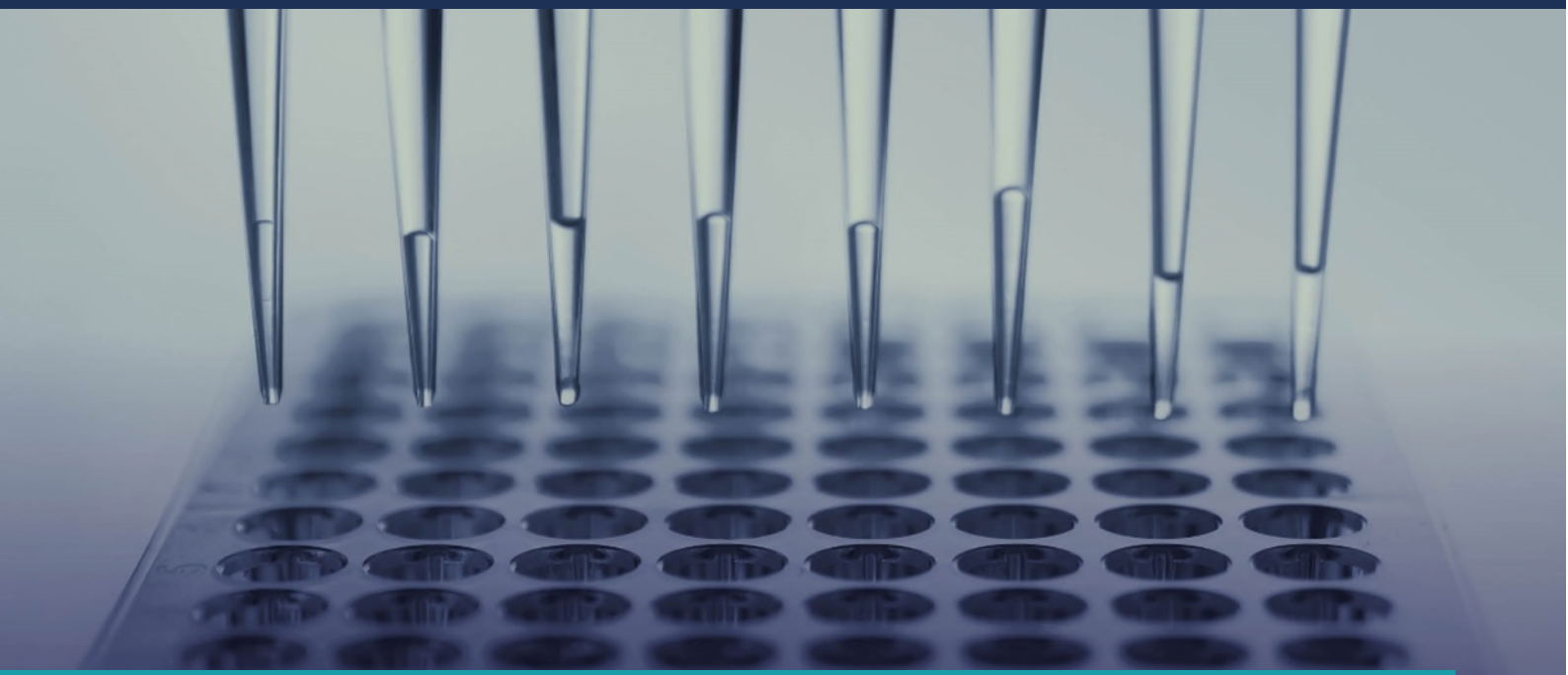
STEVENS&BOLTON



LIFE SCIENCES

Legal A-Z

CONTENTS

INTRODUCTION

Welcome to our life sciences legal A to Z.

Here we cover a wide range of topics relevant for those working in the sector, drawing from the expertise of our multidisciplinary life sciences team, which advises some of the world's largest pharmaceutical and biotech companies, healthcare providers and medical devices manufacturers.

Overleaf, we list the definition of one or two terms for each letter of the alphabet.

Many articles in this series relate to areas that have become hot legal topics for the life sciences industry. The landmark High Court decision in Cardiorentis AG v IQVIA on the conduct of clinical trials by a contract research organisation reminds us of the importance of effectively negotiating a clinical trial agreement at the outset of a project.

Another key area for life sciences businesses to prioritise now is transparency, particularly given the increased industry and public demand for clearer and more objective reporting on the R&D, distribution and advertising practices involved in bringing pharmaceutical products to the market.

We have also seen a significant increase in the accessibility and uptake of telemedicine services, which are continuing to grow following the pandemic.

Looking ahead, rapid developments in the fields of medical cannabis, digital health and gene editing will inevitably keep these areas at the top of legal and regulatory agendas for some time.

More broadly, as we had seen throughout the pandemic, collaboration between parties is often the key to finding solutions to complex problems. Our articles on joint ventures and licensing provide a useful starting point when considering what the written agreements underpinning these collaborations should include.

If you have a question on any of the areas we have covered throughout the A to Z, please do contact me.

Best wishes

Charlotte Tillett
Partner
T: +44 (0)1483 406956
M: +44 (0)7796 010908
E: charlotte.tillett@stevens-bolton.com

A:

ACTIVE INGREDIENT

An active ingredient (AI) is a substance in a medicine which is biologically active, having a therapeutic effect of its own. This is in contrast to other ingredients which are pharmaceutically inactive or neutral.

Such other ingredients may include:

- Excipients, which are used, for example, to carry the AI, to make it easier for the patient to take the drug or to aid uptake within the body (bioavailability), and
- Adjuvants, which increase or modify the activity of other ingredients. These are used in some vaccines to create a stronger immune response.

As an example, the AI in paracetamol is paracetamol, the excipients include maize starch and magnesium stearate.

In the pharmaceutical patent world, the patent on a new AI is often considered to be the core patent, protecting the core invention. Patents covering new formulations, dosages, and therapeutic uses (second medical uses) of the AI may follow on and are sometimes regarded as "secondary" patents. Such "secondary" or "follow-on" patents may incorporate very important medical advances; an example often cited is AZT (zidovudine) for use in AIDS therapy, which was considered a breakthrough in the treatment of AIDS. However, some commentators believe that secondary patents are commonly an attempt to "evergreen", i.e. to extend patent protection for the original invention without offering sufficient patient benefits. No generalisation can be made here, this will always depend on the particular case.

The question of whether the patent protects an AI is important in deciding whether a supplementary protection certificate (SPC) may be obtained by the patent owner. An SPC provides an extension of up to five years to patent protection for certain authorised medicines. The purpose of the SPC is to compensate the patent owner for the long delays in bringing the drug to market necessitated by clinical trials, which eat into the original 20-year term of patent protection. However, SPCs are only available if the patent relied on protects an AI or combination of AIs. As a result, "secondary patents" often do not qualify for SPCs, and the Court of Justice of the European Union (CJEU) has confirmed that second medical use patents will not normally qualify either.[1] This is an area of increasing interest in view of the potential importance of repurposed drugs to health services. There have been some indications that the English Court of Appeal may look favourably on the grant of SPCs for second medical uses, raising the possibility that the UK courts may diverge from the EU on this subject at some point in the future, but this is mere speculation at this time.

[1] An exception is where no marketing authority has been granted for the first use.

ARBITRATION

Arbitration is a contractually agreed method of resolving disputes. It is an alternative to litigation before a national court and so if parties have agreed to arbitrate, they will generally not be able to go to court to resolve any dispute which may arise.

An agreement to arbitrate is often (although not always) found in the agreement that parties have entered into at the outset of a relationship, so it is something to think about early in your business dealings.

Key considerations for companies in the life sciences sector when thinking about whether arbitration is for them will be:

- Enforcement
- Confidentiality
- Neutrality
- Speed and Flexibility

Enforcement

Life sciences companies routinely enter into international contracts including collaboration, licensing, supply and distribution agreements. If you may need to pursue your counterparty overseas, agreeing to arbitrate your disputes may well be the best option as arbitral awards are in general easier to enforce overseas than the judgments of national courts.

Whether you can enforce your judgment or award depends on which international conventions the relevant countries have signed up to. The most important of these from an arbitration perspective is the New York Convention, to which the UK is a signatory, along with 160 other countries from Afghanistan to Zimbabwe. In terms of the enforcement of court judgments, there is a series of conventions which apply differently between different countries.

Confidentiality

Another important distinction is that the arbitral process itself is confidential. Parties may prefer not to have commercially sensitive allegations and details of their dispute, and their business, made public. In the life sciences sector confidentiality can be crucially important, for example where patents are licensed to multiple licensees, or on the launch of a new product where sensitive intellectual property or pricing details may arise.

Neutrality

In addition, for international contracts, arbitration is often perceived as a neutral option, allowing parties to avoid opting for one or the other of their national courts as the dispute resolution forum.

Speed and flexibility

The arbitral process can be much more flexible than that of court proceedings and it can be quicker. As long as the parties agree, they can choose how the arbitration will work – who the arbitrators should be and what procedural rules should apply. It is often possible to appoint an arbitrator with relevant sector experience. In practice, the process followed is not dissimilar to court proceedings and the procedure, evidence and timing will be decided by the arbitrator(s).

A criticism of arbitration is often that the process does not allow for emergency remedies to be granted or for summary assessment of claims, but many arbitral institutions have developed rules to tackle this issue.

In terms of costs, there is generally little difference between arbitration and court proceedings. Usually, the loser pays the winner's costs, but this can be varied depending on the arbitral rules and the circumstances of the case. The private costs of the arbitrator(s) and any administering body, such as the LCIA or ICC, will need to be paid in addition to lawyers' fees. The costs of holding a final arbitration hearing in an overseas location (if a venue neutral to all parties has been chosen) should be taken into account, but the significant advantages of arbitration as set out above tend to outweigh this concern.

B:

BRAND PROTECTION

When considering which intellectual property rights are important to businesses in the life sciences industry, it is likely that patents and confidential information will be top of the list.

Clearly, these can be vital as a basis for a life sciences business and provide a crucial competitive edge in the market. However, in this extremely crowded sector, where companies of all sizes compete for space, custom and talent, having a clear and recognisable brand identity can be equally as important.

The brand built and maintained by a life sciences organisation is vital both for its overall business as well as for its individual products, particularly where there is likely to be competition from others in the market place. A carefully considered brand strategy can help to ensure that individuals and businesses feel confident in buying from, investing in and working with a particular company.

Defining what the term "brand" actually means can be quite difficult, as brands are generally comprised of several elements, which are variously tangible and intangible. For example, while a memorable name and recognisable logo might seem, on the face of it, to be the definitive components of a strong brand, it is crucial not to overlook the importance of less perceptible elements, such as the organisation's purpose, values and "personality". Together, these aspects assist consumers in shaping their perception of, and loyalty to, a certain brand.

Once a company has built up a strong brand identity, it should seek to protect it. Registration of certain rights is a key aspect of brand protection. In particular, registering a company name, a product name or a logo as a trade mark in the relevant jurisdictions provides its owner with a monopoly right, which can be protected and asserted more easily than, say, goodwill or reputation. However, applicants hoping to register colour marks may face difficulties – in a 2020 case, GSK failed to get EU trade mark protection for the colour purple, used on its asthma inhalers. In addition, it is also advisable to consider whether registration of any designs (such as the shape of a product) might be appropriate.

