JAPAN

14 October 2021

Europe Life Sciences (Part I):

Market, Corporate, Competition, Disputes & Technology Trends

Morgan Lewis

Presenters

Tim Corbett

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Morgan Lewis


Setting the Scene:
Market Dynamics in the Life Sciences Space
Morgan Lewis

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 and into the first half of 2021

Substantial amounts raised in IPOs and follow-ons

Disclosures and risk factors

- Development timelines
- Financing needs
- Health system capacity

Life Sciences Macro Trends

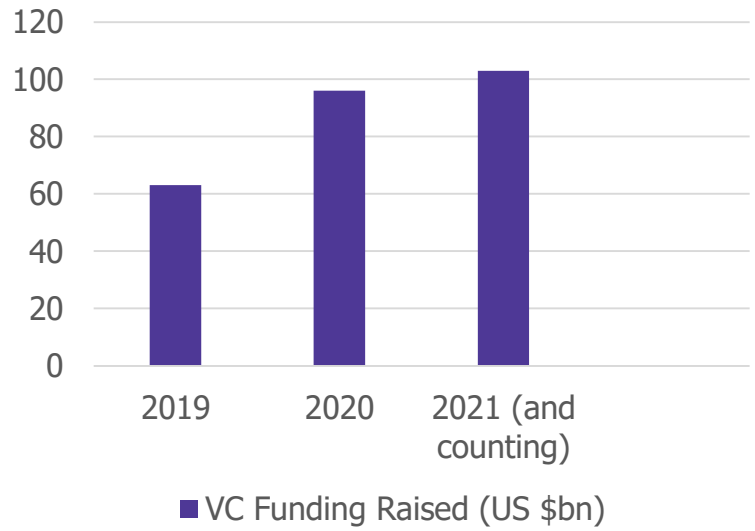
Macro Trends:

- **Record breaking 2020 in respect of VC investments and IPO markets**
- **To be surpassed in 2021**
- **Performance and returns on recently listed companies has dipped compared to 2020**
- **M&A trends have spiked since their dip in Q2 2020**
- Beyond biotech/pharma/devices → drug discovery
  investment in companies focused on discovery, screening and efficacy testing of new drugs: in 2019, 28% of all capital and 22% of deals; in 2020, 43% of capital and 28% of deals

Life Sciences Venture Capital

2021 – Record Year for VC:

- VC has continued to break records in 2021, despite a record-breaking year in 2020



Life Sciences Venture Capital

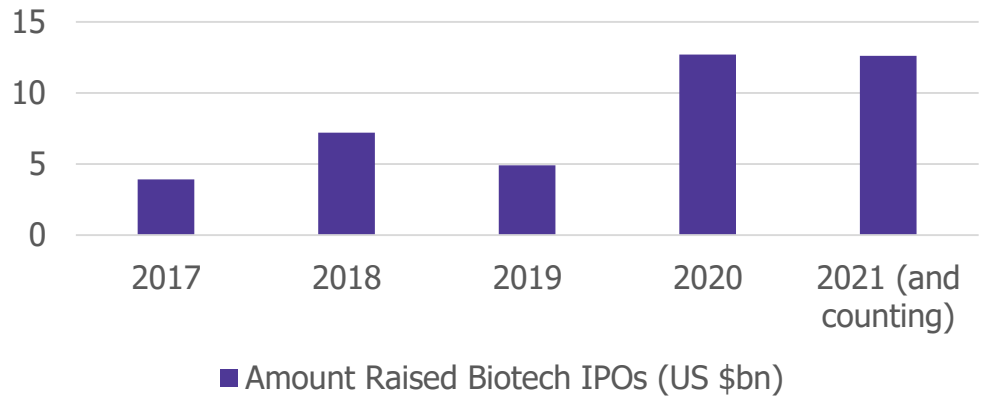
Market Trends:

- U.K. is by far Europe's biggest recipient of VC investment
- Asian conglomerates and pharmaceuticals – such as Softbank and Tencent – have invested significant sums in the U.K.'s "Golden Triangle"
- China is the second largest recipient of VC funding after the U.S.

