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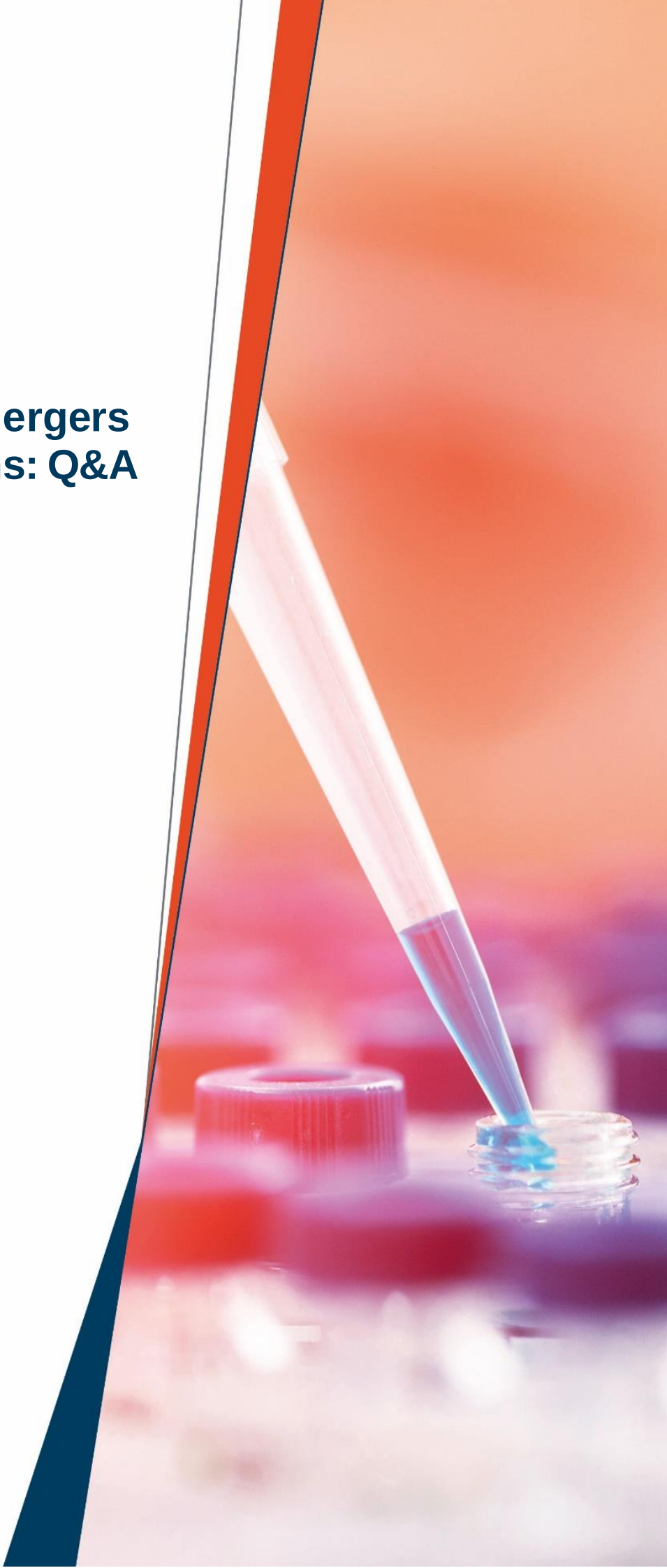
Life Sciences Mergers and Acquisitions: Q&A



Dechert LLP

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Dechert partnered with *Practical Law* on their Q&A guide to mergers and acquisitions (M&A) in the life sciences sector, with a focus on pharma and medicines. The Q&A provides a high-level overview of the factors affecting asset and share acquisitions in the sector and the key considerations for buyers and sellers. It covers the motivations of the parties; acquisition and consideration structures; risks; the due diligence process; third party consents; liability and indemnity clauses and key negotiation points in sale and purchase agreements.

Life sciences experts from Dechert's Corporate and Intellectual Property practices provided content which is in Q&A format and is reproduced below.

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Introduction

The life sciences sector is relatively broad and comprises two key constituent sub-sectors: medicines and medical devices. Medicines are any substance or combination of substances presented for treating or preventing disease, or that may be administered with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings. Companies in the medicines sector are generally pharmaceutical (or "pharma") companies or biotechnology ("biotech") companies, which are earlier-stage companies that usually develop a pharma asset and may be acquired by a pharma company. Medical devices are instruments, apparatus, materials or other articles intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of disease diagnosis or monitoring, supporting or sustaining life, controlling conception, disinfection, or providing information from the examination of specimens derived from the human body.

These two sub-sectors have important distinctions between them, both in the way that they are structured and operate, and from the perspective of mergers and acquisitions (M&A) (notwithstanding some similarities between them). Accordingly, each sub-sector gives rise to some individual considerations both in relation to M&A drivers, and the legal aspects of M&A deals relating to them.

For this reason, to avoid a note of excessive size and scope, this note primarily considers M&A relating to innovator pharma and biotech companies, which are companies that aim to develop and commercialise new medicines. Note that some, though not all, of the points mentioned below have relevance also for deals relating to medical device companies.