Complex rules apply to the naming of drugs. Numerous factors need to be considered in the choice of branding including, for example, that a name must not be easily confused with an existing drug and it must not convey misleading therapeutic and/or pharmaceutical connotations. Pharmaceutical marketing and branding teams should therefore work closely with legal and regulatory advisors from an early stage to minimise the risk of problems arising later.

There are various options available to organisations looking to strengthen their brand protection strategy in the long term. For example, it may be worthwhile to invest in a trade mark watch service in relation to any registered marks held, which will reveal any registration applications for identical and/or similar trade marks that may be of concern. In addition, using online monitoring services to search for, among other things, counterfeit goods on offer for sale to the public. Once flagged, organisations should take appropriate steps to oppose any such application, or remove any websites selling infringing products, to maintain the company's reputation, goodwill and, in turn, its brand.

Regulatory issues can arise where, for example, medicines or other products are offered for sale without authorisation via online platforms in jurisdictions where no marketing authorisation is held. This holds a number of concerns for the brand owner and trade mark

infringement (in either the company name or logo, or the product name) could be a tool for shutting down such sales.

Ensuring a consistent approach to building and maintaining a well-articulated and recognisable brand will back up all the hard work and investment in the business's products and help to promote them further. For companies operating in the highly competitive life sciences industry, even a modest amount of time invested in protecting these brands can pay dividends in the long term.

C:

CANNABIS

Cannabis and its regulation have recently received increased attention in the press and in the legal and business worlds. This is due in particular to changes in the legal status of cannabis globally, the increased availability of new cannabis treatments in the UK, and the growing prevalence of cannabis-derived Cannabidiol (CBD) products.

Global position

Though cannabis remains illegal in most countries, certain countries and regions have taken steps towards its legalisation or decriminalisation. In adopting a more permissive stance towards cannabis, those countries and regions either:

- "Tolerate" cannabis, even though it has not been legalised or decriminalised. For example in the Netherlands, where cannabis is technically illegal, the police turn a blind eye to its use in coffee shops.
- Have decriminalised, though not legalised, cannabis. Whereas under a legalised regime cannabis can be bought and sold, under a decriminalised regime (such as in Portugal) the commercialisation of cannabis is forbidden, but the use of cannabis will not constitute a criminal offence, although it may still incur a fine or other civil sanction.
- Have legalised cannabis solely for medicinal use.
- Have legalised cannabis for both medical and recreational purposes. In Canada, anyone over the age of 18 (although this age cap can vary from province to province) can purchase from dispensaries or grow certain quantities of cannabis.

Cannabis treatments in the UK

In the UK, cannabis is classified as a Class B controlled drug under Schedule 2 Part II of the Misuse of Drugs Act 1981 (MDA) and is listed as a controlled substance under Schedule 1 to the Misuse of Drugs Regulations 2001 (MDR and, together with the MDA, the Drugs Laws). Save for when operating under a Home Office licence, the possession, supply, production, importation and exportation of cannabis constitutes an offence, as does the cultivation of any plant of the genus cannabis (e.g. hemp) which, depending on the offence, can give rise to a 14-year prison sentence and/or an unlimited fine.

Following a review finding that there was conclusive evidence on the therapeutic benefits of cannabis, The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018 added "cannabis-based products for medicinal use in humans" to Schedule 2 of the MDR. Consequently, cannabis products can be prescribed for medicinal use in limited circumstances by approved specialist doctors (i.e. not a regular GP), without the need for a Home Office licence.

CBD Products

Cannabis is widely known to contain the psychoactive chemical compound Tetrahydrocannabinol (THC). However, cannabis contains over 100 distinct chemical compounds, most of which are not psychoactive and are accordingly regulated more liberally than cannabis, or cannabis products containing THC. Recently, the prevalence of products incorporating one such non-psychoactive chemical compound, CBD, has increased.

CBD is not a controlled drug under the Drugs Laws, and so pure CBD can be sold freely in the UK. However, from 2016 any business selling CBD and claiming that it has medicinal purposes must be registered with the Medicines and Healthcare products Regulatory Agency (MHRA). Due to the costs involved with this registration, companies selling products containing CBD often do not market these as having medicinal purpose, and instead rely on consumers having a general understanding of the potential health benefits.

In June 2019, the UK Food Standards Agency, following guidance from the European Food Safety Authority, defined CBD as a "novel food". Novel foods cannot be sold without first having a pre-market safety assessment and authorisation under the Novel Foods Regulation. There are currently approximately 12,000 products undergoing assessment.

Conclusion

Given the recent changes outlined above, it seems likely that the regulation of cannabis (and the growing market facilitated by these developments) will continue to be an area of interest for those in the life sciences and legal industries for some time. Whether the trend towards legalisation continues is likely to depend in part on the massed information that will result from the more widespread, permitted use of cannabis both globally and in the UK.

CLINICAL TRIAL AGREEMENTS

The effective negotiation of a clinical trial agreement (CTA) is an essential driver for getting new drugs and devices to the market.

Parties should ensure that an executed CTA is in place before undertaking any work on a clinical trial. Whilst the Health Research Authority (HRA) encourages parties to use a model form of agreement to help speed up the contracting process, a number of contentious issues can make the negotiation process challenging. The HRA regularly publishes forms of agreement and seeks industry input into the drafting. With the template agreement as a starting point, some of the key considerations for life sciences businesses when negotiating CTAs are set out below.

Intellectual property (IP)

As always, the protection of IP rights is of vital importance to life sciences businesses to safeguard the significant investment in their products.

The sponsor will want to ensure it retains sole ownership of its pre-existing background IP as well as any foreground IP created in the course of the clinical trial. On the other hand, the institution or host will seek ownership rights in any foreground IP created and the right to use any know-how developed in future trials.

As such, sponsors should be careful not to assign any background IP to the institution, and limit the transfer of any foreground IP to a licence to use such information for purely non-commercial research or educational purposes.

Confidential information

Alongside other IP rights, an area of real importance to the sponsor is the protection of their confidential information during a clinical trial. Sponsors will seek a wide definition of confidential information to ensure all information is captured, as well as confidentiality obligations for the institution that subsist for as long as possible to ensure information is not used in another clinical trial to a competitor's benefit.

Conversely, institutions will pursue lighter confidentiality obligations so that they can share improvements and the results of the clinical trial with the wider academic community. The sharing of results is one of the most contested issues in a CTA, and as a result source data (over which the sponsor cannot claim confidentiality) is often distinguished from the clinical

trial results. Furthermore, sponsors may seek to prohibit a general publication of the clinical trial results and pre-approve the form in which they are published.

Sponsors will seek to limit the sharing of confidential information to individuals on a "need to know" basis, and if including third parties only to those who have warranted that they will use the information with the same degree of care. However, confidentiality obligations that last in perpetuity after the completion of the clinical trial are often deemed unreasonable, and as a result most confidentiality obligations last up to 10 years.

A few other important areas to think about are:

- **Liability**

  Liability, risk and insurance are key in any agreement, and the importance of this is sharpened given that the CTA will need to adequately provide for the unfortunate risk that the trials have a detrimental impact on human volunteers. In the UK, the model CTAs commonly favour the institution or host site on these provisions, and the sponsor's ability to negotiate them will depend on the context of the clinical trial and its bargaining position.

- **Regulatory compliance**

  Clinical trials are subject to a high degree of regulation, and it is key to ensure that the principles of good clinical practice (GCP) are met.

- **Data protection**

  This is of particular importance owing to the fact that healthcare data is defined as special category personal data under the legislation. Patients' voluntary consent is required before they can participate in clinical trials, and parties often choose to anonymise data to aid compliance with data protection legislation.

  The parties to a CTA must also ensure that they comply with data transparency requirements as regards pre-clinical and clinical trial data, especially in light of the implementation of the Clinical Trials Regulation.

Clearly setting out the scope, responsibilities and timelines in a CTA as well as recording agreement on division of risk and ownership rights will allow for a smoother clinical trials process and should help prevent disputes between the parties further down the line.

D:

DATA EXCLUSIVITY

The data exclusivity period is relevant to authorised medicines. It protects the originator's investment in clinical trials.

The way it works: 8 + 2 (+1)

To obtain authorisation for a new medicine, originator companies must present evidence of the safety and efficacy of the medicine based on data obtained through lengthy and expensive clinical trials. Eight years after authorisation has been obtained, competing producers who wish to obtain authorisation for generic and biosimilar medicines can make an "abridged" application for authorisation of their generic/biosimilar products relying on the data initially provided by the originator. They must then wait a further two years before putting their generic or biosimilar product on the market.

This period of exclusivity (8+2) is referred to as the data exclusivity period and offers a ten-year period during which the originator can recoup its investment in clinical trials free from generic competition. An advantage of the system is that, on the one hand, it preserves the incentive to innovate by providing an exclusivity period and on the other it avoids the need to do unnecessary, repeat medical trials on humans or animals in relation to the generic products.

The exclusivity period may be extended by one year (+1) to a maximum of 11 years if the authorisation holder obtains authorisation for one or more new therapeutic indications during the first eight years. The new indication(s) must bring "significant benefit" compared with existing therapies, and this will be assessed during the authorisation process. Medicines which have complied with an agreed paediatric investigation plan and orphan medical products (products for rare diseases) may also qualify for extensions.

Interaction with patent protection

The patent regime is independent of the data exclusivity regime. A data exclusivity period may exist even where there has been no patent - or where the patent has been revoked for invalidity - and it may overlap with patent protection. In some cases, data exclusivity may extend beyond the term of patent protection, particularly where - as is common - patent protection has been applied for at the research stage.

DIGITAL HEALTH

Digital health is an umbrella term for healthcare being provided or enhanced through the use of digital technology, and covers everything from telediagnostics, wearable medical devices, use of mobile software and applications, machine learning and artificial intelligence (AI).

This is a rapid growth area in the life sciences sector. There is considerable investment in this space as well as M&A activity. Legal aspects we have been involved with in this area include transactions between digital technology companies and healthcare providers, advice on liability issues associated with the development of mobile and other software applications, and advice under privacy law associated with digital health provision.

In the current "fourth industrial revolution", studies have shown a marked shift in consumer habits towards embracing new digital health technologies such as wearable technology and AI diagnosis. From a legal perspective, digital health raises a number of interesting and challenging issues, including:

- **Regulation**
  To what extent is the '"traditional" life sciences regulatory framework appropriate to regulate digital health? For example, does national regulation still function where healthcare can be delivered globally through digital means? How do you attribute liability for issues arising in respect of AI? To what extent can regulators effectively police opaque technological solutions?
- **Data-related issues**
  What issues arise in respect of the use and protection of sensitive personal data relating to healthcare provision in the digital age? To what extent will "big data" issues lead to dominance that can be exploited by those with first-mover advantage?
- **Platform issues**
  What is the correct treatment of liabilities in peer-to-peer technologies within a digital space, and what is the impact of removing the healthcare "expert" from health treatment?

Industry expansion and consolidation

As with other areas of digital expansion, expect to see innovation, growth and then industry consolidation. These will be busy times for M&A and other related areas (for example merger control).

In light of the issues addressed above, businesses should ensure that they are keenly aware of both the risks and the opportunities presented by the rapid digital evolution of healthcare provision.