Life Sciences in the Capital Markets

2021 - Record Year for Biotech IPOs:

- U.S. markets continue to dominate public capital markets
- 2020: Record number and value of IPOs in the Biotech industry
- 2021: Expected to exceed 2020's record within the month



Life Sciences in the Capital Markets

Market Trends:

- Biotechs seeking IPOs earlier in their life cycle. 22 preclinical drug makers went public in 2021, surpassing each of the past 3 years
- Performance of Biotech stock indexes has varied widely
- Oncology biotechs and makers of gene-based medicines experienced the most growth of IPOs


Trends in Life Sciences M&A
Morgan Lewis

Life Sciences M&A

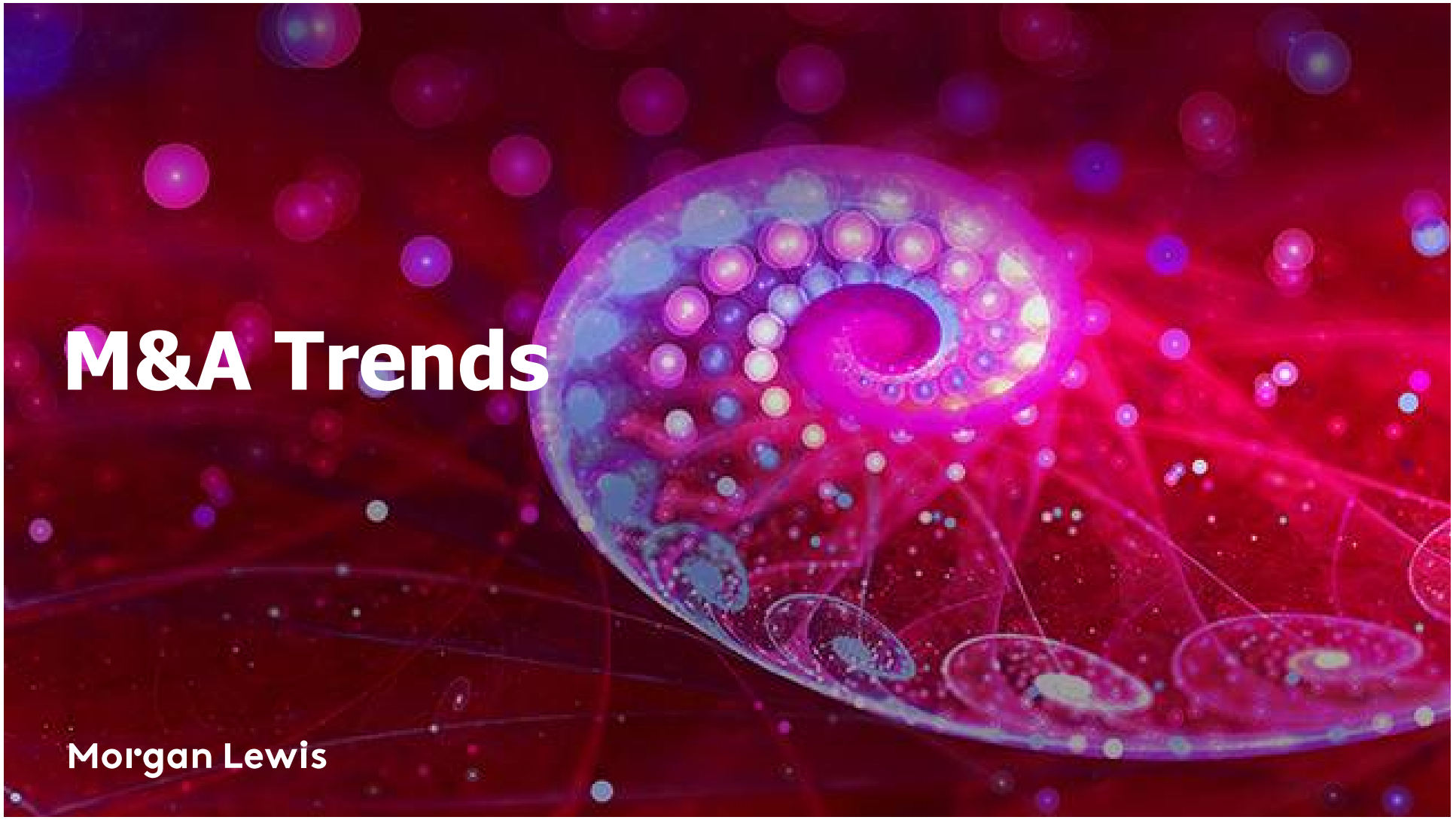
M&A Activity Spiked Since Q3 2020:

- M&A activity has spiked since Q3 2020, this is expected to continue until at least Q2 2022
- An increase in Chinese cross-border investment, particularly in biotech, is expected in the next 12 months
- Traditional big pharma players have ample dry powder for M&A
- Focus on alliances/collaborations, with some targeted bolt-on deals in key therapeutic areas/indications

U.K. – Japan Collaboration

The Japanese Pharmaceutical Group (JPG):

- Report focussing on U.K.
- The report highlights the long-lasting and deep collaboration between U.K. and Japan entities.
- Nine of these 12 companies have their European headquarters in the U.K.
- JPG invested £76 million in UK based R&D last year
- Turnover in the UK for the group in 2020 was over £800 million.


M&A Trends
Morgan Lewis

Timing

Recovery of the M&A Environment:

- Timelines for M&As slowed down during the initial waves of Covid; increase in disputes and regulatory oversight
- From Q1 2021, the timeline has started bouncing back
- Led by PE firms and fear of another economic crash

Due Diligence

Risks of Covid:

- Buyers spending more time on DD
- How well is the target protected from the pandemic
- Supply & distribution chain risks
- Government Covid funding

Valuation

High Risk / High Purchase Price Multiples:

- Large amount of "dry-powder" on the market
- High-risk and high purchase price multiples
- Underlines the importance of a vigorous DD process

Insurance

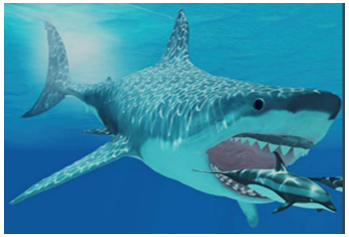
Increased use of Insurance:

- Increased use of insurance as key part of an M&A transaction
- Risk that policy pricing could increase
- Underwriting covid risks following due diligence


Competition and
Disputes
Developments
Morgan Lewis

Key Antitrust Developments in European Life Sciences

Killer acquisitions



Excessive Pricing

Pay-for-delay

What are Killer Acquisitions?

- Acquisition of **nascent or potential competitor**, typically by a large or dominant firm (usually big tech or life sciences industries). For example:
  - Pharma company with blockbuster pill acquires developer of competing biological that will treat same disease as pill.
  - Dominant company acquires multiple nascent competitors: e.g. pharma company acquires several potential rivals over a span of time, under merger control thresholds.

Key concerns of European antitrust agencies regarding killer acquisitions

- **Stifling innovation**
  - Buyer may kill development of services and products that compete with Buyer's products
- **Hampering future competition**
  - Buyer may sell at a higher price or stifle future non-price competition/ innovation
- **Making it harder for competitors to compete**
  - Acquiring upstream, downstream or potentially even complementary assets and making them exclusive

Merger control rules in the EU/ UK

- **EU Council Regulation (EC) No 139/2004 ("EU Merger Regulation")**
  - Establishes EU Commission jurisdiction on the basis of worldwide, EU-wide and national revenue thresholds – this is a "one stop shop"
  - Prohibits mergers and acquisitions where they will "significantly impede effective competition in the common market"

- **UK Enterprise Act 2002**
  - Establishes UK jurisdiction on the basis of a revenue test or a **"share of supply" test** - parties together supply 25% or more of "goods or services of any description" in the UK
  - Prohibits mergers that have resulted (or may be expected to result) in a "substantial lessening of competition in any market in the UK"
  - Although filings are voluntary, CMA may investigate ex officio and freeze integration during review
  - Flexibility in interpretation of share of supply test means that the CMA has reviewed "killer acquisitions" more frequently than the EU Commission

EC's expanding jurisdiction over killer acquisitions

- EC guidance published in March states that the EC will in certain cases accept to investigate mergers **that do not meet the EU or even national jurisdictional tests** – including e.g. where one party is:
  - an important innovator or is conducting potentially important research; or
  - is an actual or potential important competitive force.
- EU member states can request that the EC review a transaction that does not meet the EU thresholds but that affects trade between Member States and threatens competition within the requesting Member State.
- Until recently, the Commission's practice had been to discourage such referrals from Member States that did not have the power to review a deal under their own national merger control rules.

