

# Key considerations for European M&A in the life sciences sector

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M&A in the life sciences sector has remained robust, driven by factors such as:

- The need to replenish shrinking product pipelines.
- The need to maintain revenues as patents on top-selling products expire.
- The strategic diversification of business lines.
- Expansion into emerging markets.

Unique features of research, development and commercialisation of products and technologies in the life sciences sector give rise to a multitude of issues across a broad range of legal and commercial fields. Therefore, it is essential for life sciences M&A teams to include counsel who are experienced in identifying and resolving sector-specific issues across a range of practice areas. This will ensure smooth implementation of the commercial deal.

This article illustrates how a complex and evolving legal and regulatory environment gives rise to unique challenges for those engaged in European M&A in the life sciences sector, by analysing a hypothetical M&A. In particular, it examines:

- A life sciences M&A case study.
- Due diligence and its impact.
- Intellectual property issues.
- Structuring the deal.
- European competition laws.
- Anti-corruption laws.
- Employment issues.
- Tax issues.

## LIFE SCIENCES M&A: A CASE STUDY

To provide context to this article we envisage a hypothetical scenario in which a European biopharmaceutical company with a premium listing on the main market of the London Stock Exchange (Seller) seeks to divest its oncology business through a sale, for cash, of its UK subsidiary (Target) to a pharmaceutical company (Buyer).

Target's portfolio includes:

- A pipeline of early stage pre-clinical products.
- A product in Phase II clinical trials.
- A lead product on the market in the European Economic Area (EEA), but not yet outside the EEA. This product is

manufactured at a facility in The Netherlands, which is owned by Seller. Seller also uses the facility to manufacture other products in its portfolio, so it will not be included in the sale. Buyer's intention is to start manufacturing the lead product itself.

Buyer's oncology business manufactures and distributes products that do not compete with Target's lead product. However, it has:

- An early stage pipeline product that it expects will have the same therapeutic indications as Target's lead product.
- A Phase II product that it expects will be indicated for at least the same therapeutic applications as Target's Phase II product.

Target's product pipeline has been driven by the work of one of its founding scientists (Founder), who is engaged on a part-time consultancy basis which allows him to continue his research at a leading UK university. Founder, with his team of scientists employed by Target, play a key role in developing Target's oncology products.

Target uses distributors to market its lead product and relies on Seller's regulatory personnel to perform some of its regulatory obligations, such as pharmacovigilance.

## DUE DILIGENCE AND ITS IMPACT

Regulatory matters and intangible assets give rise to specific due diligence issues.

### Validity of marketing and other authorisations

In the current scenario, Buyer's due diligence would seek to establish the existence and validity of marketing authorisations, and pricing and reimbursement approvals, for the marketed lead product. In conducting its investigations, Buyer will use materials provided by Seller and information made publicly available by the relevant regulatory authorities.

Buyer should assess:

- In relation to key jurisdictions in which the lead product has not yet been granted a marketing authorisation, whether Seller's projected timelines for obtaining a marketing authorisation are reasonable, and whether there is anything to suggest that a marketing authorisation will not be granted.
- The likelihood of marketing authorisations being granted (and the associated time scales) in respect of Target's development-stage products.



While Buyer will not be able to predict these matters with complete accuracy, it should be possible for Buyer to verify that the ongoing and planned clinical trials for the development-stage products are consistent with both:

- Development plans agreed with or proposed by the applicable regulatory authorities.
- Guidelines from the European Medicines Agency or other relevant regulators.

#### Data and other regulatory exclusivity

In relation to Target's marketed product, the likely data and other regulatory exclusivity applicable to the product directly affects the likely timing of generic competition and the product's future revenue potential. Additional sources of exclusivity include orphan exclusivity, paediatric exclusivity or data exclusivity for new indications.

Understanding the likelihood and duration of data exclusivity is equally important for Target's product in Phase II trials and products in early stage pre-clinical development, to assist Buyer in making an informed assessment as to potential value.

#### Regulatory compliance

The extent of Target's compliance with regulatory obligations can affect an M&A transaction in a number of different ways. Non-compliance with applicable legal obligations can expose Target to potential civil and criminal liability.

The level of potential liability has historically been much lower in the EU than in the US. Now, where a product has been authorised through the centralised procedure, Regulation (EC) 658/2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) 726/2004 permits the authorities to impose fines of up to 5% of the marketing authorisation holder's annual turnover for breaches of the pharmaceutical rules.