E:

ENFORCEMENT

A key question for life sciences companies conducting international business is: will they be able to take enforceable action against a defaulting contract partner or licensee based overseas?

Contractual disputes between companies based within the UK are usually dealt with by the UK's domestic courts, if they cannot be resolved by negotiation or other methods of alternative dispute resolution such as mediation, first. However, life sciences companies also regularly enter into international contracts including collaboration, licensing, supply and distribution agreements. How disputes under international contracts can be formally resolved will depend on the contract drafting, the nature of the dispute and the domicile of the parties. This can be complex.

Arbitral awards

We have already looked at arbitration in our Life Sciences A to Z series (see A is for Arbitration). Essentially, if you may need to enforce a contract internationally, agreeing to arbitrate any disputes which arise may well be the best option as arbitral awards tend to be easier to enforce overseas than the judgments of national courts. This is because the UK has signed up to the New York Convention, along with 160 other countries from Afghanistan to Zimbabwe (including the USA, China and Russia). Once an arbitral award has been issued, if the losing party does not comply, the successful party will need to present the award to the national court concerned for recognition and enforcement. While this process can take some time, the grounds for refusal are very limited, for example, if the recognition or enforcement of the award would be contrary to the public policy of the country concerned.

The UK's position in respect of the New York Convention is unaffected by Brexit.

Court judgments – EU

As regards court judgments, enforcement within the EU has long been governed by the Recast Brussels Regulation or its predecessors. This no longer applies to the UK following the end of the Brexit transition period. Instead, the UK has acceded in its own right (as opposed to as a member of the EU) to the Hague Convention on Choice of Court Agreements. This took effect from 1 January 2021. The Hague Convention will make it easier to enforce a court judgment obtained in a country which the parties have nominated in an exclusive jurisdiction clause if both the nominated country and the country in which enforcement is sought are parties to the Convention.

In addition to the UK, the Hague Convention has been ratified by the EU, as well as Singapore, Mexico and Montenegro. Post-Brexit, it is therefore easier to enforce, for example, an English judgment in the EU if the parties have agreed an English exclusive jurisdiction clause, because the EU is also a party to the Hague Convention.

Where there is no exclusive jurisdiction clause, the Hague Convention does not help. A new treaty may eventually do so. The 2019 Hague Judgments Convention will allow easier enforcement of national court judgments in other countries who are parties to it. It has been described as "modern and innovative" and a "game changer". The 2019 Convention will come into force on 1 September 2023 between EU Member States (other than Denmark) and Ukraine. As of June 2023, the UK government is considering its position on possible accession, following a consultation to seek views on whether the UK should sign and ratify the 2019 Convention, which ended in February 2023.

Court judgments – elsewhere

The position outside the EU can be complex and arbitration should always be considered as a dispute resolution mechanism. If the parties decide to nominate the courts of a particular country instead, advice should be sought as to whether a judgment of that country could be enforced wherever the counterparty's assets are located.

Life sciences companies should always consider the position at the outset when a new international contract is being prepared and negotiated. Issues of jurisdiction and enforcement should be reviewed on a case-by-case basis, depending on where the counterparty and its assets are located, to ensure that the prospects of resolving any disputes and enforcing judgments or awards are maximised. These questions are often treated as a standard boilerplate, but careful thought should be given to them when the contract is drafted.

EMPLOYMENT STATUS

From employees of the largest pharmaceutical companies to healthcare workers, businesses within the life sciences sector are driven by people.

Different businesses inevitably have different needs for engaging staff, and it is increasingly common for organisations to depart from the traditional employment model when doing so. In the life sciences industry, where individuals are highly skilled and often in high demand, the relationship between company and individual may be something other than employer and employee.

Categories of engagement

Under the UK employment law regime, there are three categories of engagement:

- Genuinely self-employed individuals/consultant
- Workers, and
- Employees

Employees are entitled to the most rights and protections, while workers receive only some. In practice, there is no clear-cut rule to determine which category applies to an individual, as employment status is a question of fact and one for the courts and tribunals to determine. Despite plentiful case law in this area, the fact-specific nature of these decisions means that it is impossible to determine an individual's status with certainty without litigation.

Business protection

Business protection and the protection of intellectual property (IP) rights is a key consideration when recruiting in the life sciences sector. It is an established principle that IP created by an employee in the course of their employment belongs to their employer, although an employee can apply for compensation if their invention is of "outstanding benefit" to their employer, as seen in the 2019 Supreme Court decision in Shanks v Unilever (for more information on this case, please see our article here: www.stevens-bolton.com/site/insights/articles/shanks-v-unilever). Conversely, IP created by a self-employed consultant will belong to that consultant, unless the consultancy agreement states otherwise.

Another common concern for any life sciences company is the protection of its business interests after an individual leaves the organisation, which is commonly sought by way of restrictive covenants (RCs) in the individual's contract. However, difficulties can arise when seeking to include such restrictions in a self-employed consultant's contract, as RCs indicate a

degree of control by the company over the individual, which is one of the relevant factors considered by the courts when determining employment status. A certain degree of control exercised by a company over an individual indicates employee or worker status and could undermine an individual's supposed self-employed status.

Where businesses put RCs in place, it's important to consider the parties to the restrictions. If a company engages a contractor via a personal service company (PSC), the contract – and any RCs within it – will be between the client company and the PSC, rather than the individual contractor. The client should, therefore, consider whether it is necessary to put in place separate RC's with the individual consultant directly (subject to our comments above about the risk of this inferring an employment relationship).

Why does employment status matter?

Employment status is important for a number of reasons. In particular, the scope of rights and protections available to an individual at work is largely dependent on their employment status. Genuinely self-employed individuals are not entitled to employment law rights against the company engaging them, although they are entitled to certain protections under discrimination and health and safety legislation. On the other hand, workers and employees are entitled to far more extensive rights, and companies are subject to more wide-reaching obligations in respect of them.

Examples of workers' rights include:

- Paid holiday
- Discrimination protection
- Whistleblowing protection
- National minimum wage
- Right to pension contribution
- A written statement of their terms and conditions

Employees are entitled to all of the rights of workers and certain additional rights, including:

- Protection from unfair dismissal
- Statutory redundancy pay and statutory sick pay
- Family friendly rights, relating to both pay and leave
- Flexible working and other statutory leave requests

F:

FAIR DEALING

Fair dealing v fair use

UK copyright law contains a number of "fair dealing" exceptions that give third parties limited rights to use a copyright work for certain defined purposes without the copyright owner's consent.

Examples include fair dealing for criticism and review, fair dealing for news reporting and fair dealing for research. These are not to be confused with the US concept of "fair use", which is much more flexible and can be applied in a wide range of situations.

Non-commercial purposes only

The fair dealing exception for research[i] is potentially very important for scientific research. It applies to, among other things, journal articles and other publications. However, it is limited to research for non-commercial purposes. The question of what constitutes a non-commercial purpose is determined by the nature of the research rather than the organisation. So, for example, a not-for-profit organisation may not be able to rely on the exception if the research is in connection with a fund-raising project that involves a commercial activity. An assessment of whether "fair dealing" applies will always be fact-specific, but a narrow approach is also required. Making multiple copies or distributing the work to others would not normally fall within the exception.

Text and data mining

A further research-related exception covering text and data mining was introduced following the Hargreaves Review in 2011[ii]. However, this exception also only applies to non-commercial research. In addition, the person carrying out the data analysis must have lawful access to the work. Usually, this means either that the work must be publicly available or there must be a relevant licence in place. In response to evidence that data mining was often excluded in licences, a provision was included making terms excluding the fair dealing exception unenforceable.

[i] S.29 Copyright Designs and Patents Act 1988

[ii] Ibid S.29A

FORCE MAJEURE

The concept of "force majeure" was frequently talked about during the Coronavirus pandemic and since. A number of issues can arise in connection with the drafting of, and reliance on, force majeure clauses.

A force majeure clause is often found in commercial contracts, including a variety of contracts that life sciences companies enter into, to excuse one or both parties from performance or to suspend performance, where unforeseeable circumstances prevent them from performing their side of the bargain.

The term has no specific legal definition under English law, so you have to look at the specific contract wording to establish whether the particular factual and legal circumstances and their effects amount to force majeure in each case. Although these clauses are often superficially

quite similar, the detail can be extremely varied, not just in terms of how force majeure is defined, but also the extent to which the parties are excused from their obligations, whether it triggers a termination right, and the procedures that must be followed.

For suppliers, a wide definition of force majeure is most helpful. Commonly force majeure clauses list particular events, such as "pandemics, any action taken by a government or public authority, including without limitation imposing an export or import restriction…", as well as referring to events "beyond the parties' reasonable control" and the like. When assessing whether force majeure will apply, the specific language used in the contractual definition will be key.

Contracts normally require not merely that a force majeure situation exists, but also that the force majeure event has actually caused the failure to supply (or other contract failure), so this needs to be established too. Note that some clauses require the party affected to be "prevented" from performance. This is a high hurdle and will require parties to demonstrate that performance is legally or physically impossible, not just difficult or unprofitable. Broader wording such as "hinder" or "delay" performance are likely to be given a wider interpretation and such clauses are more likely to apply where performance has been made significantly more difficult as opposed to impossible.

Indeed, it is not difficult to imagine a situation in which government restrictions, supply chain disruption, or a shortage of materials arising out of the pandemic would lead to the delay or prevention of a party's performance of its contractual obligations.

Often force majeure clauses are framed as being of mutual benefit to both the supplier and purchaser under a supply contract. In practice, purchasers may find it hard to rely on "conventional" force majeure clauses as it may be difficult for a purchaser of unwanted goods or services to be able to establish that its performance of the contract has been prevented, hindered, or delayed by the force majeure circumstances where the position is that the purchaser simply does not need the supplies anymore.

Simply having the force majeure clause in a contract is not enough. It will normally only be effective once notice has been served in accordance with the terms of the contract. All too often parties fail to serve notice that the force majeure event is in operation and in doing so can lose the benefit of the clause. Moreover, there will often be an obligation to take reasonable steps to mitigate the effects of the force majeure and in any event, this may well be implied by law. There is also the interplay between force majeure clauses and other positive obligations to have and implement business continuity or disaster recovery plans. Often parties will not be able to rely on force majeure clauses if they do not have these plans in place or do not seek to implement them as fully as possible. Businesses having difficulty fulfilling their contractual obligations should check their contract terms sooner rather than later and take advice if necessary to make sure they protect themselves.

G:

GENE EDITING (CRISPR)

CRISPR stands for "clustered regularly interspaced short palindromic repeats", which is a mechanism that exists naturally in bacteria, helping them to resist viruses.

It came to the world's attention in 2012 when Jennifer Doudna and her team at the University of California, Berkeley (UC Berkeley) discovered that it could be used as the basis for a revolutionary new tool for editing genes, raising the prospect of eventually eliminating hereditary diseases once and for all. In October 2020 Jennifer Doudna and Emmanuelle Charpentier (Max Planck Institute) received the Nobel prize for chemistry for their work in developing the CRISPR/Cas9 genetic scissors. The Nobel Committee said: "This technology has had a revolutionary impact on the life sciences, is contributing to new cancer therapies and may make the dream of curing inherited diseases come true."