EC exercised its discretion to review Illumina/Grail

- Illumina (US gene sequencing provider) is seeking to acquire Grail (a downstream cancer testing start-up).
- The transaction did not meet EU or any EU Member State merger control thresholds – as Grail did not have any EU sales.
- The European Commission accepted the referral request by France (supported by other EU member states) to review the transaction.
- The decision to accept the referral request may be due to concerns that the transaction is a "killer acquisition".
- The European Commission opened an in-depth investigation on 22 July 2021 citing concerns that Illumina could vertical input foreclosure of its sequencing services to downstream competitors of Grail.
- Illumina has sued the European Commission before the General Court for its decision to open an investigation.

CMA exercised wide discretion to review Roche/Spark (2020)

- The CMA found jurisdiction on the basis of (i) the number of UK-based employees engaged in "activities" relating to the treatment of Hem A; and/or (ii) the number of UK patents procured from an administrative patent authority in relation to the treatment of Hem A.
- The CMA reviewed whether Roche's internal documents relating to its valuation of Spark were consistent with the pro-competitive rationale for transaction
- The CMA ultimately cleared Roche/Spark unconditionally in Phase 1

Multilateral Pharmaceutical Merger Task Force

- The Task Force was launched in March 2021 and comprises staff from the:
  - FTC
  - Canadian Competition Bureau
  - European Commission
  - CMA
- The purpose of the Task Force is to identify steps to review and update the analysis of pharmaceutical mergers
- To ensure "*fresh approaches that fully analyse and address the varied competitive concerns that these mergers and acquisitions raise, including in light of rapidly changing drug development and manufacturing approaches*"

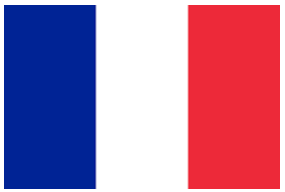
Most Acquisitions of Nascent/Potential Competitors are Not "Killer Acquisitions"!

- Pro-competitive purpose
- Start-up has its own rivals
- Start-up's chances of success uncertain
- Competing product/service's chances of success uncertain
- Start-up will not compete
- Other "big" rivals can compete in-house

Foreign Direct Investment Regimes are now widespread in Europe and often cover Biotech

- There is no harmonised EU screening regime
- Currently a cooperation regime is in place whereby EU Member States and the European Commission exchange information and are able to comment on ongoing FDI screening
- The biotech sector is a focus of various FDI screening regimes in Europe (e.g. the German FDI regime may apply to exclusive licenses)
- Particularly active jurisdictions include Italy, Austria and France

FDI Screening – France



- Since July 2020 the French FDI regime applies to acquisitions of biotech companies
- Mandatory pre-closing filing to the Ministry for the Economy
- Suspensory filing – the parties cannot close until clearance
- No filing fee
- Review time
  - Phase 1: 30 business days;
  - Phase 2: 45 additional business days

FDI Screening – United Kingdom

- New screening regime will come into force on 4 January 2022
- The regime will apply to among others to companies active in "synthetic biology" including (among activities):
  - the design, engineering of biological-based parts of enzymes, genetic circuits and cells and novel devices and systems;
  - Gene editing and gene therapy; and
  - The use of DNA for data storage, encryption and bio-enabled computing
- Voluntary notifications possible for transactions outside mandatory sectors
- UK government will be able to call in transactions for a national security review potentially up to 5 years from closing.
- Review time:
  - Phase 1: 30 business days
  - Phase 2: 30 additional business days (extendable by a further 45 business days)

What is Excessive Pricing?

- The practice of fixing prices at a significantly higher level than in a competitive market, on the basis of a dominant position.
- Excessive pricing is prohibited under UK and EU competition law. Historically the CMA and the EC have avoided pursuing excessive pricing cases.
- Recently a number of competition enforcement actions for excessive pricing against pharmaceutical companies have taken place.

Excessive Pricing - the Legal Test

- 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?