Failures by Target to comply with regulatory obligations during development or commercialisation may have other, less obvious, effects on the value of Target. For example:

- Failure to comply with good clinical practices undermines the integrity of clinical trial data. This could prevent Target from using trial data to support marketing authorisation applications, therefore increasing development costs and delaying commercialisation while the non-conforming trials are repeated.
- Repeated or serious non-compliance with good manufacturing practices (GMP) could suggest that a manufacturer's authorisation may be suspended or not renewed, jeopardising the supply chain for existing products and future revenues derived from them. It may also be necessary to conduct expensive recalls of non-conforming products that are already on the market.
- Pharmacovigilance and other safety issues could result in a withdrawal of the marketing authorisation, or changes to the product's labelling that adversely affect the product's commercial potential.

#### Intangible assets

The value of most life sciences businesses is principally driven by the ability to translate innovation into profit. The relevance

of physical asset balance sheet values may be diminished, and increased importance is put on the valuation of a Target's intangible assets. These may not even appear on the balance sheet and, in the case of products still in development, may not yet generate revenue. Commercial and legal diligence is therefore of critical importance to Buyer. For some M&A transactions, diligence may be merely confirmatory in nature: a check to see that Target's business contains the expected bundle of assets without any unanticipated liabilities. For a life sciences target, diligence investigations are a key element that drives the valuation and sale process.

The commercial value of an innovation depends in part on the strength of Target's right to exploit and protect the exploitation of such technology. Due diligence should seek to discover and assess the strength of:

- The sources of Target's technology.
- How Target protects such technology against third party exploitation.

A key characteristic of M&A in the life sciences sector is Buyer's need for thorough due diligence investigation of what is often detailed and highly confidential information. To protect Seller and Target, not only must robust confidentiality agreements be put in place between the parties, but Target will often operate a two stage disclosure process, under which:

- Buyer's due diligence team is initially given access to basic information to enable Buyer to more firmly establish a proposed purchase price.
- Only if this price is acceptable to Seller is Buyer then granted access to more sensitive second stage diligence information.

From Buyer's perspective, these diligence investigations can be costly and time consuming. Accordingly, Buyer can seek either:

- Assurances in the form of exclusivity undertakings (by which Seller agrees not to sell, or solicit rival buyers, for a fixed period).
- Break fees (by which Seller agrees to make a payment to Buyer if the sale does not proceed in circumstances where Seller is at fault).

Whether or not Seller agrees to give any such assurance is principally a commercial decision. However, the parties should be mindful of relevant legal restrictions which may apply. In the present scenario, Seller has a premium listing on the London Stock Exchange and is consequently subject to the requirements of the UK Listing Rules, rule 10.2.7 of which prohibits break fees in excess of 1% of Seller's market capitalisation. This rule may contrast with Buyer's experience of M&A transactions in other jurisdictions, such as the US where break fees are not so expressly limited.

#### INTELLECTUAL PROPERTY ISSUES

Typically, in a sizeable acquisition, it is not feasible to carry out a comprehensive freedom to operate analysis or a detailed review of the intellectual property rights being acquired in all current and anticipated markets. It is therefore necessary to prioritise the investigation of certain products and jurisdictions.



### Ownership and exploitation issues

Problems for life sciences companies are commonly encountered where research has been conducted by inventors with multiple affiliations. In these cases, intellectual property rights may not be properly vested in the apparent owner. Target's product pipeline has been driven by the work of Founder, who is engaged on a part-time consultancy basis, which allows him to continue his research at a leading UK university. Particular care should be taken when investigating Target's ownership of intellectual property generated by Founder.

Further complexity can arise where research has been undertaken in collaboration with third parties. This can lead to limitations on Target's right to exploit, license and assign the resulting intellectual property. The laws on intellectual property use and ownership rights vary between jurisdictions. Advice on a variety of countries may be required to ensure that a complete picture of Target's intellectual property ownership rights is established. For example, it is not uncommon for collaboration agreements to refer to arising intellectual property as being "jointly owned", without defining the implications of such joint ownership.

Unless the rights of joint owners are contractually specified, national laws on joint ownership will apply in each country where intellectual property has arisen, irrespective of the governing law of the collaboration agreement. This can have different legal consequences in different jurisdictions, and the consequences will also depend on the type of intellectual property rights involved. For example:

- Joint owners in the US have greater freedom to independently exploit jointly owned patents.
- In contrast, co-patentees under English law are not allowed to assign or license the patent without the prior consent of all co-owners.

Few companies can realistically market a product on a worldwide basis on their own, so an inability to license a patent can be a serious obstacle.

The principal means by which most life sciences companies safeguard their core products is through patent protection. Assessing the extent to which there are patents which relate to Target's products is essential.

### Analysing the extent of patent protection

Patents can protect, among others:

- The active ingredient in a product.
- Use of a product for treating certain conditions.
- A dosage regime.
- Particular formulations or delivery systems.
- Manufacturing processes.