CRISPR, which has been described as being like the "find and replace" function in Word, is best known for its ability to target and cut specific DNA within a cell, changing the sequence of genes. However, it can also be used to turn genes on or off without changing the sequence. Developments to the original idea, known as "base" and "prime" editing, have also allowed more precise control of the changes made, making the technology more predictable and safe.

Quicker and easier

CRISPR has transformed the area of gene editing because, compared to before, it is precise, quick, and easy to use, making it relatively inexpensive. It is widely used in research, with CRISPR-based research tools being a significant area, and a number of clinical trials have also enjoyed success in using CRISPR, particularly in relation to safety. CRISPR clearly offers great promise in medicine, although it is still early days with regard to showing that the technique will be safe and effective in the clinic.[2]

Applications of CRISPR

The applications of CRISPR currently being worked on are wide-ranging. In medicine, these include cancer therapy, virus detection, curing inherited blindness and restoring lost neurons after a stroke. CRISPR is also expected to play an important role in developing personalised medicines. In agriculture, CRISPR has been used to engineer silkworms to resist a lethal virus, to produce trans-fat-free oils and create lower-gluten wheat.

Ethical issues

Although there are many beneficial applications of CRISPR, there are inevitably also ethical issues. Particular risks revolve around human germline editing which can result in heritable changes, potentially changing the course of evolution. In China the biophysicist who claimed to have created CRISPR-edited babies was sentenced to three years in jail. The use of CRISPR in agriculture is generally less controversial, although public perceptions of genetically modified (GM) food are varied, and can include strong opposition. CRISPR may be regarded as less controversial by some because it does not involve transgenic changes, just changes to the organism's own genes, so it arguably falls outside traditional definitions of GM food.

Patent disputes

As more real-life applications of CRISPR technology come to fruition and prove themselves, the commercial value of the technology is likely to be huge. There is significant interest,

---

[2] Nature 06.01.20 – Quest to use CRISPR against disease gains ground, by Heidi Ledford

therefore, in the ownership position. Unfortunately, this is currently rather opaque. Ownership of fundamental aspects of the technology continues to be heavily disputed between two US bodies: UC Berkeley and The Broad Institute (Broad); this is despite a significant victory for Broad in the US in February 2022. Both UC Berkeley and Broad also face validity challenges from third parties in respect of the relevant patents, and it appears that UC Berkeley may have the upper hand in Europe at the moment[3]. It is to be hoped that the future licensing and exploitation of the technology is not hampered by uncertainties as to who owns what.

GDPR

GDPR and the life sciences industry

The General Data Protection Regulation (GDPR) is an EU data privacy and security law that seeks to ensure the fair and proper use of people's personal information, by regulating how businesses process personal data. Post-Brexit, the GDPR has been retained in UK law as the UK GDPR[4].

The GDPR may apply to organisations regardless of their geographic location if they process personal data relating to data subjects in the EU, or the UK for the purpose of the UK GDPR. Organisations subject to the GDPR are broadly required to comply with seven overarching principles, which are intended to embody the general spirit of the legislation.

More specifically, the GDPR imposes separate obligations on controllers (those who determine the purposes and means of processing personal data) and processors (those responsible for processing personal data on behalf of a controller). Additionally, the GDPR grants certain rights to data subjects, and organisations must therefore be aware of how they are required to respond to the exercise of such rights.

Organisations should endeavour to comply with the GDPR as fully as possible, as failure to do so can carry a fine of up to £17.5m in the UK and €20m in the EU, or 4% of total worldwide annual turnover, whichever is the greater.

GDPR and the life sciences industry

The GDPR has had a fundamental impact on the life sciences industry. Pharmaceutical and biotechnology organisations frequently make use of personal data and should therefore be aware of their obligations under the GDPR to avoid any regulatory “trip wires”. Businesses in the life sciences sector should consider how the GDPR may impact upon:

- Their ability to process data
- Medical research
- Other regulatory obligations

The ability to process personal data

To process personal data in compliance with the GDPR, organisations must first identify a valid lawful ground. There are six lawful bases for processing set out in the GDPR, and the most appropriate ground will be determined by the specific nature of the processing being

[3] Nature 17.01.20 Major CRISPR patent decision won’t end tangled dispute, by Heidi Ledford
[4] Unless specified otherwise, references in this section to the GDPR encompass both the GDPR and the UK GDPR.

carried out. Further, where any "special category" data is being processed (e.g. health or biometric data), organisations need to identify both a lawful basis for general processing and satisfy an additional condition, due to the particularly sensitive nature of special category data.

Medical research

A key area involving significant data processing for life sciences companies is medical research. Organisations involved in this area therefore need to ensure that any processing of personal data complies with the seven principles of the GDPR, namely: lawfulness, fairness and transparency; purpose limitation; data minimisation; accuracy; storage limitation, integrity and confidentiality (security) and accountability. It should however be noted that certain principles apply more flexibly where scientific research is being carried out, for example data can be stored for longer than would otherwise be permissible under the storage limitation principle, provided that appropriate safeguards are in place.

Life sciences businesses should also be aware that the rights which individuals have under the GDPR may also have implications for medical research. For example, individuals have a right to have their personal data erased in certain circumstances, which could extend to research data. However, the GDPR does provide an exemption from the right of erasure of personal data for scientific research purposes, insofar as the right of erasure is likely to impair or render impossible the achievement of the research objectives.

Other regulatory obligations

Given the highly regulated nature of the life sciences industry, it is common for organisations' obligations under the GDPR to overlap with their other regulatory obligations. Most commonly, we see overlaps in relation to clinical trials and pharmacovigilance.

Clinical trials

Whereas the GDPR seeks to protect individuals with regard to the processing of personal data, the Clinical Trials Regulations (CTR) aim to greater harmonise the rules for conducting clinical trials throughout the EU. Notwithstanding the data protection provisions set out in the CTR, the European Data Protection Board (EDPB) has confirmed that compliance with the CTR does not justify any derogation from GDPR standards. The EDPB have particularly emphasized that "informed consent" provided under the CTR to participate in a clinical trial is not the same as consent to process personal data under the EU GDPR. Even where giving informed consent under the CTR is possible, an imbalance of power between the participant and the sponsor/investigator may not enable consent to be "freely given", as required by the GDPR.

Organisations should therefore be careful not to assume that compliance with the CTR will guarantee compliance with the GDPR.

Pharmacovigilance

EU pharmacovigilance legislation requires organisations to report the effects of drugs once they have been licensed for use. The pharmacovigilance legislation provides that it shall apply "without prejudice to" the data protection laws (i.e. the EU GDPR), and therefore the EU GDPR will continue to apply in addition to any pharmacovigilance obligations.

H:

HUMAN MEDICINES REGULATIONS

The Human Medicines Regulations 2012 (the regulations) is the main legislation in the UK covering the manufacture, importation, distribution, advertising, labelling, sale and supply of medical products for human use and pharmacovigilance (the monitoring of the effect and safety of medical drugs after they have been licensed for use).

The regulations amended, consolidated and repealed a significant number of prior laws in this area, and underpin much of the regulation of medicines in the UK.

In relation to the key areas covered by the regulations, these include:

- **Manufacturing and wholesale dealing (grant of licenses)** (Part 3) – covers the manufacture, importation and wholesale dealing in products.
- **Requirement for authorisation** (Part 4) – sets out that products must not be sold or supplied in the UK unless authorised by the UK licensing authority.
- **Marketing authorisations** (Part 5) – sets out the procedures for authorisation of medical products in various categories by the UK licensing authority.
- **Certification of homoeopathic medicinal products** (Part 6) – sets out the application process for obtaining a certificate of registration for homeopathic medicinal products.
- **Traditional herbal registrations** (Part 7) – set out the process for registration of herbal medicinal products.
- **The concept of "force majeure" was frequently talked about during the Coronavirus pandemic and since authorisations** (Part 8) – sets out the limited situations in which the UK licensing authority may grant an Article 126a authorisation for a medical product in Northern Ireland only where a medicinal product has been authorised in another EEA member state.
- **Borderline products** (Part 9) – sets out how to determine whether products supplied without authorisation are medical products and, therefore, subject to the regulations.
- **Exceptions to requirement for marketing authorisations etc**. (Part 10) – sets the conditions under which a person may sell or supply or offer to sell or supply a medical product without first obtaining a marketing authorisation, a certificate of registration, a traditional herbal registration or an Article 126a authorisation.
- **Pharmacovigilance** (Part 11) – consolidates previous legislation concerning the monitoring of the safety of medicines in clinical use.
- **Dealings with medicinal products** (Part 12) – sets out the circumstances in which products may be sold, supplied or administered, as well as provisions in relation to sale of medicines to the public at a distance.
- **Packaging and leaflets** (Part 13) – sets out the information that is to be supplied with products and consolidates provisions on child safety.
- **Advertising** (Part 14) - sets out the requirements and standards for the advertisement of medicines.

- **British Pharmacopoeia** (Part 15) – stipulates that the British Pharmacopoeia Commission must periodically prepare editions of British Pharmacopoeia and also a compendium containing relevant information relating to certain substances.

I:

INJUNCTION

Injunctive relief for life sciences companies

An injunction is a court order that requires a party to either (i) take a particular action (a **mandatory injunction**) or (ii) to refrain from taking a particular action (a **prohibitory injunction**).

For example, an injunction to restrain Company A infringing the patents of Company B or an injunction to restrain Company A from wrongfully using trade secrets belonging to Company B.

An injunction may be temporary, in place until judgment is entered (**an interim injunction**), or permanent, continuing after the conclusion of proceedings either perpetually or until a specified date (**a final injunction**).

An injunction is an equitable remedy. The court has discretion to grant an injunction "in all cases in which it appears to the court to be just and convenient to do so". If a party breaches the terms of an injunction, it may be held in contempt of court, which is punishable by a fine or imprisonment.

Grounds for an injunction

For the court to consider granting an injunction, the party seeking injunctive relief must be able to establish:

1. There is a **substantive cause of action** (i.e. there is a serious question to be considered in the underlying claim), and the other party is either threatening to invade (or has invaded) your equitable rights or is threatening to behave (or has behaved) in an unconscionable manner.

2. The **balance of convenience** *test* is met – the court will weigh up the likely inconvenience or damage that would be suffered by the applicant if the injunction is not granted against the likely inconvenience or cost for the respondent if it is. An injunction is unlikely to be granted if damages would be an adequate remedy for the applicant if he succeeds at trial.

3. It is **just and convenient** to grant the injunction, and no equitable bars exist (e.g. undue delay or unreasonable conduct on the part of the applicant).

The English courts have shown that they are prepared to adopt a flexible and creative approach to the type of injunctive relief they are willing to grant applicants in life sciences claims. In this regard, the court will not only consider the interests of the parties themselves but it will also consider the wider public interest.

Urgent injunctive relief

There is a lot of potential for intellectual property infringement in the life sciences sector, particularly given the wide variety of patent claims that could cover products in the industry. The increased use of software as a medical device also gives rise to potential copyright, trademark and design right claims. In addition, general commercial issues can arise, such as breach of contract, breach of confidence, dealings with competitors' customers or suppliers, and those touching upon employment issues where, for example, restrictive covenants have not been followed. It is not uncommon for urgent injunctive relief to be sought in the life sciences sector.