Excessive Pricing Investigations

Pfizer/Phenytoin (2020)

- CMA held that Pfizer and Flynn had set unfairly high prices for phenytoin sodium capsules, in breach of competition law (December 2016)
- Fines imposed: £90 million
- The decision was appealed to the UK Competition Appeal Tribunal ("CAT") – that ruled against the finding of abuse
- Following a CMA appeal - the Court of Appeal dismissed Flynn's case entirely and found legal errors in the CAT's decision – the CAT should not have required the CMA to go beyond a cost plus calculation to determine whether prices were excessive
- Following the Court of Appeal judgment - the CMA issued a statement of objections in August 2021 in its remittal investigation

Excessive Pricing Investigations

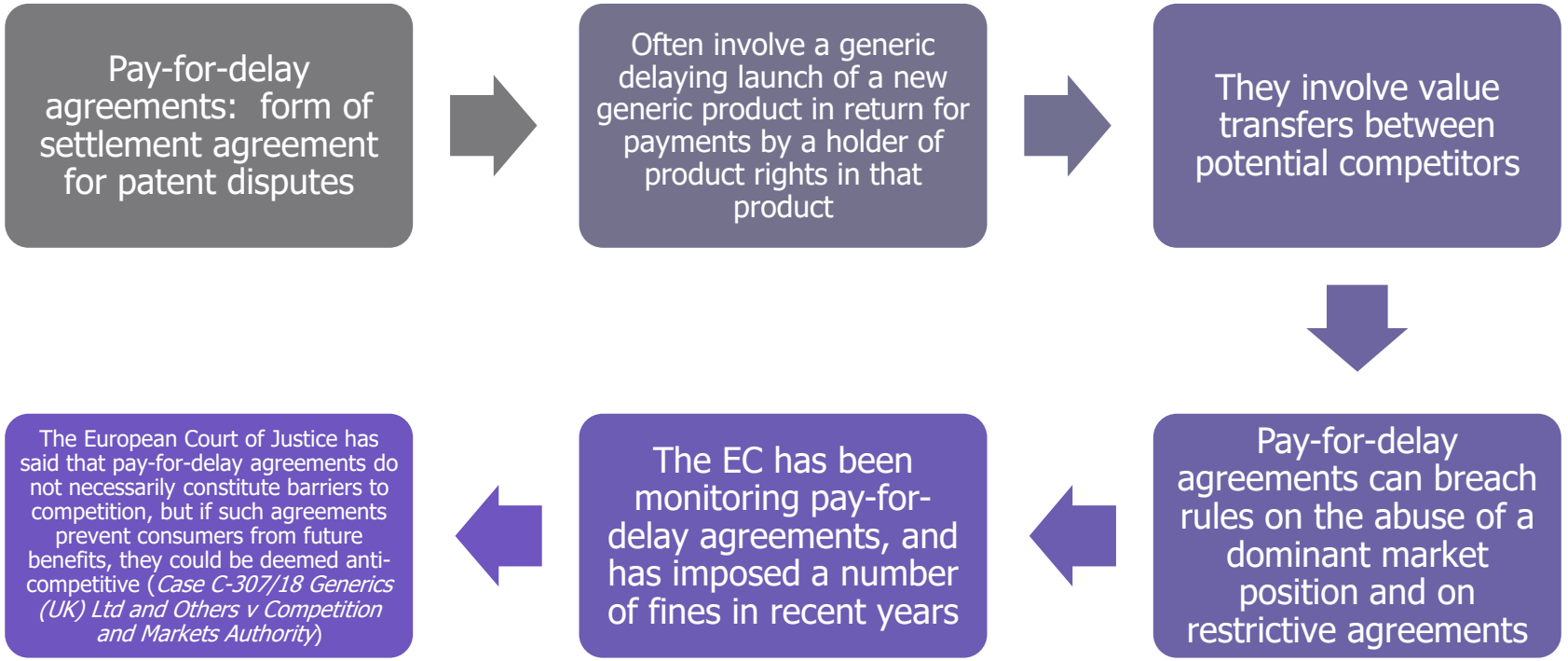
Liothyronine tablets: suspected excessive and unfair pricing

- The CMA investigated a large pharmaceutical company for the alleged excessive and unfair price fixing of Liothyronine, an ingredient used in hypothyroid drugs
- In July 2021, the CMA issued an Infringement Decision and found that the pharmaceutical company held a dominant market position and had abused that position

Cancer medication: suspected excessive and unfair pricing

- In 2017, the EC investigated the alleged excessive pricing of cancer drugs by a large pharmaceutical company
- The EC's preliminary review found that the pharmaceutical company had regularly earned high profits from the sale of these cancer drugs
- In February 2021 the EC accepted commitments inter alia to reduce its prices by 73% on average

What are Pay-for-delay Agreements?