1. What are the key value drivers for private M&A in the life sciences sector?

The value of a life sciences company is driven by several key factors. Note that sophisticated intellectual property (IP), although important, is not of itself generally sufficient and the value of a target will usually lie in how readily this innovation has been, or can be, turned into sustainable profit. The following factors are important to consider when assessing the value of a pharma or biotech M&A target.

Life cycle

Traditionally, a drug begins life as a molecule following extensive screening and optimisation. The path from discovery to commercialisation is lengthy and expensive. There is no hard and fast rule, but industry experience demonstrates that getting a commercially-successful drug from "bench" to "patient" (taking into account failure rates), can require roughly £500 million to £1 billion in capital, and take seven to ten years. The path to approval in a major market for a drug requires several phases of clinical testing, and approval by an appropriate regulatory body. So, the point that a drug is at in its life cycle is of critical importance to value; the later in term that a molecule is, the more it is generally de-risked. A promising molecule for the same indication for first-line treatment which is about to commence Phase I testing (where a drug is tested on healthy volunteers, for safety and limited, if any, efficacy) will be worth many multiples less than one about to complete a successful Phase III study (a test of efficacy in a statistically well-powered clinical trial, before submission for regulatory approval). Where a molecule is in its life cycle has a multiple of impacts, not least remaining costs to get a drug to market, but also its likelihood of failing to achieve commercial success. Even once approved and on sale, the remaining time that a drug has "on patent" (see below, *IP/ patents*) will further affect its value.

IP/ patents

For innovator companies, physical assets, other than manufacturing facilities, are significantly less important than intangible assets (IP in particular). For a pharma company, it is important that the right to exploit, manufacture and distribute the drug(s) it owns can be protected and enforced. This ability directly affects its value. The primary

source of IP protection for an innovator company is via patent protection. Patents have specific scopes, validity and duration. "Stronger" and "weaker" patents will have direct effects on value; as will a lack of patent protection itself. The value of a drug or molecule will be driven by the owner's right to use the technology and to protect such use. Patenting a technology provides exclusivity to protect against competition. When a product's patent exclusivity finishes, it will be exposed to the risk of competition from generic drugs and biosimilar drugs.

Focus

Like any industry, the life sciences industry is subject to trends, and areas of particular focus and interest. Areas such as oncology, immunology and inflammation and chronic pain, are currently regarded as growth areas where there is both increasing demand for new products and drugs, and several innovative advances in treatments that may make it possible to improve quality of treatment. Companies which operate in these sectors may therefore benefit from a value boost.

Human capital

Although a substantial portion of the commercial value of a life sciences asset is driven by its innovation and IP protection (to defend that innovation), and also the stage in the life cycle of its assets, the value of high quality and proven management teams cannot be overlooked. A target which has a strong person, team or division, and/or has a good record of moving assets out of the clinic and on to patients, may be deemed particularly valuable because of the potential for further innovation, and because of the experience it will have. An assessment of how transportable or well-motivated a target's personnel are is also important, as value could be lost if a key person or team does not stay following an acquisition.

Profile

A target company with a strong brand or profile may have more value on an acquisition. Having proven products or robust clinical trial data may contribute to a company's profile, as may scientific breakthroughs and innovative approaches.

2. What are the main risks affecting private M&A in the life sciences sector?

Disruptive technologies

The life sciences industry is seeing growth through the introduction of disruptive technologies such as 3D printing, artificial intelligence and bioinformatics. This is also driven by increasingly empowered consumers. While technological advancements often bring about positive outcomes in terms of creating effective drugs, tracking the outcomes of treatment, and preventing disease, this can in fact pose significant risks to pharma and biotech companies. A new piece of technology may be cheaper to produce or more effective than an existing drug or product and may undermine the value of certain products being developed by these companies. For example, applications which sit on a mobile telephone and help monitor and manage a patient's mood may be beneficial for society in general, but are likely to be negative for a pharma company with an innovative product to treat depression (due to a reduced potential market for the drug).

Patent risk

A substantial part of the value of an innovator company derives from the patents that protect its key drug assets (usually with around twelve years for the effective life of its typical 20-year lifespan, taking into account the approximate eight years it will take to get for a molecule to receive marketing authorisation).

It is this patent protection which supports the prices charged for the drugs. As patents for a small molecule drug begin to expire, that usually heralds the entry into the market of "generic" competitors for the drug – usually sold at

much lower prices, and often demolishing the drug's previous market share. In recent years, this cycle of competition and price reduction has been playing out with biologic (or large molecule) drugs when so-called "biosimilars" come to the market. Without another asset to replace the now off-patent drug, the revenues of an innovator company can fall significantly.

Regulatory compliance

Non-compliance with regulatory and legal obligations can both reduce the value of the target and expose it to civil and criminal liability. Fines under EU law in relation to marketing authorisations can be significant. Non-compliance could also lead to certain authorisations being suspended or withdrawn, which may affect the target's ability to market its products. It will be important for a buyer to assess a target's compliance profile during its due diligence process.

Pricing and reimbursement challenges

A key element of a drug company's success is its ability to negotiate pricing and reimbursement with both government authorities and insurance companies. In the UK, a company must prove the value of its drug against any competing products for the NHS to be able to provide it to patients. Insurance companies will also need to approve the drug for it to be prescribed to certain patients. Pricing and reimbursement will have a significant impact on the profitability of a product as without reimbursement approval, a drug may never generate any meaningful profits (noting that several categories of drugs may be exempt from this rule, for example, "life style"-type drugs for which reimbursement is often less relevant to the decision to use). Making a drug cost-effective can be difficult given the huge costs of development. Currently, in the US, significant attention is being paid to the rising cost of drugs, and public pressure is being applied to drug companies to restrict the yearly price increases that have driven significant revenue growth.