Patent analysis is multi-factorial, detailed and complex. It covers:

- Duration.
- Validity.
- Scope.

- The possibility of competitors circumventing the patent by designing around it.
- The likely appetite of third parties for challenging the patent.

Patent applications must be considered especially carefully, as a patent may not ultimately be granted. If one is granted, it may not have sufficiently wide claims to give any meaningful protection to Target's products. National differences in substantive patent law mean that the prospects for life science companies obtaining patents on subject matters such as gene sequences, stem cells, and methods of treatment vary from country to country.

In the scenario considered by this article, some of the patents which Target relies on to protect its products are licensed to it by Seller. Other patents are licensed by third parties to Target. Key terms of the licences, such as duration, territory and field of use, must be considered to determine whether the rights granted are sufficiently broad for Buyer's current and proposed activities. It is essential to determine whether these licences will be adversely affected by the proposed transaction. If there is a change of control clause which would be triggered by the proposed transaction, the structure of the transaction may need to be re-considered.

### Third party rights and experimental use defence

Target's owned or in-licensed patent portfolio will not present Buyer with a complete picture when seeking to establish the value of Target's technologies. Even if Target owns or licenses one or more patents protecting a particular product, that product may still infringe third party intellectual property rights. Buyer should therefore seek to understand the extent to which third party patents might affect future sales, and would typically conduct "freedom to operate" searches. As patents offer territorial protections, the risks posed by third party patents vary between different jurisdictions. Given that Buyer intends to start manufacturing the marketed product itself, it is important to consider patents which may affect the proposed method of manufacture.

Target's research activities must also be carefully considered. Life science companies sometimes assume that research and development activities will invariably be covered by "experimental use" exemptions to patent infringement. These assumptions are not necessarily justified, at least in some jurisdictions. Even if the R&D work itself is not actionable, patent infringement issues may arise when the product enters later stages of development or is put on the market.

### Alternative means of protection

If Target does not own or exclusively license patents which provide effective protection for the key products that drive the valuation of Target, Seller should provide some other convincing rationale to explain why these products will not rapidly lose market share to cheaper copy-cat products. These alternative means of protection include:

- Data exclusivity.
- Difficulties in manufacturing the product.
- The law on confidentiality and trade secrets.



## STRUCTURING THE DEAL

On the face of it, the mechanism by which a life sciences company is sold will follow the same basic framework as any M&A transaction: shares are transferred, consideration is paid and warranties and other assurances may be given. However, what makes the sale of a life sciences company different is not the basic structure of the sale, but the nature of the underlying business.

### Deferred consideration

In the life sciences sector, M&A transactions increasingly feature deferred consideration (in some transactions these can be structured as contingent value rights (CVRs) or contingent payment rights), payable only on the achievement of certain events or performance targets.

Contingent consideration features in M&A transactions of all sizes, but is less common where the target is a European listed company. This is because securities laws (such as Directive 2003/71/EC on the prospectus to be published when securities are offered to the public or admitted to trading) may require a prospectus to be published when CVR securities are offered to the public or admitted to trading.

The outcome of future events crucial to the value of a target often cannot be determined with confidence. Sellers typically value pipeline products on the assumption that they will be successfully developed, approved and commercialised. On the other hand, buyers will be mindful of further development costs and the risks that product candidates might never be approved or, even if they are approved, that they will not be commercially successful. Contingent consideration structures based around milestones in the lifecycle of a target's product(s) can help to bridge a valuation gap between the parties.

Milestones, the achievement of which may trigger payment of contingent consideration, are typically either regulatory, developmental or commercial in the life science industry. Regulatory/development milestones include the filing of:

- A Clinical Trial Application (CTA).
- A New Drug Application (NDA).
- An equivalent of any of the above.
- The first dosing of a patient in Phase I, Phase II or Phase III clinical trials.
- The receipt of regulatory approval in Europe, the US or other markets.

Commercial milestones can include the commencement of commercial sales and the achievement of a specified level of net sales of a particular product.

It is important that milestones are clearly defined to avoid a subsequent dispute about their meaning (and whether or not that milestone has been achieved). In the case of regulatory milestones, it is critical to involve a regulatory specialist in crafting the milestone definitions to help identify and assess the associated risks and to ensure that the milestones are clearly defined so that they are workable in practice.

Regulatory approval (granted in Europe in the form of a marketing authorisation) is a key milestone because a product cannot normally

be prescribed or sold without approval. Approval will not be granted unless the regulator is satisfied that the product meets the required standards of safety, quality and efficacy.

