business experience encompasses a number of corporate matters, including international public and private acquisitions, corporate reorganizations, joint ventures, and private equity transactions—with a particular focus on cross-border transactions. Jayne also advises clients on general corporate and commercial matters. Prior to joining Morgan Lewis, Jayne was an associate in the London office of a leading international law firm.

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Mike Pierides' practice encompasses a wide breadth of commercial and technology transactions. Mike advises on major outsourcings, strategic restructurings following divestments or acquisitions, and technology-specific transactions such as licensing and "as a service" arrangements. He is also active advising on new technologies such as blockchain and artificial intelligence.

Biography

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Omar Shah represents clients in complex global cartel and anticorruption investigations and civil proceedings for damages for breach of antitrust laws, as well in merger control procedures and on antitrust matters, particularly those involving the intersection of competition law with media/communications regulation. His practice involves representing clients before UK, EU, and other competition authorities, courts, and tribunals and in commercial and regulatory litigation proceedings, including judicial reviews. *Chambers UK* 2016 describes him as a "charming and effective partner who instantly wins the client's confidence and respect."

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