Geopolitical uncertainty

Drug companies often need to adapt to changing regulatory developments in different parts of the world. Currently, in Europe, Brexit has created significant uncertainty and the transfer of several regulated activities from the UK to other EU member states may lead to disruption in supply chains.

Cybersecurity

The life sciences industry is particularly vulnerable to cybersecurity risks as it relies heavily on technology, sensitive IP and trade secrets. Smaller biotech companies may be more at risk as they tend to have less sophisticated IT systems and could provide a gateway for those looking to attack larger pharma companies. Cybersecurity breaches could lead to loss of vital IP, regulatory fines and disruption of operations which could, in turn, cause significant monetary losses.

Non-traditional buyers

Traditional buyers of innovator companies face increased competition from non-traditional buyers such as Amazon. The rise of such buyers is linked to increasingly empowered consumers (and vendors) and technology companies which are quickly developing innovative ways to engage with those consumers, and to extract further value from pharma companies in an environment which may already be financially pressuring them.

3. Are there any other key factors that affect private M&A in the life sciences sector?

Presence of private capital

The life sciences industry is becoming increasingly popular with venture capital investors, who can use sophisticated structures and capital to attempt to accelerate and maximise the value and growth of biotech companies. This increases the amount of capital available to fund research and development (R&D) in the industry and can increase the level of sophistication of transaction activity in the industry.

Creating focused portfolios

Life sciences companies have tended towards consolidating their portfolios in recent years with a desire to focus on key areas of therapy. This allows companies to raise their profile and concentrate on key assets. It also means that companies are looking to make strategic divestitures which could lead to more assets being on the market.

Alliances

It is increasingly common for life sciences companies to form alliances to hedge potential risks and share potential rewards on some of the more uncertain clinical trials. For example, Merck KGaA and Pfizer set up a strategic alliance in July 2017 in relation to a particular drug. The rise of alliances allows assets to be developed to the fullest extent possible and to test combinations, and also to share the significant costs of R&D.

Increased wealth

The increased wealth of the population means that there is an increasing demand for new drugs, including for conditions that are elective. In a society that is increasingly consumer-led, patients and customers are calling for a wide range of solutions for superficial and aesthetic conditions.

Aging population

An aging population and a higher percentage of citizens over 65 in the West, and Europe in particular (together with Japan), is creating opportunities for the pharma industry. Many people over 50 have at least one chronic health complaint, and the need to treat conditions such as arthritis, diabetes and cancer is driving drug development and market consolidation significantly.

Mega-mergers

It is currently predicted that the life sciences market may begin to see more mega-mergers of substantial life sciences companies. The Takeda/Shire merger completed in January 2019, and Bristol Myers-Squibb acquired Celgene in November 2019 for more than US$70 billion in cash and contingent value rights. These mergers are driven by an increased need to consolidate resources and market focus, limit exposure to R&D failure, and ensure access to new pools of on-patent drugs.

4. Is one structure more common than another for acquisitions in the life sciences sector and what are the key factors that determine how an acquisition is structured?

In determining transaction structuring in the life sciences M&A area, similar considerations prevail as for general M&A.

Share sales

It will usually be most straightforward to structure a transaction as a share sale. A particular benefit of a share sale for a life sciences company is that in the usual course, all the target's contracts and regulatory consents will be transferred. This will be particularly important where the target's business relies on a particular regulatory consent or a particular contract (for example, a public sector contract) being in place.

Asset sales

An asset sale may be more appropriate in certain circumstances. The target may have certain liabilities which the buyer does not want to take on, such as any litigation or clinical trial liabilities. The buyer may only want to acquire a particular business unit or asset line rather than the entire business of the target company. There may also be a requirement to restructure part of the business before a sale.

Structuring a life sciences M&A deal as an asset sale can create a number of complexities, however, and subsequent contractual relationships between the seller and buyer may be required to ensure the target's continued value and ability to commercialise its assets following a deal. For instance, continued access to IP will be required by the business assets acquired, and this is likely to require the negotiation of suitable licensing agreements as part of the acquisition. In the case of more mature (that is, on sale) drugs, it is likely that acquiring only certain assets from a target company may leave behind some of the supporting infrastructure required to manufacture the drug. This could require the formalisation of manufacturing and other licensing agreements between buyer and seller, which would operate on an ongoing basis, to make the contemplated deal viable. A buyer should be mindful that relevant regulatory consents may not be transferred on an asset sale. Due diligence should be carried out to determine the consents required for the target assets and the sale could be made conditional on consents being obtained by the buyer.

5. What types of consideration and price adjustment mechanisms are commonly used in acquisitions in the life sciences sector?

Deferred consideration

The majority of private M&A deals in the sector will be structured to include some element of deferred consideration. This is partly due to the nature of the life cycle of the target assets. The likelihood of success of a given drug will depend on the stage of its life cycle and the earlier a drug is in its existence, the harder it will be to determine its potential value. Buyers will need to be mindful of further development costs, and of the risk that products may not obtain approval or become commercially successful. To bridge the "valuation gap" between buyer and seller, it is usual to employ some type of deferred consideration structure.