Pay-for-delay Investigation

GlaxoSmithKline/Paroxetine (2020)

- The European Court of Justice ("ECJ") endorsed the CMA's 2016 ruling against GlaxoSmithKline ("GSK") for breaches of competition law in January 2020, clarifying that "*it is necessary to determine how the market will probably operate and be structured in the absence of the concerted practice*"
- The CMA investigated GSK over certain pay-for-delay agreements entered into by GSK with other generic manufacturers of paroxetine
- The CMA found that:
  - GSK had infringed the prohibition on restrictive agreements by entering into these pay-for-delay agreements; and
  - the pay-for-delay arrangements had deprived the NHS of price reductions
- Fines imposed: £38 million


Current Trends -
Technology
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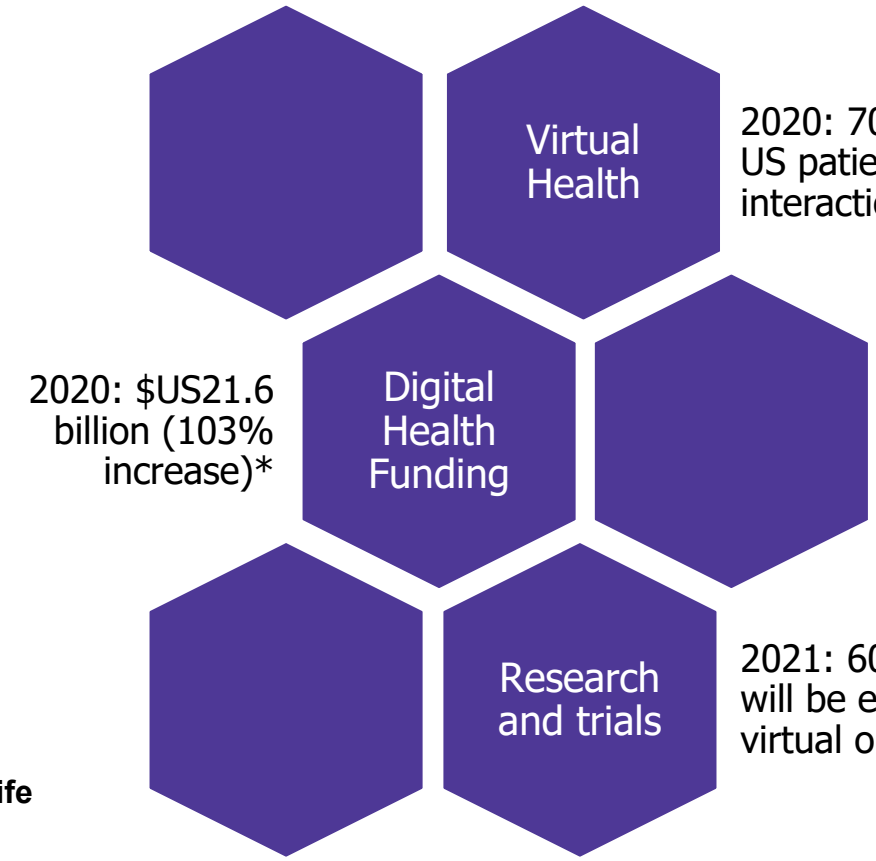
Trends



2020: 70% of all US patient provider interactions virtual*

2020: $US21.6 billion (103% increase)*

2021: 60% of trials will be entirely virtual or hybrid*

***Deloitte 2021 Global Life Sciences Outlook**

Trends

- How the market has adopted
  - Cloud computing is an essential part of digital transformation, and the "big three" cloud providers (Amazon, Google and Microsoft) continue to grow significantly, and have further developed sector-specific offerings for heal care cloud e.g. Amazon HealthLake, Google's Healthcare Data Engine.
  - This technology has developed:
    - Initially, a technology base: systems which allow healthcare companies to store their applications and data on the cloud
    - Next, standardising and accurately labelling and configuring data
    - Through to to systems which through the use of AI (in particular) will themselves propose and implement health care solutions.