In an emergency, an injunction can be obtained very quickly without giving notice to the other party. Urgency arises most often where the other party would take advantage if given

notice of the application or where further damage would result from any delay in making the application.

If you're arbitrating, don't forget…

Typically, a number of disputes in the life sciences sector proceed down the arbitration route rather than the court route. This does not **necessarily** mean that you cannot go to court to seek an injunction, but it will therefore be important for parties to check the relevant arbitration agreement or institutional rules as to the emergency relief available.

IR35

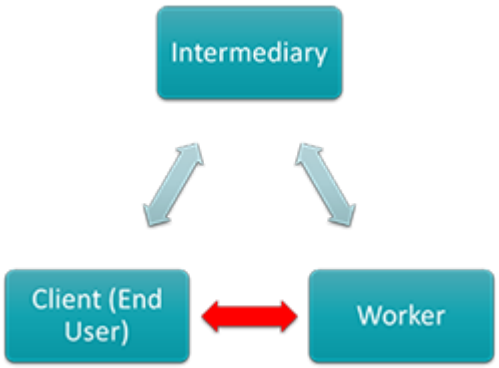
The IR35 rules, also referred to as the "off-payroll working rules" or "intermediaries legislation", are anti-avoidance measures designed to tackle abusive use of personal services companies (PSCs) by contractors.

In 2000, the onus to determine self-employed tax status in the public sector shifted from the contractor to the end client, marking a substantial reform in the regime. From April 2021, this was extended to the private sector, affecting all medium and large businesses in the life sciences sector that engage contractors or freelancers through PSCs.

While HMRC stated that it would support businesses to comply with the new rules, taking a "light touch" approach to penalties for the first year, this has now come to an end. Further enforcement is anticipated in this area, particularly in regards to the use of umbrella companies after the call for evidence issued at the end of 2021.

When do the rules apply?

IR35 applies to individual contractors who work like employees but provide their services through intermediary entities (often PSCs) where, if that individual contractor had provided their services directly to the end customer, they would be regarded as an employee for tax purposes. The legislation looks beyond the contracts in place and instead considers the practical implications of an arrangement (i.e. the hypothetical contract shown by the red arrow in the diagram below).



Where IR35 applies, payments made to the intermediary must be subject to deductions of tax and employee national insurance contributions, plus the paying entity must account for employer's national insurance contributions (and, if relevant, the apprenticeship levy). It is important to note that businesses must also continue to pay VAT on the gross fees invoiced by the PSC, which may require new procedures to be followed in finance departments to reconcile the VAT position and the IR35 consequences.

What are the terms of the hypothetical contract?

The key criteria which are applied to determine whether the arrangement is a form of "disguised employment" or true self-employment are:

- Mutuality of obligation on both the individual and end user
- Right of substitution for the individual contractor
- Degree of control held by the end user over the worker

There are numerous additional factors to consider in each case, such as financial risk, length of the engagement, and equipment provision. Overall, the end user must take a holistic, and not a tick-box, approach when assessing the nature of its engagement with the worker.

Impact of the April 2021 IR35 reforms on life sciences businesses

Engaging contractors or freelance workers through PSCs is common practice in the life sciences industry. From April 2021, medium and large private businesses in the sector who do so will have needed to:

- Identify the workers impacted by the rules
- Assess the underlying hypothetical contract between each worker and the end user
- Decide the workers' employment status, keeping records of the reasoning behind each determination, and communicate this to the worker in writing before he/she is paid – keeping in mind that workers have the right to appeal the determination

The rules will also apply to complex labour supply chains (e.g. those involving multiple agencies) and to public sector bodies (who were already within the regime). Small private businesses (broadly those meeting at least two of the following tests: annual turnover of not more than £10.2m, balance sheet total of not more than £5.1m, and not more than 50 employees) will stay within the old regime, although the new rules will apply if they expand to become medium or large entities.

What actions should life sciences companies take to comply with the new rules?

Small companies

Small private companies in the life sciences sector who are expanding to become medium or large entities in the near future may wish to:

- Audit their labour supply chain.
- Identify who will have responsibility for implementing the rules within the business.
- Analyse the cost implications of status determinations.
- Adjust existing contracts and/or working practices to clarify in advance which workers are self-employed and which should be engaged formally as employees.
- Provide training within the business on any new processes, contract templates and controls to be followed.
- Communicate with affected workers about contract amendments, status determinations and any dispute resolution procedures.

Medium and large companies

Medium and large private companies in the life sciences sector, who have already implemented the new rules, should consider:

- Refreshing status determinations on a regular basis, and in particular when new contracts are signed or existing contracts are altered or extended

- Reviewing and updating their processes as legislation and guidance changes.
- Providing refresher training within the business at regular intervals on the processes, contract templates and controls to be followed.

Businesses concerned about the implications of the IR35 rules or how best to comply with them should contact their legal and tax advisors in the first instance.

J:

JURISDICTION

Court jurisdiction for life sciences companies

Life sciences companies conducting international business will routinely enter into international contracts, including collaboration, licensing, supply and distribution agreements.

An important question to consider is where the parties' differences should be resolved, be that through national courts or through arbitration.

Contractual jurisdiction clauses deal with this question. A jurisdiction clause is a common boilerplate clause often included when contracts are drafted. Sometimes the jurisdiction clause does not receive much attention, as the focus is on the commercial terms to be agreed. However, this can lead to standard wording being included almost as an afterthought without due consideration to the specific contractual arrangements being negotiated.

A common standard jurisdiction clause insofar as English contracts are concerned provides for the "exclusive jurisdiction of the English Courts". Other clauses may provide for disputes to be resolved by arbitration instead and set out details of how that will be done. We have written a piece on arbitration which can be found here. This article focuses on court jurisdiction.

Should I include a jurisdiction clause at all?

Yes. The question of jurisdiction can be of utmost importance. If a dispute arises, how that can be resolved, or the terms of the contract enforced, will depend on how the question of jurisdiction is dealt with (or not) in the contract. If the parties have agreed their preferred dispute resolution mechanism and forum, this will avoid uncertainty and potential costly satellite disputes about where the dispute should be resolved.

Which courts?

The question of which court should determine any dispute will largely depend on factors such as the geographical location of the parties, where business is conducted and the location of any assets of the parties. By default a party tends to opt for its home courts as this is more familiar and convenient. But if the business in question is being conducted in the territory of an overseas party, and that is where that party's assets are located, then it may make sense to allow for the courts of that place to have at least non-exclusive jurisdiction, so disputes can be resolved and court orders enforced there.

The efficacy of any chosen legal system should also be taken into consideration. In some jurisdictions it can take many years to obtain a judgment, and the costs of pursuing legal action (and recovery of those costs) can also vary enormously from country to country.

Exclusive or non-exclusive?

An exclusive jurisdiction clause will mean that all parties to the contract have agreed that the courts of one place have jurisdiction to hear and resolve disputes under the contract. This provides certainty. However, if the parties are located or business is being conducted in different territories, then a non-exclusive jurisdiction clause will provide additional flexibility, should there be a compelling need to pursue a dispute elsewhere, although post-Brexit, exclusive jurisdiction clauses are generally preferable from an enforcement perspective. There are also other, less common options such as "hybrid" jurisdiction clauses, which allow one party wider rights to commence court action in different jurisdictions than the other party. These clauses can be complex and may not always be enforceable.

"Escalation" clauses provide for more informal dispute resolution methods (such as senior management meetings and mediation) to take place before the matter is escalated to court action or arbitration.

Enforcement

Enforcement is one of the most important aspects when thinking about your jurisdiction clause. There is no point agreeing the exclusive jurisdiction of the English courts if action may need to be taken against a party resident in a territory which does not recognise or enforce English court judgments. In such a case, it may be better to agree that the courts of that other location have jurisdiction. If an overseas jurisdiction is to be considered, local law advice should be taken to check for any disadvantages or peculiarities which may need to be factored into your drafting.

We have previously written specifically about enforcement and addressed the enforcement of court judgments both within and outside the EU here.

Alternatively, you could opt for an arbitration clause. Arbitration has the benefit of being seen as a more "neutral" option, it is (generally) confidential and, crucially, arbitration awards can be enforced widely internationally under the New York Convention regime, for more information see here.

In any event, when drafting your contract it is important to give the jurisdiction clause careful consideration and take into account the locations and specific circumstances of the parties themselves as well as the nature of the proposed business collaboration and the wider context. This is crucial in the international arena in which life sciences companies operate, even more so in times of political uncertainty. The question of jurisdiction should always be reviewed on an individual case by case basis depending on where the counterparty and its assets are located to ensure that the prospects of resolving disputes in a favourable manner, enforcing judgments and making recovery, are maximised.

JOINT VENTURE

Two or more parties establish a joint venture (JV) when they combine their resources to pursue a common goal.

JVs have a vast range of applications in the life sciences sector, from cross-border drug development initiatives between leading pharmaceutical companies to NHS trusts collaborating with specialist healthcare providers. Numerous JVs have been established to tackle the coronavirus pandemic, such as to develop vaccines and therapeutics and to manufacture and distribute medical devices, personal protective equipment and testing materials.

Key areas to consider before establishing a JV include:

- Structure
- Contribution of resources and financing
- Management and control
- Deadlock and termination

Structure

In the UK, JVs are most commonly structured as private limited companies or non-statutory contractual arrangements. Less common structures include limited liability partnerships and partnerships.

Limited companies have the advantage of clear separation of the business activities of the JV company from the JV partners. This separate legal personality enables the JV company to own assets, contract with third parties in its own right, employ staff, open a bank account and raise third party finance. The liability of the JV partners is limited to the amount paid up on their shares in the JV company. The Companies Act provides an established legal framework for the governance and reporting obligations of the JV company. Share ownership provides a clear exit strategy for JV partners and can also be used to incentivise employees of the JV company.

Unincorporated contractual arrangements, on the other hand, provide more flexibility, enable JV partners to retain direct ownership and control of the resources being contributed to the JV and reduce the administrative burden and disclosure requirements.

Operational, tax, regulatory, competition law and accounting considerations frequently influence the choice of JV structure, especially in more complex and cross-border JVs.

The remainder of this article focuses on the private limited company structure.

Contribution of resourcing and financing

Non-cash resources to be contributed by the JV partners may include tangible assets, intangible assets (such as intellectual property), employees (who may be seconded to the JV company), supply and distribution arrangements etc.

If a limited company structure is used, all relevant terms will need to be included in ancillary agreements between the relevant party and the JV company. It is important to consider termination provisions in ancillary agreements in conjunction with those in any shareholders' agreement between the JV partners and the JV company.

The JV company will often undertake due diligence on the assets being contributed and obtain warranties from the JV partner contributing them. There is also the question of how the contributed assets will be valued and how this will affect the contributing JV partner's funding obligation.

JV partners typically fund the JV company by subscribing for shares and/or loan capital. They may also provide guarantees of the JV company's obligations to third parties. The JV company may additionally seek third party debt finance. In any case, the future financing requirements of the JV company will need to be considered.

Management and control

Management and control of a JV company will typically be determined by a combination of the shareholdings of the JV partners, their representation on the board of the JV company and their contractual veto rights.