Note that under English law, there is no automatic right of contractual set-off, so a buyer may not be entitled to set-off liabilities against deferred payments unless this is expressly provided for in the contract.

Milestone payments

Deferred payments may often be linked to milestones, so that the payment obligation is triggered on the occurrence of specific facts or events. Possible milestones include application for a clinical trial for a new molecule, first dosing in Phase I, II or III trials and receipt of regulatory approvals. Payments for drugs that have authorisation to be sold may also be linked to net sales in certain jurisdictions. Milestone payment obligations are often complex to draft and care should be taken to ensure that the trigger for payment is defined correctly to avoid any dispute over interpretation. Several recent significant pieces of litigation have been driven by milestone provisions which were imperfectly drafted. It is usually prudent to involve specialist counsel in this process to ensure that regulatory or scientific terms are accurate, and clearly defined.

"Commercially Reasonable Efforts"

Given that significant future value arises as a result of the deferred payment structures typically used in life sciences M&A, it is common to require the buyer to take reasonable steps to continue the development or sale of the acquired drug assets, so that the seller can be comfortable that it will have an opportunity to earn the deferred sums. The efforts required from the buyer in this regard are typically negotiated and defined as "Commercially Reasonable Efforts". Although formulations of this "Commercially Reasonable Efforts" requirement ultimately vary, it is normal for it to be related to the efforts which would typically be expended to develop, commercialise and sell the drug that would be expended by a typical pharma company of a similar size and scope. Inevitably, this is a somewhat general and imperfect definition.

6. Are auction sales common in the life sciences sector? Are there any sector-specific considerations which affect the auction process?

While auction sales are not the norm in the context of private company life sciences M&A, they are becoming more common. This is because of both the increased competition to acquire high profile and/or late-stage drugs and the increasing presence of financial buyers (particularly private equity sponsors) operating in the life sciences market. Generally, the considerations will be much the same as for general M&A. A few sector-specific considerations are set out below.

IP

Due to the vital nature of the IP in the life sciences industry, auction sales in the life sciences sector may have a greater emphasis on the protection of IP, particularly at the bid stage and when drafting non-disclosure agreements and controlling the content of the data room.

Transaction approvals

As the industry is highly regulated, potential buyers may require that the transaction is conditional on obtaining certain regulatory consents and approvals. A buyer who can do the deal with minimal regulatory conditions or demonstrate credible previous interactions with the relevant regulators may therefore be more attractive than others in the auction process.

7. Are any other business combination, collaboration, licensing or joint venturing structures commonly used as alternatives to share or asset acquisitions in the life sciences sector? What factors typically drive the choice of these structures?

There are two key structures used as alternatives to acquisitions in the life sciences sectors. These are considered below.

Licensing transactions

In some instances, a buyer may only wish to acquire the right to sell a drug, in certain countries, or for certain conditions (known as "indications"), and does not need or desire to acquire all of the rights to a drug, or a wider portfolio of assets. In such a case, it is not uncommon that instead of an acquisition, a licensing deal will be effected, giving the licensee rights to sell, market, and in certain cases, manufacture a drug, either worldwide, or in certain jurisdictions. It is typical that in exchange, an up-front licence fee and royalties (typically as a percentage of net sales), together with milestones, will be paid.

Strategic collaborations

A further method used in cases where a pharma company may not consider an asset sufficiently developed to justify a full acquisition, but where it wishes to retain the rights to acquire an asset at a future time, is a strategic collaboration. The parties to a strategic collaboration are typically a biotech company with a promising molecule that has not yet received regulatory approval for sale (typically, the asset will still be in the early stages of its clinical trials), and a larger pharma company, with interest in co-developing the asset with the biotech, and ultimately acquiring it. In such a case, it is typical that the biotech and pharma company will work together to establish a collaboration company or entity (CollabCo), often owned by the biotech's shareholders. CollabCo will typically be given IP from the biotech to operate the collaboration, and will enter into a Licence and Collaboration Agreement (LCA) with the pharma company. Under the LCA, the pharma company will make regular payments to CollabCo and, in return, CollabCo will use the payments to develop the idea. The LCA will prescribe certain conditions as to how the IP is to be operated and developed, and joint governance provisions. It is typical that the pharma company will have an option (often with a pre-agreed and negotiated share purchase agreement to accompany it) to acquire CollabCo at a future time, if it has achieved certain milestones. The sum to be paid can either be pre-agreed or calculated based on the state of development of the relevant molecule at the time. It is also typical to include post-acquisition milestone payments. These strategic collaboration structures can become complex, particularly in cases where the holding company may have structured itself as a "platform" company, that is, a technological platform with IP that can be used to treat several different conditions. In such a case, the biotech's IP structures can become complicated and require multiple layers of agreements to ensure that CollabCo receives the IP and services that it needs to effect the collaboration.

8. Are there any sector-specific considerations that apply in relation to preparing a target for disposal in the life sciences sector? Do the preliminary agreements that the parties enter into have any sector-specific features?