Artificial Intelligence

- What is it in the context?
  - Machine learning and deep learning
  - "*These disciplines are comprised of AI algorithms which seek to create expert systems which make* ***predictions or classifications*** *based on input data.*" – IBM
  - Google and Mayo Clinic – 10 year "AI Factory" agreement
    - Algorithms making predictions and classifications in the context of healthcare, which can be deployed at scale and on a repeatable basis
    - Radiation therapy planning
    - Analysis of radiology images

EU Regulation

- EU Commission has published a proposed EU-wide AI legislative framework (the EU Regulation) which is part of the Commission's overall "AI package".
- The EU Regulation is focused on ensuring the safety of individuals and the protection of fundamental human rights, and categorises AI into unacceptable, high- or low-risk use cases.
- Much of the EU Regulation is focused on imposing prescribed obligations in respect of such high-risk use cases, including obligations to undertake relevant "risk assessments", to have in place mitigation systems such as human oversight, and to provide transparent information to users.
- We expect that as well as driving AI policies within providers and users of AI, many of these obligations will be flowed down by customers to their contracts with AI providers.

EU Regulation

- Non-compliance with the regulation could mean heavy GDPR-style fines for companies and providers, with proposed fines of up to the greater of €30m or 6% of worldwide turnover.
- The regulation anticipates the establishment of a European Artificial Intelligence Board to oversee the matters covered by the regulation.
- From a life sciences perspective, AI usage will be regulated both as a component of products (e.g. where used with medical devices) or as products in their own right.

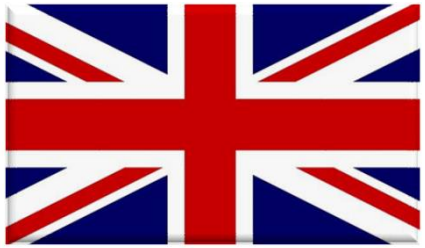
EU Regulation

- **High Risk AI Systems**
- High-risk AI systems are permissible, subject to the implementation of the controls specified in the regulations.
- They are defined in two separate categories:
  - AI used as a safety component of products (or which are themselves a product) covered by EU product safety legislation, such as the Medical Devices Regulation.
  - The high-risk list includes products which are also covered by EU regulations on personal protective equipment, medical devices in vitro diagnostic medical devices, among many others.
  - AI systems whose use may have an impact on fundamental rights.

EU Regulation

- **Controls**
- The controls specified in the regulations fall primarily on the suppliers AI systems:
  - Transparency
  - Security
  - Accountability
  - Risk Management
  - Testing
- The users of AI systems are also subject to requirements as set down in the regulations.
- Extra-territorial effect.

UK AI Strategy



- UK government has announced an assertive agenda on artificial intelligence (AI) by launching a UK Cyber Security Council and in September published a National Artificial Intelligence Strategy (the UK Strategy).
- The UK's strategy is focused in particular on promoting growth of the economy through widespread use of AI with, and at the same time, an emphasis on ethical, safe, and trustworthy development of AI.
- The UK appears will not, it appears, be moving to a single legislative framework for AI. If anything, this will be done on a sectoral basis, and the UK Strategy paper itself does not specifically call-out the life sciences sector.

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Q&A

Upcoming Session – Part 2: Current Trends and Brexit Implications (Employment, Data Privacy, Regulatory)

Louise Skinner

Lee Harding

Paul Ranson

Morgan Lewis

WHEN

Thursday, November 18, 2021
5:00pm JST / 4.00pm CST / 9:00am BST

The life sciences industry is undergoing transformation across the globe and facing challenges and opportunities arising from the COVID-19 pandemic. In addition, the United Kingdom's exit from the European Union has brought significant changes for the industry in relation to issues including pharmaceutical and medical device regulation, antitrust and competition, and corporate transactions.

Please join us for a two-part webinar series on key legal, employment, and regulatory trends and issues impacting the European life sciences market. This second session will focus on employment, data privacy, and regulatory matters.

Other Upcoming Sessions – Life Sciences Growth Series

Date / Time	Title	Speaker(s)
Tuesday, November 30, 2021 8:00 pm EST / 5:00 pm PST Wednesday, December 1, 2021 10:00 am JST / 9:00 am CST	Patenting digital therapies – crossroad of life science and technology	Janice Logan, Brett Lovejoy
Wednesday, December 8, 2021 9:00 pm EST / 6:00 pm PST Thursday, December 9, 2021 11:00 am JST / 10:00 am CST	Governance constructs considerations in Japan-US cross-border strategic alliances and collaborations	Suzanne L. Filippi
Tuesday, December 14, 2021 8:00 pm EST / 5:00 pm PST Wednesday, December 15, 2021 10:00 am JST / 9:00 am CST	Using AI in Pharma R&D and Clinical Testing—Regulatory and Legal Issues for the US landscape	Kathleen Sanzo, Jacqueline R. Berman, Nancy Yamaguchi, Jitsuro Morishita

Coronavirus COVID-19 Resources

We have formed a multidisciplinary **Coronavirus/COVID-19 Task Force** to help guide clients through the broad scope of legal issues brought on by this public health challenge.