The need for government pricing and reimbursement approval and the proliferation of cost-effectiveness assessments by bodies such as the UK's NICE has increasing importance in Europe. Without reimbursement approval, a product may never generate meaningful revenues, despite having obtained marketing authorisation.

Authorities increasingly view marketing authorisations as public health tools, rather than purely commercial assets, which means that some approvals can be vulnerable and burdensome. As a result, commercial flexibility is reduced. Regulators often impose post-approval commitments or attach conditions or restrictions to authorisations, such as the need to conduct post-approval safety studies. Therefore, a buyer can seek to persuade the seller to agree that the size of a deferred consideration payment triggered by the grant of a marketing authorisation will depend on whether the product is approved for reimbursement, and the extent of any required post-approval or risk management commitments.

Milestones in respect of Target's product already on the market can include the achievement of sales targets and/or regulatory approval for a second use of the product.

If part of the purchase price is contingent on the achievement of certain milestones that are in the control of Buyer, Seller will want to protect its position by imposing performance obligations on Buyer. For its part, Buyer will seek to ensure that these obligations are reasonable and not unduly onerous. Notably, Buyer should not be obliged to keep investing in the development of the products if previously unforeseen regulatory hurdles or other factors emerge, making further development or commercialisation of the products unviable.

Various phrases are commonly used in commercial contracts, such as licensing and collaboration agreements, to qualify performance, such as "reasonable efforts", "commercially reasonable endeavours" and "diligent efforts". While these phrases are concise, and on their face can appear equitable from a business perspective, they typically do not have definitive legal meanings. Interpretation difficulties are exacerbated in a context in which such phrases must be applied to a wide range of activities during the lifecycle of a product, from non-clinical and clinical R&D, to the obtaining of regulatory approvals and commercialisation activities such as marketing and post-marketing studies.

A well-established approach which seeks to address this problem is to define terms. For example, "Commercially Reasonable Efforts" means, with respect to a party's obligations relating to a licensed product, the carrying out of such obligations in a diligent and sustained manner using efforts substantially similar to the efforts a biopharmaceutical company of comparable size and resources would typically devote to a product of similar market potential, profit potential, similar stage in development or commercialisation, or strategic value, and taking into account all relevant factors, including technical, medical, efficacy, safety, manufacturing, and delivery considerations, product labelling, the patent and other proprietary position of the product, the regulatory environment and the competitiveness of the marketplace.



A licensee may also be required to carry out specific, measurable activities (such as making a minimum financial investment) in seeking to achieve milestones or perform to an agreed development plan. The licensee's performance obligations will commonly be coupled with means for the licensor to monitor performance and impose sanctions for non-compliance (such as reversion of rights and assets, grant-backs of rights, and liquidated damages). This approach will not eliminate the possibility of a dispute between the parties in connection with the level of efforts but it provides a substantially clearer contractual framework.

Negotiations regarding performance obligations are often lengthy and complex. The skills of advisers familiar with life sciences licensing and collaboration transactions will be invaluable when considering contingent consideration structures which employ analogous commercial concepts. Both buyers and sellers should ensure that their respective deal teams contain, or can draw on, the necessary regulatory and collaboration/licensing expertise in the life sciences sector to enable effective negotiation and execution.

The key points of negotiation typically concern:

- Defining those milestone events that trigger payments to Seller (for example, initiation or successful completion of trials, marketing authorisations and product sales).
- Buyer's development and commercialisation obligations leading to the satisfaction of the payment milestones (and Seller's monitoring rights).
- The amount of the contingent payments. This may be a series of lump sums and/or formulae referable to, for example, product sales (analogous to a royalty).
- Dependent on the nature of the milestones, appropriate restrictions and controls on the business operations of Buyer (and Target) post-closing.
- Events which may lead to accelerated payment of the contingent consideration whether or not the milestones are satisfied. (For example, if Buyer re-sells Target and/or its product programmes.)

### Transitional provisions

When structuring the deal and negotiating the transaction documents, it will be necessary for Buyer to consider possible transitional issues. On a sale of the share capital of Target, marketing authorisations and other regulatory licences held by Target will generally be retained by Target. Transitional issues are therefore likely to cover branding. For example, if Target's corporate name is similar to Seller's name, Seller can require Buyer to change it after completion. Changing the names of companies holding regulatory licences or otherwise named in marketing authorisations will likely trigger regulatory filings. Implementing these changes in product labelling and promotional materials, among others, may not be permissible until the regulatory authorities have granted approval.

Seller is retaining the Dutch facility in which the marketed product is manufactured. To ensure continuity of supply, Buyer will need to conclude a transitional manufacturing and supply agreement with Seller, which takes effect on completion of the acquisition. Under this arrangement:

- Seller will continue to manufacture and supply Target's products on a temporary basis.