When preparing a pharma or biotech target for disposal, some of the considerations which must be taken into account will be universal and apply generally to all businesses; others will be driven by the fact that the target is a pharma asset, firstly, and then secondly, by the stage in its life cycle that the target is at, and the structure of the particular asset being sold. Please see earlier questions (and *1. What are the key value drivers for private M&A in the life sciences sector?*, in particular) for some more detailed points on the life cycle of a pharma company/asset.

From a commercial perspective, there are a few general value inflexion points at which it is typical to try and realise the value of a pharma or biotech company. These tend to arise near the conclusion of clinical trials (assuming that the anticipated results are positive), or the attainment (or near attainment) of certain commercial milestones, for example, marketing authorisation approval for sale in certain jurisdictions. That said, transactions can also be undertaken for strategic reasons not always related to the target's specific life cycle, so in reality, disposals can happen at most times.

As part of the preparation for sale, a few issues can arise, as detailed below.

Transferability restrictions

An important question to determine is whether all aspects of the target's business are readily or quickly transferable at the time of the sale. For instance, during a clinical trial, delays can be caused when attempting to change the sponsor of the trial (if needed). Also, it is likely that where a business is actively selling drugs pursuant to a marketing authorisation in Europe, the transfer of those permissions can require third party consents and may also be delayed, for example, if there are ongoing applications in relation to the scope of the marketing authorisation itself. Further, certain contracts on which the target may rely (for example, third party or governmental contracts) may contain specific change of control restrictions that may need to be planned around.

Can the target be cleanly separated from the selling group?

In the case of a pharma target, it may be impossible, or challenging, to entirely separate the target from its selling group. As mentioned above (see *4. Is one structure more common than another for acquisitions in the life sciences sector and what are the key factors that determine how an acquisition is structured?*), the target may require ongoing access to IP or manufacturing support from the selling group. This would require appropriate transitional arrangements to be established, potentially alongside more permanent arrangements, such as ongoing IP licences. None of these factors are reasons that a disposal cannot be effectively completed; but preparing for a disposal will inevitably require an assessment of whether the target can operate on its own going forward, and the development of strategies to address any need for ongoing support.

Preliminary agreements

The preliminary agreements entered into in a life sciences M&A transaction will usually be largely the same as in general M&A transactions. However, the nature of the underlying assets in a life sciences transaction will mean that certain aspects are given greater importance and require more thought and planning. Firstly, given the usual vital importance of IP to innovator targets in this context, the parties will need to give some thought to its protection. Non-disclosure agreements will therefore be of great significance and terms such as the definition of confidential information and restrictions on its use may be subject to lengthy negotiations. In many cases, in a competitive situation, the release of sensitive confidential information to bidders is likely to be staggered, so that only the successful bidder receives the most sensitive information. Secondly, data protection (particularly in relation to patient data) will also need to be considered in the context of life sciences transactions, and preliminary agreements are likely to include thorough data protection provisions. The data collected in relation to clinical trials, for instance, is exceptionally sensitive and will be covered by the *General Data Protection Regulation ((EU) 2016/679)* (GDPR) in the EU, or the Health Insurance Portability and Accountability Act 1996 (HIPAA) in the US. The requirements of applicable legislation will need to be reflected in these preliminary agreements. Finally, the preliminary stages of a life sciences deal may involve the transfer of materials (for example, for testing). If this is the case, then it will be necessary for the parties to agree provisions relating to the transfer and use of such materials. This may be done by way of a separate materials transfer agreement or as part of any non-disclosure agreement.

9. What are the main areas of focus of the buyer's legal due diligence enquiry for targets in the life sciences sector? Do the key areas of focus differ depending on whether the transaction is a share purchase or an asset purchase?

When undertaking due diligence on a pharma or biotech target, particularly one which is a trading business, there will be several aspects of that target which are similar to the acquisition of non-drug-related trading entities. This note does not cover those.

There will, however, be several aspects of a life sciences target that will be the subject of highly-specialised due diligence. This is due to the complex and often regulated nature of the assets, together with the importance that an IP portfolio can play in the business. This will be the case whether the deal is structured as a share or asset purchase.

As outlined above, however, there will be some specific issues which arise, depending on whether the acquisition is to be structured as a share or asset sale (see *4. Is one structure more common than another for acquisitions in the life sciences sector and what are the key factors that determine how an acquisition is structured?*). These issues are too exhaustive to cover here in full detail, but for instance, on a share sale, the buyer will need to understand the degree to which consents (both regulatory and contractual) may be required to consummate the sale, as well as considering the tax history of the corporate entities to be acquired. On an asset sale, the buyer will need to understand the degree to which the assets being acquired are sufficient to operate the business as it is presently being carried on, and the degree to which transitional support may be needed from the seller's group, as well as

considering how smoothly the underlying operating contracts of the business can be assigned to an acquirer (as they will not automatically transfer on an acquisition).

The main areas of general focus which arise in relation to due diligence of a pharma company are discussed below.