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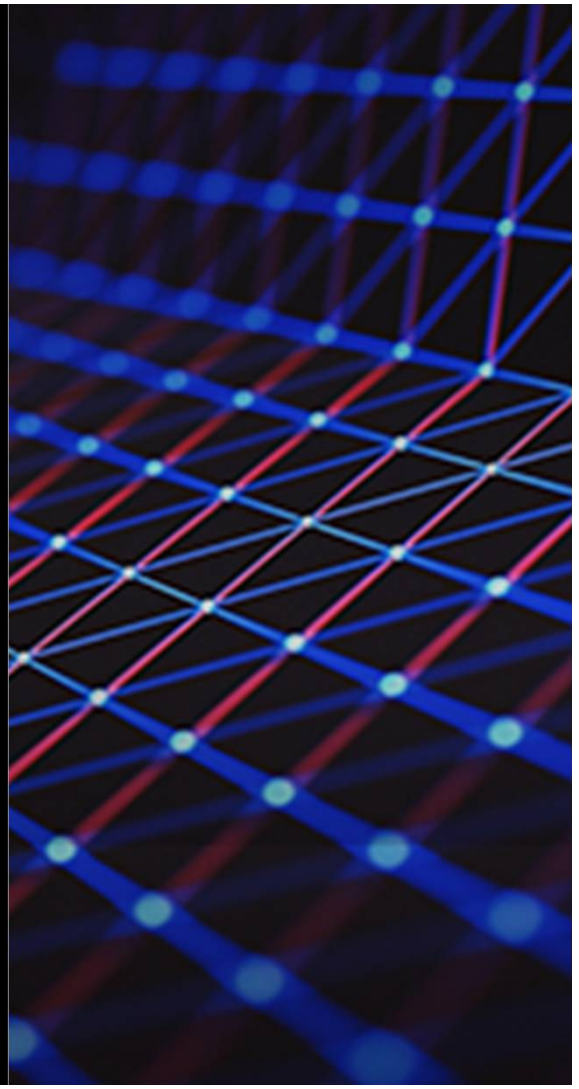
To help keep you on top of developments as they unfold, we also have launched a resource page on our website at **www.morganlewis.com/topics/coronavirus-covid-19**

If you would like to receive a daily digest of all new updates to the page, please visit the resource page to **subscribe** using the purple "Stay Up to Date" button.



Biography

Motonori Araki
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Motonori Araki primarily advises on mergers and acquisitions (M&A), commercial transactions, intellectual property licensing, and international dispute resolution. Moto has worked with clients across all industries with a focus on life sciences and technology, representing major US and Japanese companies in cross-border transactions and regulatory matters. His M&A work includes representing buyers and sellers on cross-border transactions and covers structuring, documenting, and negotiating transactions. Moto serves as the office managing partner of the firm's Tokyo office as well as the leader of the firm's Tokyo corporate and business transactions practice.

Biography

Timothy J. Corbett
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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.

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 intellectual property as well as media/communications, pharmaceutical, transport, financial services, and data privacy regulations.

Biography

Mike Pierides
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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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Dr. Joachim Heine leads clients through complex public and private mergers and acquisitions, carve-outs, joint ventures, private equity transactions, and venture capital financings with an emphasis on life sciences transactions. During his accomplished career of more than 20 years, he has handled over 100 international projects ranging from multibillion-dollar public takeovers, to mid-size M&A deals and venture capital financing for clients in Germany, Sweden, the United States, China, and Japan.

Our Global Reach

Africa
Asia Pacific
Europe
Latin America
Middle East
North America

Our Locations

Abu Dhabi
Almaty
Beijing*
Boston
Brussels
Century City
Chicago
Dallas
Dubai
Frankfurt
Hartford
Hong Kong*
Houston
London
Los Angeles
Miami
Moscow
New York
Nur-Sultan
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