In a 50/50 JV company, each JV partner has an equal shareholding and enjoys equal representation. In contrast, a shareholder with over 50% of the voting shares will be able to appoint and remove directors and pass ordinary resolutions of the shareholders.

Minority shareholders will seek negative control in the form of contractual veto rights. These usually comprise specified matters which the JV company may not undertake unless all or a specified proportion of the shareholders agree.

Such matters may include the:

- Issue of new shares (other than pro-rata)
- Transfer of shares (either at all or within a specified period)
- Alteration of constitutional documents
- Entry by the JV company into material contracts or capital expenditure

- Dealings between the JV company and any JV partner
- Winding up

Further matters affecting the management and control of the JV company include the rights attaching to the shares, the frequency and procedures for shareholder and board meetings, the number of directors, the process for their appointment and removal, and who is to be chairman (and whether they have a casting vote).

Deadlock and termination

JVs can become deadlocked when the board of the JV company cannot agree on a proposed course of action or a minority JV partner exercises its right of veto. The shareholders' agreement will typically define what constitutes a dispute or deadlock and set out the method of resolution.

This may include escalation of the matter to senior representatives of the JV partners or similar procedures. However, once exhausted, dispute resolution procedures will often result in the termination of the JV. There are a number of different ways this can be achieved.

The aggrieved party may have the right to buy shares from (or sell them to) the other party (though query on what terms) or to require the liquidation of the JV company. "Texas shootout" provisions enable shareholders to make an offer (on a highest sealed bid basis) for the other's shares. While "Russian roulette" provisions enable shareholders to offer to either sell to or buy out the other shareholder at a given price and the offeree has the right to accept or elect to do the opposite on the same terms.

The JV may also terminate automatically either upon all shares in the JV company being held by one party, upon the JV company's winding up, after the end of fixed period, upon termination of key ancillary agreements or other key events such as destruction of a material asset.

JV partners may enjoy voluntary termination rights, for example if another JV partner fails to remedy a material breach, becomes insolvent or undergoes a change of control.

The consequences of any such automatic or voluntary termination of the JV will need to be considered, including whether the shareholder terminating the JV has the right to sell its shares to or acquire shares from the defaulting shareholder (and on what terms).

The rights of the shareholders on the dissolution of the JV company also require consideration, including the distribution of assets, outstanding contracts and rights to the JV company's intellectual property and know-how.

Summary

JV arrangements are commonplace in the life sciences sector as they present an established and efficient framework for two or more parties to combine their resources and individual expertise when working towards a common goal.

K:

KNOW-HOW

The successful protection and licensing of valuable know-how is a key priority for many life sciences companies. This article provides answers to some common questions on the subject.

What is the definition of "know-how"?
Impossible to pin down, often thought of as referring to practical expertise and "tricks of the trade" as opposed to specific scientific or technical knowledge. However, it often has a wider meaning and can include very valuable technology.

Does it have to be technical?
No, think of franchising know-how, business know-how.

Is it secret?
Not necessarily, although most valuable know-how is secret.

Is it a property right?
This is controversial. Know-how is often bought and sold as if it were property, but fundamentally it is based either on contractual confidentiality undertakings or on equitable duties of confidence (often both).

Is it useful?
Very. For example, a patent may provide a 20-year monopoly on a new process or product and disclose the basics of how to implement or make it. But secret manufacturing or processing know-how developed by the patent owner can help to preserve the business' position after expiry of the patent by making it difficult for others to achieve the same quality. Another example is franchising know-how where the confidential business and marketing know-how provided by the franchisor forms the backbone of the business and helps to ensure consistent quality across the franchises.

How can you protect know-how?
Some aspects of know-how may be protected by intellectual property rights such as copyright or design rights, but usually the main protection is keeping it secret. Non-disclosure agreements, restrictive covenants and carefully drafted employee contracts are therefore key to protecting it.

Do you have to write it down?
In principle, no. But documenting it is important both from a legal and practical point of view – to enforce your rights in the event of disclosure or misuse, you will need to demonstrate to the court that you have treated it as confidential, for example by using passwords and restricting access.

What if some of it is in the public domain?
As a rule, know-how will be protectable even if some of it is in the public domain if, as a body of information, it is not generally known to the kind of people who normally deal with the kind of information in question.

Can you license it?
Yes, know-how is often licensed both in connection with patents and otherwise.

LICENSING

The process of drug development in the life sciences sector often involves collaboration between a number of different parties, with both the process of development and the drugs themselves having become increasingly complex over time. To set the framework for collaborative drug development, companies will often enter into licensing arrangements, which govern the use and ownership of certain intellectual property (IP) rights throughout the life of a product.

What is a licensing agreement?

In the context of the life sciences sector, a licensing agreement may set out the terms under which an inventor or proprietor (the licensor) grants a customer (the licensee) rights to use its patents or know-how, often to aid the development of a product. A licensor's IP is a significant asset that is often the result of a number of years of research and development work. Before granting a licence under its IP, a licensor will often carry out in-depth research into a potential licensee by assessing both the commercial benefits and risks of entering into the collaboration. For example, a licensor will wish to ensure its IP will remain protected in the long term and will consider how likely it is that details of the licensed IP may be exposed whilst on licence to the potential licensor.

Exclusivity

Licences granted by a licensor can be either exclusive, sole or non-exclusive. Where a licence is exclusive, the licensor agrees not to grant any other licences in respect of the same IP to third parties, nor to use the licensed IP itself. This contrasts with a non-exclusive licence, whereby the licensor may grant other licences for the same IP to third parties, as well as using the licensed IP itself. With a sole licence, both the licensee and licensor can use the licensed IP but it cannot also be licensed out to a third party.

The level of exclusivity granted under a licence can heavily affect the value attributed to it. For example, a licensee will often be willing to pay far greater fees for an exclusive licence than for a non-exclusive licence.

Payment structures

Payments due under a licensing agreement can vary depending on a number of factors, for example the degree of exclusivity granted under the licence (as described above) and the nature of the licensed IP. At the point of entering into the licence, an initial one-off payment is sometimes payable by the licensee. This is particularly common where an exclusive licence is granted, and where the licensor has made a significant investment in developing and protecting the IP.

In addition to any one-off milestone payments – be those upon entering the licence, annual fees or upon achieving certain regulatory hurdles, there are often royalty payment provisions in a licence whereby the licensee pays the licensor royalties calculated as a percentage of the net sale price of any products sold that were made or developed using the licensed IP. Royalty provisions in a licensing agreement can be complex and can vary significantly depending on the sector and the anticipated commercial benefits for each of the parties. The bargaining power of each of the parties is also a significant factor, for example a licensee with a large turnover may be in a position to negotiate a lower royalty rate on the basis that its net sales figure is likely to be higher than a smaller licensee.

Controlling access to the licensed IP

One area of licensing agreements that tends to be heavily negotiated is any provision relating to sublicensing. To minimise the risk of its valuable IP and confidential information getting into the unauthorised possession of a third party, a licensor will often request that the IP cannot be sublicensed without its consent. This is particularly common where exclusive, or more valuable, licences are granted and where there is an international element. For example, a licensor may require this provision where a potential licensee is based in a jurisdiction in which the licensor has carried out minimal prior business and where there are less stringent trade secret laws and enforcement, which would ordinarily provide comfort against the risks relating to exposure of confidential IP.

M:

MARKETING AUTHORISATION

A marketing authorisation (MA) is the regulatory gateway to the market for medicinal products. A pharmaceutical company must have an MA – sometimes referred to as a licence – before it can advertise and sell a new medicinal product, for example a medicine or vaccine.

The MA will state the illnesses or conditions and age of patients the product is intended for and will specify the dosage and how it should be administered (e.g. tablet or cream). This will appear on the patient information that comes with the product.

Obtaining an MA – originator products

To obtain an MA, the pharmaceutical company must provide evidence to the licensing authority both that the product is safe and that it is effective to treat (or in the case of a vaccine, for example, to prevent) the relevant illness or condition. In the case of new medicines and vaccines, this will usually involve evidence of tests and clinical trials carried out by the originator company. Once the MA has been granted, the MA holder will have a period of data exclusivity during which others cannot rely on that evidence to obtain an MA for the same drug. In practice, the result is usually that competitors cannot sell copycat drugs during this period, even if the product is not protected by a patent. Read more about data exclusivity in our previous article here.

Obtaining an MA – generics

If the medicine has been successful, it is common for generic companies to enter the market after both the data exclusivity period and the period of any patent protection has run out. Generics can obtain an MA through an abridged procedure by demonstrating that their product is the same as the original product, so avoiding the need to repeat trials on animals and humans unnecessarily and allowing generics a quick entry to the market.

Off-label medicines

A medicinal product cannot be sold or promoted for a particular use without an MA relating to that use. In some instances, however, medical opinion indicates that a drug is effective for a different use and a doctor may prescribe that drug "off-label" for that use. A controversial instance of this arose in relation to Avastin (which is licensed for cancer treatment) for treating wet age-related macular degeneration, use of which became widespread, not because there were no alternative licensed treatments, but because those treatments were more expensive.

Applications

MAs are generally country-specific – they are obtained by applying to the relevant medical health authority. Applications for MAs for the UK are made to the UK Medical and Healthcare products Regulatory Agency (MHRA).

Effect of Brexit

Following the end of the Brexit transition period on 31 December 2020 new applications for UK MAs can no longer be made through EU procedures. However, under the Northern Ireland Protocol, Northern Ireland is treated differently and is still subject to EU requirements governing medicinal products. An MA for Northern Ireland can, therefore, still be obtained via the centralised, decentralised or mutual recognition procedures operating in the EU. In addition, an MA covering Northern Ireland may be obtained through an application to the MHRA.

UK businesses are still able to use the EU procedures to obtain MAs in the EU Member States, Iceland, Liechtenstein and Norway.

MEDICAL DEVICES

Businesses wishing to sell medical devices to the UK market must ensure regulatory compliance in the UK. Such regulation relates, amongst other things, to product safety, supply chain transparency and import/export control.

Medical devices sold in Northern Ireland are currently subject to a separate regulatory regime to the rest of the UK. Given these differences, and the prospect of changes to the regime in Northern Ireland, this article only covers the current position in Great Britain.

What is a medical device?

The Medical Devices Regulations 2002 (UK MDR) describe a medical device as any instrument, apparatus, appliance, software, material or other article used alone or combined for humans to:

- Diagnose, prevent, monitor, treat or alleviate disease
- Diagnose, monitor, treat, alleviate or compensate for an injury or handicap
- Investigate, replace or modify the anatomy or a physiological process
- Control conception

How are medical devices regulated in the UK?

The Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health and Social Care, is responsible for regulating the UK medical devices market.

Medical device regulation in the UK is governed by the UK MDR, which implements various EU medical device regulations, including:

- EU Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
- EU Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)
- EU Directive 93/42/EEC on medical devices (EU MDD)

Post-Brexit, much of the EU medical device regulation has been retained as UK domestic law, although the UK MDR was amended by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 to remove elements particular to the EU.

Changes to EU medical device regulation (not applicable in the UK)

The EU has undergone recent reforms to its medical device regulation, comprising the Medical Devices Regulation (EU) 2017/745 which became fully applicable in May 2021 and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 which entered into force in May 2022. As these reforms took effect after the expiry of the Brexit transition period, they have not become UK law.