IP rights

Given that the right to commercialise and protect the use of sophisticated IP assets lies at the heart of the commercial activities of many innovator companies, conducting due diligence on the IP aspects of a life sciences transaction is generally of vital importance. A buyer should consider the validity and scope of any patents, to avoid acquiring a target company or target business which cannot operate in important jurisdictions or could face a challenge as to the validity of its patents, as well as understanding the patent lifespan remaining for each of the exploited assets of the company. Additionally, whether the target owns or has the exclusive right to use all the IP needed to run the target business should be considered. This can be a particular issue where some of the IP of the target company may have been developed via collaborations with other companies. Additionally, an assessment of how the IP was created, by whom, and in what circumstances (for example, certain scientists work for several different institutions at one time, and arguments can arise as to who owns certain discoveries) may also be important to determine whether any employees or contractors have any rights to the IP. It will also be important to check whether any IP litigation is ongoing or has occurred which may affect the strength of the target's IP. Finally, certain countries, such as China and Germany, require that any patent inventor have been "reasonably" compensated for developing an invention and this financial obligation should be examined as part of any due diligence.

Regulatory

A buyer should assess the regulatory position of the target in several areas, including those detailed below.

Marketing authorisations

Does that target have appropriate authorisations to market the drugs that they are selling? Are they properly described and in full effect?

GXP

Does the target comply with industry guidelines and regulations on good clinical practice, good distribution practice, good manufacturing practice and good vigilance practice?

Pharmacovigilance is the practice of monitoring the effects of medical drugs after they have been licensed for use, especially to identify and evaluate previously unreported adverse reactions. This is a process mandated by law, requiring some specific compliance actions to be taken. It will be critical for the target to be able to demonstrate its compliance. As an example, non-compliance with pharmacovigilance requirements can lead to the suspension of a target's marketing authorisation.

Data

As highlighted above, the correct and careful treatment of sensitive data is of increasing importance in the pharma industry, as governmental agencies become ever more vigilant and stringent in their requirements around the treatment of sensitive data. Given the importance of data protection in this context, in particular, in relation to patient data, an assessment of historical compliance with the *GDPR*, HIPAA and other relevant data protection laws may be appropriate.

Pricing/reimbursement

Depending on what stage of development the underlying product is in, pricing and reimbursement issues may also need to be considered during due diligence. If the product is not yet being marketed, then a buyer should consider its potential for being approved for reimbursement and any potential reimbursement issues. If the product is already being marketed, then the buyer should also consider its compliance with healthcare and pricing regulations and contracts. This is impacted additionally by the position taken by key government agencies to various drugs, for example, the National Institute for Health and Care Excellence (NICE) and the NHS in the UK.

10. What third party consents and approvals (board, shareholder, regulatory or contractual) must typically be considered and obtained for acquisitions in the life sciences sector?

The board and shareholder consents and approvals on a life sciences transaction are, overall, largely the same as those required in general M&A. However, there are two main areas where specific third party consents may arise in the context of life sciences M&A.

Regulatory consents

Some transactions may require regulatory consents to be obtained, for instance where it is intended to transfer marketing authorisations to other entities within its group following completion. Antitrust clearances (or notifications, at the very least) may also be relevant depending on the value of the deal and the size of the buyer. Analysis should be carried out to determine whether any filings or approvals are required and if so, the deal timetable should be structured accordingly. There may also be further regulatory consents that a buyer requires to complete a transaction, such as consent to market a product in a particular jurisdiction.

Contractual consents

The contractual relationships of a target may be of significant value to the business, for example manufacturing contracts and government contracts. The terms of such contracts may require consents for change of control or assignment, on the completion of a share or asset sale. Although the obtaining of such consents may not be mandatory from a regulatory perspective, some of the underlying contracts that a target asset has may be fundamental to its value, and therefore the obtaining of such consent is required from a commercial perspective.

11. Is it common to have a split signing and completion in transactions in the life sciences sector? If so, what are the key reasons why an interval between exchange and completion may be necessary for deals in this sector? What are the common conditions to completion?

It is common for life sciences M&A transactions to be structured with a split signing and completion. This is largely due to the complexity of the underlying assets and the fact that third party governmental consents will often be involved. The substantive reasons for these consents are outlined in *10. What third party consents and approvals (board, shareholder, regulatory or contractual) must typically be considered and obtained for acquisitions in the life sciences sector?*.

12. To what extent and in what respect are the main substantive provisions of a generic sale and purchase agreement (other than the warranty schedule (see Questions 14-17 below)) amended to reflect the sector-specific requirements of an acquisition in the life sciences sector?

The specific nature of a life sciences deal will tend to require the amendment of certain clauses of the generic share purchase agreement. In particular, the following sections of the agreement may need to be tailored to reflect specific requirements of an acquisition in the life sciences sector.

Deferred consideration

The consideration on a life sciences transaction will often involve a significant deferred element on most non-public deals. This is for several reasons. Firstly, the assets typically to be acquired have not yet realised their full value, and may never realise it, due to the often exploratory nature of some of the assets acquired. It can be difficult to quantify the genuine value of an asset which is still in Phase I testing, and which may not achieve commercial success (or may, conversely, prove to be a blockbuster drug). Additionally, the expectations of both the buyer and seller in terms of value may not align, and an element of deferred consideration can be helpful in bridging this valuation gap.

Deferred consideration is most typically payable on the occurrence of several agreed "milestones" (as explained in more detail in *5. What types of consideration and price adjustment mechanisms are commonly used in acquisitions in the life sciences sector?*). The buyer is typically required to use its "Commercially Reasonable Efforts" to attain these milestones. As previously outlined, the drafting of these deferred consideration provisions can require specialist input, from an accounting, regulatory and IP perspective, among others.