- Buyer establishes its own manufacturing and regulatory arrangements.

In addition to containing customary manufacturing and supply agreement terms, the transitional agreement should also require Seller to effect a transfer of manufacturing technology to Buyer in relation to the acquired product. Methods commonly used to achieve this include:

- Training provided by personnel of Seller.
- The delivery to Buyer of written standard operating procedures.
- The provision of on-call technical assistance services.

In relation to each activity to be carried out as part of the transitional arrangements, the agreement must clearly set out whether Seller can charge for that service and, if so, how the charges are determined and charged back to Buyer.

Parties must also consider whether the proposed transfers of technology assets or the provision of transitional or longer-term employee support will trigger either employee transfers under Directive 2001/23/EC on safeguarding employees' rights on transfers of undertakings, businesses or parts of businesses (and the Dutch law implementing this directive) or redundancies in The Netherlands or other country where Buyer plans to manufacture. If these issues apply, then the written agreement should reflect Buyer and Seller's respective positions on the split of associated liabilities and responsibility for statutory or other procedures (such as employee or works council consultation).

The transfer of manufacturing from Seller's Dutch facility to Buyer's facility could pose significant regulatory issues:

- Buyer may need to expand or modify existing facilities or establish new facilities. These facilities must be validated and licensed by the regulatory authorities.
- Once Buyer is ready to start manufacturing the products, the marketing authorisations for the relevant products must be amended or updated to reflect the fact that Buyer is the new manufacturer.
- In some circumstances, the change might need regulatory authority approval rather than simple notification. Regulatory authority approval can take many months to obtain and be subject to a successful GMP inspection.
- The product packaging and labelling, such as the patient information leaflet, must be updated to identify Buyer as the manufacturer.

### Post-closing regulatory provisions

If Buyer seeks to integrate the acquired business into its existing business, marketing authorisations and other regulatory licences may need to be transferred. Such transfers will be subject to regulatory authority approval.

In many countries it is not possible to submit transfer applications when there are ongoing regulatory procedures, such as applications to vary or renew the marketing authorisation. In these countries a detailed integration plan and timeline should be prepared in advance to help co-ordinate regulatory submissions with corporate change.



Even if the acquired business remains a standalone business, the corporate transaction can prompt a restructuring of the distribution and sales structures. For example, this might be done to take advantage of a more favourable tax regime (see *below, Tax*). When structuring or re-structuring a distribution system, it is usually preferable to determine first the preferred tax structure and physical supply chain. The regulatory structure can then be made to fit around this.

However, it is important to be aware that regulatory requirements may apply to entities that are involved in the flow of legal title, even if they are not involved in the physical supply chain. For example, some EU countries require entities that take title to medicinal products to hold a wholesale distributor's licence. New legislation due to take effect at the beginning of 2013 will require such entities in other EU countries to hold a new broker's authorisation.

## EUROPEAN COMPETITION LAW

The two main competition law considerations raised by an M&A transaction are:

- Whether a filing is required.
- Whether it raises substantive concerns.

The driving factor in determining whether any competition approvals are required for the transaction is the revenue generated by Buyer and Target in the EU as a whole and in individual EEA member states. Additional information, including the location of subsidiaries and value of assets, is also required in some jurisdictions (including Ireland and Russia). Market shares/shares of supply are relevant in other countries (such as Latvia, Portugal, Spain and the UK). This issue is not decided by the place of incorporation or the choice of law for the transaction.

In our example, Target will probably determine whether merger filings are required. For example, the European Commission (Commission) will only have jurisdiction if Target generated EU-wide turnover of at least EUR100 million, of which at least EUR25 million was generated in each of at least three EU member states (in which Buyer also generated at least EUR25 million, so that the combined revenue of Target in Buyer in those three member states also exceeded EUR100 million). (As at 1 November 2011, US\$1 was about EUR0.7.)

If the EU threshold is not met, approvals can still be required in one or more EEA member states. The thresholds in a number of member states (such as Austria, Germany, Ireland, Italy, Norway, Slovakia and Slovenia) can be met if Target's activity in the member states is limited. If at least three EU member states could review the transaction, Buyer can request that it be referred to the Commission.

It is also important to assess the potential nature and extent of any substantive competition issues in the due diligence phase, so that transaction documents are realistic about timing and so on. The first task is to define the relevant markets in which Target's and Buyer's products fall, and to identify overlaps. Where Target's and Buyer's products are neither generic nor biosimilars, the starting point for the definition of the relevant market will ordinarily be the third level of the Anatomical

Therapeutic Chemical (ATC) classification system as devised by the European Pharmaceutical Marketing Research Association. In addition to the ATC classification, the prescribing practices of doctors may be taken into account as well as differences in dosage and pharmaceutical form. The challenge in our example is categorising pipeline products still in development. However, this can usually be done by following the treatment of existing products.