There are three elements in relation to the new regime that businesses need to take particular note of:

- Businesses operating under a European conformity assessment and approval (CE mark) will now need to carry out a UK-specific conformity assessment and approval (UKCA mark). That can be challenging where the device requires independent approval from a

so-called UK-approved body, and complications have led to significant delay to UK government deadlines in this regard.

- The new regime may require the establishment in, or the use of a third-party representative in, the UK for EU based businesses.
- There is now divergence between the UK and the EU, developments will need to be kept under review for businesses that operate across borders.

N:

NOVATION

Contractual relationships in the life sciences sector

As an increasingly complex sector in which numerous stakeholders and parties may be involved in any given project, contractual arrangements that evolve throughout the life cycle of a particular product play a key role in the life sciences industry.

On one project alone, a pharmaceutical or biotech business could be party to a variety of different contracts. These may include, for example, licensing agreements governing the use of certain intellectual property, service agreements relating to the development and manufacture of drugs, or contracts for the hire or purchase of pharmaceutical processing or manufacturing equipment. Each of these contracts is crucial to enable the companies involved to achieve commercial success and to progress drug research and development.

Expansion and consolidation through asset purchases

To streamline and develop project workstreams, it is very common for businesses in the life sciences sector to add new assets to, and sell assets from, their portfolios. Such acquisitions can enable a company to consolidate its position in a specific market, reduce research and development costs by bringing certain functions in-house, or expand into a new market altogether. Meanwhile, the disposal of certain assets may take place following a decision to conclude research in a certain area, or to raise capital by selling an asset that is deemed valuable in the wider market.

To ensure that a company benefits fully from any asset it purchases, it is important that all contracts relating to that asset continue to be performed following an acquisition. In particular, a buyer will wish to ensure that the relevant obligations and benefits under a contract are passed onto them and that they can continue to enforce that contract going forward.

How are the benefit and burden of a contract passed on to a buyer of an asset?

Novation is a mechanism of transferring one party's rights and obligations under a contract to a third party. Novation is used to effectively "extinguish" one contract and replace it with a different one, allowing a third party (i.e. the incoming party) to agree to perform the outstanding obligations of an outgoing party. Novation is a particularly useful mechanism where the transfer of contractual obligations, such as to provide a service or to make payment, is required. Such obligations cannot be transferred by simply assigning a contract and can only be transferred by novation.

Consideration

As novation extinguishes one contract and replaces it with another, it is important that the new contract satisfies the legal requirements for formation of a valid contract. One of these requirements is consideration, based on the notion of reciprocity and the idea that a promisee cannot enforce a promise unless he has given or promised something in exchange for that promise. Generally, the promises agreed between each of the parties in a novation agreement will be deemed adequate consideration but, for the avoidance of doubt, novation agreements are often entered into in the form of deeds.

Consent

In order for a novation to be valid, all parties to the original agreement (i.e. the outgoing and the continuing parties) as well as the incoming party must consent to the novation. This is generally not an issue for the incoming and outgoing parties, however, obtaining the consent

of the continuing party may be problematic in certain circumstances. For example, the continuing party may not consent to a novation where it deems the incoming party to be inferior to the outgoing party in some respect, for instance, where it perceives a greater risk that the incoming party will breach key terms of the agreement. These risks are usually considered by the continuing party against the benefits of maintaining the commercial relationship before a decision is made regarding whether or not to agree to the novation.

A novation agreement generally releases the outgoing party from any future liabilities under the original contract, however it should also address the status of the pre-novation liabilities. Unless the novation agreement specifically states that these liabilities shall transfer over to the incoming party, they will generally stay with the outgoing party.

Invalid novation agreements

If the requirements for an effective novation are not fulfilled, then the novation may be considered invalid and the transfer ineffective. Instead, it may be inferred that an assignment of the benefit of the contract has taken place instead (assuming this is it not prohibited in the original agreement), meaning that the outgoing party remains liable for the incoming party's defaults under the contract.

Considering the above, in the event of an asset sale between businesses in the life sciences sector, it is important that the parties carefully consider whether there are any existing contracts that require novation, to ensure that performance of those contracts can continue and to minimise disruption to any related projects.

O:

ORPHAN MEDICINES

The significant financial investment required for the research and development of a new medicine means that, in normal market conditions, there is generally insufficient commercial incentive for pharmaceutical companies to develop drugs intended for use by only small numbers of patients.

Rare diseases

It is estimated that between 5,000 and 8,000 distinct rare diseases exist, affecting between 6% and 8% of the total population. In the UK this amounts to approximately 3.5m people suffering from rare diseases.

To encourage the research and development of medicines for rare diseases, known as "orphan" drugs, the UK regulatory framework offers a number incentives where a medicine meets certain criteria. If an organisation wishes to obtain such incentives, it must submit the Great Britain Orphan Drug Designation Application Form to the Medicines and Healthcare products Regulatory Agency (MHRA) with its marketing authorisation (MA) application.

Criteria for orphan designation

To qualify for orphan designation, a medicine must be intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition. There must also be no existing satisfactory method of diagnosis, prevention or treatment for the relevant condition or, if there is, the new medicine must be of significant benefit over current methods.

In addition, the medicine must meet either the "prevalence" or the "insufficient return on investment" criterion. These are as follows:

- **Prevalence** - The applicant must show that the condition the medicine is intended for affects no more than five in 10,000 people in the UK when the application is made.
- **Insufficient return on investment** - The applicant must show that, without incentives, it is unlikely that the marketing of the medicine would generate sufficient return to justify the necessary investment.

Incentives for orphan designation

Ten-year market exclusivity

Once MA is granted for an orphan designated medicine, it will benefit from market exclusivity in Great Britain for up to 10 years in respect of the particular indication. During this period, no other marketing authorisation will be issued for the same therapeutic indication in respect of a "similar medicinal product" unless:

- The MA holder for the original orphan medicinal product gives consent to the second applicant, or
- The MA holder for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product, or
- The second applicant can establish that the second medicinal product is safer, more effective or otherwise clinically superior to the orphan medicinal product.

Fee reductions

Companies applying for regulatory approval in respect of a designated orphan medicine may also be entitles to pay reduced fees for MA applications.

GB and UK orphan medicines post-Brexit

If a medicinal product has been designated orphan in the EU before 1 January 2021, a GB orphan MA application can be made. A UK-wide orphan MA application can only be considered in the absence of an active EU orphan designation.

If a UK-wide orphan MA is granted and the medicinal product subsequently receives EU orphan designation, the MA holder would need to submit a variation to change this to a GB orphan MA.

OUTSOURCING

The life sciences sector is an industry in which competition is constantly evolving, particularly due to rapid developments in technology and heavy investment in the sector.

The stages involved in taking a product from initial research to market are wide-ranging, many requiring specialist equipment, materials and highly trained individuals. The inevitable consequence of being involved with such complex product cycles for life sciences companies is significant overhead costs.

What is outsourcing?

As a result of increasing costs, it is common for life sciences companies to source and engage third-party organisations to provide certain services, otherwise known as outsourcing.

One particular distinction between outsourcing arrangements and more traditional "supply of services" arrangements is that outsourcing is generally carried out for functions or services that would otherwise have been controlled and performed in-house by the customer itself. As such, it is common for a customer in an outsourcing arrangement to retain an element of strategic responsibility and control over the outsourced function or service.

The benefits of outsourcing in the life sciences sector

Outsourcing certain functions and services is particularly common for smaller pharmaceutical or biotech companies that are not able to commit resources to every stage of product development. Indeed, regardless of an organisation's capacity or available resources, outsourcing can allow a company to streamline its research and development work, become more efficient and reduce a product's "time to market".

Aside from enabling life sciences companies to operate in a more cost-effective manner, outsourcing also allows businesses to benefit from the use of third-party specialist equipment and to share the risks associated with offering such services, whilst retaining ultimate control of the research and development process.

Risks and considerations of outsourcing in the life sciences sector

As is the case when entering into any agreement, there are several important factors that companies should consider when entering into outsourcing arrangements. Such agreements should clearly cover the description of the services or function being provided, set out remedies for poor performance, indicate the fees payable for the outsourcing arrangements, specify the length of the arrangement and provide for any rights to terminate the arrangement early.

It is also important that the distribution of risk is considered in an outsourcing agreement. The customer should identify the risks and issues that could arise during the lifetime of the arrangement and ensure that appropriate provisions are included in the agreement to mitigate these risks. A particular risk for life sciences companies is the potential that an unsuccessful outsourcing arrangement could cause significant delays in getting a product to

market and the associated cost implications, liabilities and reputational damage relating to such delays.

Separately, it is important that companies consider any employment liabilities relating to an outsourcing arrangement, particularly where there are staff transfers or TUPE arrangements as part of the arrangement.

Finally, confidentiality is another area of key importance for life sciences companies. In outsourcing certain functions, a customer may be required to share highly confidential information regarding its work and intellectual property. It is important that the confidentiality provisions contained in outsourcing agreements reflect the nature of the work and the risks relating to the transfer of such confidential information. Further, the agreement should have clear parameters around exactly where the customer's confidential materials can be held, who can access them and what must happen to them at the end of the outsourcing arrangement.

P:

PATENT

The importance of patents to the life sciences industry can hardly be overestimated. Patents are monopoly rights which protect research and new products.

The ability to obtain a patent on a potential new drug candidate is likely to be key to decisions about investment and whether to proceed. Similarly, the loss of patent protection for a successful product, perhaps following an invalidity ruling, may result in very significant financial losses to the innovator company as the market opens up to the generics.

Patents for inventions

Patents may protect products, such as new drugs or medical devices, or processes such as a method of gene editing. They are applied for throughout the product development cycle. For example, in the case of a new drug, patents are typically obtained on the active ingredient itself and then further patents are added as new compounds and formulations are developed. This might include patents on second medical uses (repurposing) and sometimes even new dosage regimes if these are genuinely innovative.

SPCs – extended protection for some drugs

It can take 10 years or more and over £1bn to develop and obtain marketing authorisation to launch a new medicine. Patent protection normally lasts for 20 years. This means that if a patent is obtained early in the development process, the period of patent protection left in which to exploit the product in the market is severely reduced. To compensate life sciences patent owners for the time "lost" in this way, extended patent protection of up to five years can be obtained in respect of some authorised medicines. The extension is known as a "Supplementary Protection Certificate" (SPC) and can only be obtained for products that contain a new active ingredient – not, for example, for repurposed drugs or reformulations. This is a controversial issue. Many argue that in a time of financial pressure on health services, the financial incentive provided by the SPC should be available to repurposed drugs in particular, as they are potentially more cost effective than developing new active ingredients from scratch. On the other hand, health services need cost-effective generic drugs. The SPC system was originally an EU system which the UK has retained post-Brexit, so it is now open to the UK to adjust these rules in the future if it wishes – this is an area to watch.

PAY FOR DELAY

Broadly "pay for delay" refers to cases where patent holders pay generic companies to delay entry to markets containing a patent protected drug.

Often such payments occur in the context of settling patent litigation. There have been a number of cases in Europe, the US and the UK establishing that such agreements have the potential to infringe competition/antitrust law.

Put simply, these cases turn on the distinction between:

- An agreement by which competitors agree not to compete and instead to share monopoly profits (which one might say is typically unlawful), and

- The right that parties have to settle litigation, which may well include an agreement not to engage in potential patent-infringing conduct (which one might describe as typically lawful).