Completion

A life sciences M&A transaction will often be structured with a split signing and completion for the buyer to obtain the necessary governmental and third party consents (as detailed in *10. What third party consents and approvals (board, shareholder, regulatory or contractual) must typically be considered and obtained for acquisitions in the life sciences sector?* and *11. Is it common to have a split signing and completion in transactions in the life sciences sector? If so, what are the key reasons why an interval between exchange and completion may be necessary for deals in this sector? What are the common conditions to completion?*). The share purchase agreement (SPA) will therefore need to be drafted with this in mind. This will have particular importance when considering the interim (pre-closing) covenants. Life sciences targets can often have most of their value in their IP and in their various contracts, so interim covenants should protect these key areas in particular, as well as ensuring that the regulatory compliance of the target is not compromised. As ever with pre-closing covenants, however, careful drafting should be used to avoid giving a potential buyer sufficient negative control over a business for it to be considered "gun-jumping" from an antitrust perspective.

Restrictive covenants

Restrictive covenants will be of great importance in preserving the value of the target post-sale. Where the target has important human capital, the buyer will want to ensure that it has non-solicitation protections in place. Given the importance of IP, specific covenants may be needed to protect aspects of the target such as brand names. The buyer may wish to require that the seller does not develop a new drug in the same field as the target asset for a certain period of time post-completion. Confidentiality provisions will also be important.

Indemnities

Depending on the outcome of due diligence, if specific problems are identified, the buyer may wish to include indemnities from the seller in favour of the buyer in the agreements. Typical subjects of indemnities in the purchase agreement are detailed below.

Regulatory compliance

If it appears that the target may have issues with some of its regulatory compliance, the buyer may request an indemnity to compensate it for any associated commercial detriment.

Third-party IP claims

Notwithstanding the extensive due diligence that will likely be undertaken as part of the analysis of the target, it is always difficult to exclude the possibility that a third party may challenge some aspect of the target's IP portfolio. As a risk-sharing mechanism, indemnities focused on compensating the buyer in the case of such a third-party claim (including its associated costs, whether or not such a claim is successful) can be negotiated.

13. What are the key areas of negotiation in an acquisition in the life sciences sector? Are there specific points that tend to be heavily negotiated?

The following issues are examples of areas that may be heavily negotiated in a life sciences M&A transaction. This list is not exhaustive and there may be other areas of contention depending on the specific terms of the deal. In larger deals, most points tend to be negotiated as there can be significant amounts of value at stake. Many of the key areas of negotiation are areas, for example warranties, which are heavily negotiated in most types of M&A deal. Specifically in relation to life sciences deals, some key points of value are discussed below.

Consideration

The future value of a life sciences asset can be difficult to determine, so transactions will usually include an element of deferred consideration. The balance between upfront and deferred payments will be carefully negotiated. Additionally, the degree to which deferred payments may be set-off against obligations owed to the buyer by the seller (for example, in relation to indemnity breaches) will be discussed. As explained above, the scope and triggers of milestone and royalty payments, and the revenue which is subject to them, will be particularly negotiated.

Disclosure

The way in which disclosure is handled is often the subject of significant negotiation, particularly where there is a period between signing and closing. Typically, contested issues will include whether disclosure can be repeated at closing (if warranties are repeated at closing), and how loss is apportioned between buyer and seller in relation to any issue which is disclosed at closing, in circumstances where the deal will close, irrespective of the disclosure.

Post-closing restrictions

Particularly in circumstances where the seller may have other assets which could compete with the assets of the target being sold, or where the buyer may only be acquiring the rights to exploit certain drugs in specific geographies, the scope of any non-competition between the buyer and the seller following closing will be carefully discussed.

14. What amendments would typically be made to the warranties in Schedule 4 of *Standard document, Share purchase agreement: single corporate seller: non-simultaneous exchange and completion* for an acquisition in the life sciences sector?

The amendments required to be made to the warranties in Schedule 4 of *Standard document, Share purchase agreement: single corporate seller: non-simultaneous exchange and completion* for an acquisition in the life sciences sector will vary from transaction to transaction and will be driven both by the specifics of the target's operations, and the outcome of the buyer's specific due diligence investigations. That said, there are common areas where amendments to the warranties are likely to be required as detailed below.

Licences and consents

The buyer will likely seek to ensure that warranty protection is given as to the status of required licences (especially marketing authorisations) and consents which it deems are required by the target. It may also request that the target gives a general warranty that it has the licences and consents required to operate; for example, that the target may have certain marketing consents or licences to use IP.

Disputes and investigations

The buyer of a life sciences company will want to ensure that appropriate warranties relating to potential disputes and investigations which might affect the target are included, given the potential risk of unknown liabilities in this area, and their potentially high quantum. For instance, the buyer may wish to include a warranty that there are no circumstances existing which could give rise to a dispute or investigation. This would shift the risk of unknown liabilities onto the seller.

IP

Given the importance of IP to the value of a life sciences target, IP warranties are likely to be heavily negotiated and will require specialist input. A buyer will want to ensure that the IP warranties are amended to offer extensive protection, particularly in relation to the validity and enforceability of the target's IP, and the likelihood of unforeseen third party infringement claims. Warranties as to the expiry dates of patents may also be added, to provide comfort around patent terms.