It is important thoroughly to review the competitive situation by looking at:

- Products currently on the market (reviewing their current shares and forecasts).
- Any products withdrawn temporarily to address regulatory or other concerns.
- Other pipeline products (particularly products that might be "game changers" with the potential to rapidly capture the market on release).

The potential overlap between Buyer's early stage pipeline product and Target's lead product should not raise material concerns. The high degree of uncertainty that early phase products will even make it to market means that they are not generally considered to be a relevant competitive constraint in the market.

It is important to ensure that the deal timetable leaves sufficient time for the necessary merger approvals to be obtained. In most EEA jurisdictions deals cannot close before they are cleared (or the time for review lapses). There are limited exceptions to this rule, including public offers. It is possible to notify on the basis of a binding memorandum of understanding (that is, before the definitive agreement is signed) to the Commission and in most EEA jurisdictions. However, it is important to allow at least six working weeks from first engagement with the relevant competition authority before closing. Longer may be required if, for example:

- Filings are required in jurisdictions with longer review periods (such as two months in Slovakia).
- Remedies must be offered to obtain clearance (such as commitments for Buyer to divest assets).

## ANTI-CORRUPTION LAWS

There has been a dramatic increase in the enforcement of anti-bribery/anti-money laundering laws in the US, the UK and many other countries over the past few years. In addition, new anti-bribery legislation has been approved recently in a number of countries. Penalties for bribery in both the public and private sectors have increased significantly over the past few years. The UK Bribery Act 2010 prohibits bribery in both the public and private sectors. Although the US Foreign Corrupt Practices Act (FCPA) does not itself cover private sector bribery, this area is governed by federal and state law to the same extent as the UK Bribery Act 2010.

Several pharmaceutical companies have paid substantial anti-bribery fines for conduct that occurred before they acquired the company. In addition to any fine that may be imposed, as a result of Target's pre-acquisition violations of anti-bribery and/

or anti-money laundering statutes, Buyer could be damaged severely by the adverse publicity accompanying the conclusion of a bribery prosecution.

Because government officials play a very large role in authorising the marketing of biopharmaceutical products, and so many customers of biopharmaceutical companies such as Target qualify as government officials, the bribery risks faced by biopharmaceutical companies are much larger than the bribery risks faced by most other companies.

To avoid bribery-related liability, Buyer should:

- Identify the countries in which Target is “carrying on its business, or part of its business.” (Demands for bribes are much more common in some countries than others.)
- Review the policies and procedures that Target has developed and implemented to combat bribery.
- Conduct due diligence beyond the data room.
- Conduct interviews with key individuals in Target.

If Buyer discovers a bribery problem during its investigations, it should:

- Consider the commercial consequences.
- Ensure that obligations to notify relevant enforcement authorities are properly addressed and consider whether the agreement of such authorities may be sought in respect of any remedial measures to be implemented post-transaction.
- Obtain guidance on the authorities’ approach to enforcement.

Officials at the Serious Fraud Office in the UK have shown a willingness to work with potential acquirers to sort out “legacy liability” bribery problems, if they are notified before the transaction has closed.

## EMPLOYMENT ISSUES

While patents and other rights can be evidence of a company’s ownership of technology, it is often the individuals engaged within the business who are the source of innovation. Their knowledge, experience and understanding of the company’s technology enable a product portfolio to be translated into profit. Such a reliance on key individuals can be particularly acute when products are still in development.

The following factors should be considered by a buyer:

- Which persons are essential to the target’s business? Are they required post-sale, and if so, how will they be retained?
- Will the buyer wish to reduce the number of a target company’s employees post-sale (for example, because of a change of business focus or duplication with the buyer’s existing resources)?

### Key individuals

In the scenario considered in this article, Founder and his team of scientists are identified as key to Target’s business. In different circumstances, it may be a management team or sales team which Buyer is particularly keen to retain. Careful diligence should be

undertaken with regards to the terms on which key individuals are engaged in Target’s business. Some individuals may not be employees of Target and may be consultants or seconded from other companies in Seller’s group.

Buyer may wish to ensure Founder’s and the scientific team’s continued commitment to Target by offering incentives. These can take the form of enhanced contractual packages designed to tie them to Target going forwards, such as:

- Equity or performance-related pay.
- Milestone or other fixed bonuses (golden handcuffs).
- Discretionary bonuses.
- Royalties.
- Longer notice periods and/or enhanced fees/salaries and benefits.