Data protection

Data protection also represents an area of potential unknown liability for a buyer, because a life sciences company may have access to and use of large amounts of patient data, and laws in both the US and Europe are becoming more stringent in this area. An area of negotiation between buyer and seller will be the balance of risk outlined in the warranties, in relation to the treatment of patient data.

Environment and health and safety

The buyer will want to ensure that the target has in place all necessary environmental and health and safety permits, consents and certificates, and will seek appropriate warranties to underwrite this position, together with warranties relating to the outcome of any environmental due diligence undertaken. Warranties may be required for specific aspects, depending on the activities and scope of the target company's operations. For instance, warranties relating to the condition of land occupied by the target, and any hazardous substances used by it, may be required if the target operates a manufacturing plant.

Compliance

The buyer may wish to amend general warranties relating to compliance with laws to refer specifically to certain areas of compliance which are more relevant to a life sciences company. For example, the warranties may need to be amended to include compliance with good manufacturing practices and good clinical practices. A buyer is likely to also wish to include warranties relating to compliance with pharmacovigilance laws or practices, if the target has medicines for sale in the market.

15. What amendments would typically be made to the warranties in Schedule 13 of *Standard document, Asset purchase agreement* for an acquisition in the life sciences sector?

From the perspective of a pharma acquisition (though not always generally), the considerations which apply on an asset purchase are generally similar to those on a sale purchase. For the amendments that would typically be made to the warranties in Schedule 13 to *Standard document, Asset purchase agreement*, see *14. What amendments would typically be made to the warranties in Schedule 4 of Standard document, Share purchase agreement: single corporate seller: non-simultaneous exchange and completion for an acquisition in the life sciences sector?*.

16. What are the common areas of indemnity cover in the life sciences sector?

Given that the general use of an indemnity in M&A transactions is related to the outcome of the buyer's due diligence investigations, the focus on indemnities included in the purchase agreement for the target will be bespoke to the individual deal. However, there are (as with warranties), some common themes which appear in specific indemnities. Liabilities relating to historic actions or breaches can potentially be high in the life sciences sector, so a buyer is likely to seek indemnities for material red flag issues that arise during the due diligence process. Examples of where such issues may arise are set out below.

IP

Given the importance of IP to pharma and biotech targets, a buyer may seek an indemnity if any material IP-related issues are raised during the due diligence process. For example, if there are any third party IP claims in relation to any of the target's IP or if there are any known instances of infringement (or it is deemed that there is a material risk of the same).

Product liability

Product liability claims can often be expensive both to conduct and to settle. This is particularly so in the case of class actions. Additionally, product liability cases in the life sciences sector may involve severe injury or death. A buyer is likely to want to be indemnified against any costs or risks arising from any past product liability infringements (or material potential infringements).

Clinical trials

Similarly, any patient liabilities arising from clinical trials could potentially be extensive and are likely to be subject to indemnity obligations in the SPA.

17. Is warranty and indemnity insurance a common feature of acquisitions in the life sciences sector?

Warranty and indemnity insurance is a less common feature of acquisitions in the life sciences sector than in other sectors. This is partly because life sciences assets are, as we have seen, relatively difficult to value, and partly due

to the potential for extensive liabilities (including relating to death or injury) if warranties or indemnities are breached. Warranty and indemnity insurance is, however, becoming more prevalent in the sector. This has been driven by an increase in non-life sciences companies seeking to enter the sector (thus increasing an appetite to insure against less-well-understood risks in general) and by a growing understanding by insurers of the risks associated with life sciences deals, together with increased competition in the insurance market overall, prompting insurers to broaden their scope of activities. Insurance companies can, as part of their policies, seek to exclude certain high risk areas of cover such as product liability and cyber liabilities, as well as coverage for IP and failure to withhold tax for consultants who should have been treated as employees. These exclusions will be a subject of negotiation when arranging a policy.

18. Beyond the core ancillary documents that routinely feature in M&A transactions, are there any additional sector-specific documents that are commonly required in transactions in the life sciences sector?

Transitional agreements

As described more fully in the answers to questions above, in some transactions, the parties may wish to put in place transitional services agreements (TSA), to cover transitional periods following acquisition, in relation to various services to the target which may currently be being provided by the group. Examples of these include IP licences, IT services agreements or manufacturing agreements.

Ongoing arrangements

It may also be necessary to put in place more permanent arrangements, such as ongoing IP licences or ongoing manufacturing agreements.

19. Are there any key steps to be taken on completion or post-completion in relation to an acquisition that are specific to the life sciences sector?

The steps at completion and post-completion on a life sciences transaction will largely depend on how the deal has been structured and what is being transferred. The following steps may need to be considered.

Transfer authorisations

If marketing or other authorisations are being transferred between entities as part of the transaction, then the parties will need to ensure that these transfers are effected as a completion item. This may require updating the relevant authority with the transferee's details.

Transitional arrangements

If transitional arrangements are in place at completion, the buyer will need to consider its longer-term plans to obtain the services currently covered by the TSA.

IP

Given the importance of IP to life sciences companies, the buyer should ensure that all IP has been effectively transferred and that any updates required to IP registers are made as soon as possible following completion.

Intangible assets

Certain intangible assets such as know-how may need to be transferred (particularly on an asset sale). The buyer should ensure that delivery of such assets is clearly considered and described in purchase agreements.

Content published and produced in August 2020.

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