In exchange, Buyer may wish to strengthen or introduce contractual provisions such as:

- More extensive restrictive covenants.
- Intellectual property protections.
- Confidentiality obligations.

Founder undertakes research work at a leading UK university. If Founder will continue his role at the university post-sale, it may be necessary to ensure that any revision of his consultancy terms do not conflict with any restrictions which the university may impose. This applies particularly if the subject of Founder’s university research overlaps with Target’s technology.

In addition to key persons who may be directly engaged in Target’s business, Buyer should also identify those performing key regulatory roles for the benefit of Target, but who are not themselves Target employees. It is common for certain regulatory compliance functions (such as pharmacovigilance) to be undertaken at a group level. These individuals might not transfer with Target, and Buyer must ensure that any mandatory regulatory roles can be filled with its own employees or contractors, so there is continuous coverage for regulatory purposes.

### Reduction of employees

Many of the mergers between large pharmaceutical companies over recent years have been accompanied by restructuring and rationalisation programmes, which in some instances have seen reductions in employee head-count.

Buyer should be mindful of the protections afforded to Target employees if Buyer envisages implementing a reduction in the number of Target employees post-sale. In particular, employment rights in European jurisdictions may be more extensive than those applicable in Buyer’s home jurisdiction and, as a result, may require particular attention as part of Buyer’s transaction planning.

In the scenario considered in this article, Target employees are located in the UK. Any redundancies planned by Buyer will trigger procedural requirements, if employee claims (such as unfair dismissal) are to be avoided. If Buyer is proposing to make less than 20 employees in total redundant at any one establishment or workplace, then only individual consultation with affected employees must be carried out. This might take up to two weeks, but could take longer.



If 20 or more employees are to be made redundant at any one establishment within a 90 day period, then collective redundancy obligations apply, which include:

- The election of employee representatives for consultation purposes (or an existing trade union representing affected employees for these purposes).
- The provision of prescribed statutory information.
- A minimum 30 day consultation period.
- An obligation to notify the UK government of the proposed redundancies.

Failure to comply with statutory redundancy obligations towards affected employees could result in an award against Buyer of up to 90 days' gross pay per employee. Redundant employees with two or more years of continuous service are entitled to a statutory redundancy payment.

If redundancies are carried out post-completion, then Buyer must carry out any required redundancy procedures and shoulder any liabilities, although timing will not be a particular issue.

If Buyer wished Seller to carry out the redundancies pre-completion, then the cost of doing so can become part of the negotiation over the purchase price (Seller seeking a discount). Any collective redundancy consultation process must be carried out prior to purchase, potentially delaying the sale timetable.

## TAX ISSUES

A number of specific tax issues must be considered in a life sciences context.

### Capital gains relief

Seller may be able to claim capital gains relief on the disposal of the shares in Target since many European jurisdictions have a capital gains participation exemption enabling the disposal of subsidiaries without triggering a tax charge provided certain criteria are satisfied.

### Tax credits

Development costs for life sciences companies are notoriously high. Even once the initial innovative step has unlocked the technology on which a product is based, trials and further refinements may take many years to complete. There are no guarantees that regulatory approval or eligibility for reimbursement will be afforded to the product.

Consequently, the ability of Target to claim R&D tax credits will be of significant importance because they can trigger tax losses or (in some cases) cash refunds. As part of the due diligence checks, Buyer will want to satisfy itself that any tax losses shown in the accounts have been properly claimed and that any amount recovered from a tax authority cannot be clawed back.

### Tax planning

Buyer may wish to consider whether any tax planning should be put in place post-closing to minimise taxes on future profits once the products are released onto the market.

**Choice of jurisdiction and strategic relocation.** Buyer can analyse whether any intellectual property assets managed in a high tax jurisdiction should be moved to a low tax jurisdiction. Life science companies generally prefer to manage their intellectual property portfolios in jurisdictions with a low tax regime for royalty income but which also have a large network of double tax treaties to minimise withholding taxes on royalties received from other jurisdictions. Notable jurisdictions commonly considered include Ireland, Luxembourg and Switzerland. The UK has announced that a new "patent box" regime will be introduced for qualifying income which will mean that such income is taxed at 10%. The success of this new regime remains to be seen since it may be possible to obtain lower tax rates (through planning and local tax rulings) in other European jurisdictions.

**Supply chain restructuring.** Buyer may also be keen to use a more tax efficient supply chain for Target's marketed products.

This typically involves inserting a marketing company in a low tax jurisdiction. (Switzerland is currently favoured by many companies given its proximity to key European markets, although Ireland is also popular). The low tax marketing company then assumes responsibility for the co-ordination and marketing of the product. It also assumes the liabilities and risks attached to the delivery of the product.

The intention of such a structure is to locate a significant portion of the group's revenues and costs (and therefore profit) in the low tax jurisdiction company. This reduces the overall global tax cost to Buyer's group.

Carefully documented transfer pricing analysis must be carried out to support the margins earned by the low tax jurisdiction company. Any tax driven re-organisation should only be implemented after a thorough assessment from a regulatory perspective. A reorganisation may involve the transfer of marketing authorisations and licences to ensure continued regulatory compliance by Buyer's group.

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**Areas of practice.** Corporate; commercial; IP; data privacy; life sciences; software and technology.

#### Recent transactions

- Represented UCB in relation to its strategic partnership with Synosia Therapeutics in which Synosia granted UCB a licence for exclusive, worldwide rights to the development compound SYN-115 and rights to a second compound, SYN-118, for non-orphan indications, both compounds being in Phase II clinical development for the treatment of Parkinson's disease.
- Represented Minster Pharmaceuticals PLC, an AIM-quoted drug development company specialising in compounds for the treatment of neurological and psychiatric conditions, on intellectual property aspects of its recommended takeover by Proximagen Neuroscience PLC.
- Represented Biocompatibles International plc on numerous transactional matters including an option agreement with a major multinational Japanese pharmaceutical company in respect of Biocompatibles' Drug-Eluting Bead Products in Japan and distribution agreements.



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#### Recent transactions

- Advised Axis-Shield plc on the GB£235 million all cash public takeover offer from Alere, Inc., a US company listed on the New York Stock Exchange. Alere's offer for the company was initially made on a hostile basis and vigorously defended by Axis-Shield and its advisors. Ultimately, the board of Axis-Shield recommended an increased cash offer from Alere valuing the company at GB£235 million.
- Advised CeNes Pharmaceuticals plc, a company then listed on the AIM market of the London Stock Exchange, on the all-share public offer and acquisition by Paion AG.
- Represented Acambis, a vaccine company listed on the London main market, in relation to the GB£276 million recommended takeover offer by Sanofi-Aventis, implemented by a court-approved Scheme of Arrangement.



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**Areas of practice.** Corporate, commercial, regulatory; life sciences.

#### Recent transactions

- Advising Novartis Vaccines and Diagnostics on a wide variety of transactions and commercial matters.
- Providing regulatory advice to a number of the major national and multinational pharmaceutical companies and biotechnology, diagnostic, medical device, and consumer product manufacturers in the United Kingdom and mainland Europe.
- Assisting clients with applications for the centralised approval of medicinal products and for EU orphan drug designation, and with regulatory issues in the national approval process for medicines, including the EU decentralised and mutual recognition procedures.



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**Areas of practice.** Employment; litigation; life sciences; financial services; software and technology.

#### Recent transactions

- Serving as UK employment counsel to a major US/UK life sciences client, advising on all aspects of employment, employee benefits and agency worker issues.
- Representing a US/UK pharmaceutical company in defending a religious discrimination claim.
- Advising listed UK bioscience companies in relation to executive director departures.

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**Qualified.** Australia (Queensland), 1995; England and Wales, 1997

**Areas of practice.** Competition; communications and media policy; life sciences; software and technology.

### Recent transactions

- Serving as European competition counsel to Microsoft in relation to its acquisition of Skype.
- Serving as European competition counsel to King in its acquisition by Pfizer.
- Serving as European competition counsel to Axis-Shield in relation to its public takeover by Alere, Inc.



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### Recent transactions

- Implementing a tax efficient supply chain structure for life sciences companies.
- Advising on the tax and employee incentive arrangements for the acquisition and disposal of life sciences companies.
- Structuring a collaboration arrangement between two life sciences companies to enable repayable R&D tax credits to be claimed.



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### Recent transactions

- Represented Intercell AG in connection with its acquisition of Cytos Biotechnology Ltd's platform technology for monoclonal antibody discovery.
- Represented Cambridge Antibody Technology in its successful English court litigation for royalties in relation to sales of the monoclonal antibody product Humira.
- Drafting and advising on patent licence and R&D agreements relating to various life science technologies for a major UK research body.



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**Areas of practice.** Anti-corruption; litigation; white collar defence and investigations.

### Recent transactions

- Drafting policies and procedures to combat bribery and other related forms of corruption for numerous clients, including clients operating in the life sciences sector, oil and gas sector, defence industry, technology sector, chemicals and consumer products.
- Designing and conducting compliance gap analysis for numerous clients, including clients in all of the sectors/industries noted above.
- Conducting internal investigations for many clients in numerous countries, including countries in Africa, the Middle East, Europe and Asia.