Pay for delay cases are particularly difficult, as the outcome of the litigation is uncertain because of the settlement. For example, if, but for the settlement, the patent would have been upheld, then the generic would not in any event be entitled to enter the market. In such circumstances the settlement has not in fact led to a reduction in competition in the market.

From a generic company's perspective, the question becomes: when is it legal to forfeit a chance to compete for a commercially rational alternative strategy? From a patent holder's perspective, the question is: when is it legal to pay money to a generic in order to avoid the costs, and uncertainty of outcome, associated with litigation? For the regulator this may involve a difficult assessment of the strength of the patent being litigated against the size of any value transfer resulting from settlement.

The boundary between lawful and unlawful conduct in this area is often unclear.

As with many competition law issues in the pharmaceutical sector, this has been an active area for enforcement that companies need to be wary of.

Q:

QUALITY OF CONFIDENCE

To claim for breach of confidence in the UK, there are three key requirements: (i) the information itself must have the necessary "quality of confidence", (ii) the information must have been imparted in circumstances importing an obligation of confidence, and (iii) there must be an unauthorised use of that information.

This article explores the boundaries of "quality of confidence" and how this has particular relevance for businesses operating in the life sciences sector where, in an ever evolving and highly competitive industry, protecting confidential information is paramount.

When will information have the necessary "quality of confidence"?

This will of course be fact specific and simply describing or labelling a document as "confidential" will not in itself determine whether the information in question is inherently confidential and capable of protection.

In many cases, it will be clear that the information has the necessary quality of confidence by its very nature. For companies in the life sciences industry, this is likely to capture categories of information such as secret chemical formulas, proprietary manufacturing processes and related documentation (e.g. manuals and technical drawings), algorithms, data and results from confidential research, biological sequence information and technical data to support regulatory filings (e.g. cell line history).

However, disputes often arise where the information relied on can potentially be ascertained from existing material in the public domain or is constructed solely from publicly available information. In these circumstances, to merit protection under the laws of confidentiality, something new and confidential must have been created by the application of skill and ingenuity. Whilst this would not cover very basic collections of non-confidential items, certain compilations of commercially valuable data such as customer lists may nevertheless attract protection.

Another challenge arises where the confidential information relied upon (for example, a manufacturing process or recipe) is ascertainable by reverse engineering. However, the English courts have recognised that such information may still have the requisite quality of confidence where the reverse engineering would involve a significant amount of work (or "special labours") and injunctions may be granted to compensate for the time saved by misusing such confidential information.

What practical steps can help to maintain confidentiality?

To ensure that proprietary information continues to attract the necessary quality of confidence, there are practical steps that can be taken. For example:

- Restricting internal access to confidential information on a strict need-to-know basis and maintaining a record of individuals who have been granted access.
- Physical and electronic security, such as firewalls, secure e-mails, encryption and password-protecting documents.
- Training employees with access to particularly sensitive information, to ensure valuable trade secrets are not inadvertently made public through presentations, trade shows or customer meetings.

- Ensuring that contractual agreements with third parties include appropriate restrictions on use/disclosure and oblige the recipient to return or destroy confidential materials.
- Keeping written development records for key projects to demonstrate the origin of valuable information and trade secrets.

R:

RESEARCH AND DEVELOPMENT

Research and development (R&D) refers to a specific project aimed at developing new products or processes that make an advance in science or technology.

Commonly, carrying out a full R&D project is beyond the capabilities of a single entity, either because it does not have the capital investment required or because it lacks sufficient technical expertise. Consequently, R&D projects often involve a collaboration between two or more enterprises that together enter into an R&D agreement.

Successful R&D projects can generate substantial rewards for both commercial and academic organisations, not least because the UK government has made available various tax reliefs and capital allowances for R&D projects with the intention of encouraging innovation. However, there are considerable risks involved in R&D projects, which should be mitigated in a carefully drafted R&D agreement.

Some of the key issues that collaborators should consider when entering into an R&D agreement are discussed below.

Objectives

Although R&D collaborations are most common amongst organisations within a particular sector, links between industry and higher education institutions have grown in recent years. Where R&D agreements are entered into between universities and industry, the parties are especially likely to have differing objectives throughout the process.

It is important to consider each party's objectives before entering into an R&D agreement. In this context, a university is typically primarily concerned with securing financial support for high quality research, the results of which can subsequently be published to raise its profile and attract increased public funding and prospective students/staff.

On the other hand, industrial collaborators' primary focus usually relates to accelerating innovation through access to external expertise, particularly in fields outside the experience of its own research staff, and generating valuable intellectual property (IP) rights capable of commercial exploitation.

Ownership and exploitation of IP rights

Where both parties are industrial collaborators, ownership of resulting IP rights will be determined by the participants' respective businesses and bargaining power, as well as the nature of the project.

Likewise, there are no set rules on the ownership and exploitation of IP rights arising from R&D collaborations between industry and academic institutions. To address this, the Lambert Review of Business-University Collaboration (2003) proposed an IP protocol for negotiations between such parties, the main features of which were as follows:

- As a starting point, universities should own any resulting IP, with industry free to negotiate licence terms to exploit it. However, an industrial partner could own the IP if it makes a significant contribution.
- Regardless of who owns the IP, the following conditions should be met:
    - The university is not restricted in its future research capability
    - All applications are developed by the company in a timely manner

- The substantive results of the research are published within an agreed period

In 2016 the UK Intellectual Property Office published an enhanced version of its Lambert Toolkit, a set of model agreements and decision-making tools designed for collaborative projects involving industry and research institutions, to help overcome barriers to the commercialisation of intellectual property generated by universities.

In reality, provided that each party obtains the necessary rights it needs under licence, ownership of rights may not be a crucial issue. However, it is crucial at the outset of any R&D project to ensure that all IP rights will belong to the commissioner of any third party works.

Confidentiality

The R&D agreement should also deal carefully with confidentiality obligations relating to technical information generated both before and in the course of the R&D project. This can be a particularly challenging issue during negotiations between universities and industry as conflicts often arise between the need for commercial confidentiality and the university or individual scientist's objective of publication.

Parties should ensure that no confidential information is disclosed without an appropriate confidentiality agreement having been signed. Where work commences before a formal R&D agreement is signed, an interim confidentiality agreement should be in place to bind the parties until the main agreement is signed.

Critically, the commercial collaborator should consider incorporating a publication reporting provision in the R&D agreement. This allows the business to file patent applications in respect of an invention prior to its publication by the university, and prevent premature public disclosure in order for the invention to remain patentable.

Incentives

Though R&D projects can be complex and therefore expensive, R&D tax reliefs play a key role in incentivising investment by reducing the costs of innovation. There are two key tax reliefs available for such expenditure in the UK:

- Corporation tax relief for expenditure on R&D, of which there are two categories:
  - Relief for small and medium-sized enterprises
  - Expenditure credit, primarily for large companies
- R&D capital allowances for capital expenditure

Along with the tax reliefs above, companies can elect into the Patent Box to apply a lower rate of corporation tax, which is 10%, to profits earned from its patented inventions.

REGULATORS

As a heavily regulated sector, healthcare products, services and professionals are all subject to extensive legislative requirements, which are monitored and enforced by various regulatory authorities. We set out below an overview of the main regulators and regulations in the life sciences sector.

The **UK Medicines and Healthcare products Regulatory Agency (MHRA)** is the executive arm of the Department of Health and Social Care (DHSC) responsible for protecting and improving public health and supporting innovation through scientific research and development. The MHRA monitors and sets the applicable standards of safety, quality and efficacy of medicines,

medical devices and blood components, as well as pursuing international harmonisation across the UK, EU and wider regulatory frameworks to ensure that these provide effective safeguards for public health whilst remaining risk proportionate. The MHRA also authorises and oversees the supply of these devices to the market, carries out post-market surveillance, and enforces sanctions on organisations responsible for supplying any non-compliant or unsafe medical devices.

The UK's overarching framework regulating medicines and medical devices includes the amended Medical Devices Regulations 2002, the Medicines for Human Use (Clinical Trials) Regulations 2004, the Human Medicines Regulations 2012, the Veterinary Medicines Regulations 2013, and Medicines and Medical Devices Act 2021. The latter seeks to address the regulatory gap left by the repeal of the European Communities Act 1972 and provides the UK with the primary legislation it needs to be able to update its medicine and medical device laws.

The **Care Quality Commission (CQC)** is the independent regulator for the quality and safety of care in England (with Scotland and Wales regulating the same under their own independent Care Inspectorates), responsible for regulating providers of healthcare services, social care services and services for those whose rights are restricted under the Mental Health Act 1983. These powers extend to oversight of the NHS, local authorities, independent providers and certain voluntary organisations. The CQC registers and carries out inspections of care services and issues public information in relation to them. Under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 the CQC also holds a range of enforcement powers, including penalties and prosecution, where it finds that fundamental care standards have been breached.

Various authorities regulate UK health and care professionals, including:

- **The General Medical Council (GMC)**, mandated under the Medical Act 1983 to oversee the medical education, registration and revalidation of doctors, provide them with guidance on professional conduct, performance and ethics issues, and protect patients across the UK.
- **The General Pharmaceutical Council (GPhC)**, the independent regulatory authority for pharmacists, pharmacy technicians and pharmacy premises in the UK governed by the Medicines Act 1968, Poisons Act 1972, the Health and Social Care Acts, the Pharmacy Order 2010 and the Human Medicines Regulations 2012.
- **The General Dental Council (GDC)**, mandated under the Dentists Act 1984 to regulate dental professionals in the UK, including clinical dental technicians and dental hygienists.
- **The General Optical Council (GOC)**, mandated to regulate optometrists, dispensing opticians, student opticians and optical businesses in the UK under the Medicines Act 1968, Opticians Act 1989 as amended in 2005 and the Human Medicines Regulations 2012.
- **The Nursing and Midwifery Council (NMC)**, which regulates nurses, midwives and nursing associates under the Health and Social Care Acts and the Nursing and Midwifery Order 2001.
- Councils are also in place for the independent regulation of chiropractors, osteopaths and a range of other health and care professionals including podiatrists, paramedics, speech and language therapists and social workers.
- The obligations of these regulatory authorities are in turn regulated by the **Professional Standards Authority (PSA)**, established by the Health and Social Care Act 2012. The PSA seeks to protect the health and well-being of medical patients and the public by setting professional standards for the training and conduct of health and care professionals and monitoring the work of the independent regulatory bodies.

The regulators and regulations set out above are supplemented by the activities and standards of a variety of trade associations and voluntary codes. These are intended to provide guidance to and oversight of entities that are active in the life sciences sector. Self-regulatory regimes intend to maintain best practice without the need to resort to formal action by regulators under legislation. One important example is the **Association of the British Pharmaceutical Industry (ABPI)** which publishes the ABPI Code. This is enforced by the **Prescription Medicines Code of Practice Authority (PMCPA)**.

Given the range of regulators, regulations and other bodies covering the life sciences sector, businesses need to tread carefully in relation to the products and services that they provide.

S:

SECOND MEDICAL USE

Second medical use, or “repurposing”, refers to the use of a known drug for a new therapeutic purpose.

A major advantage compared to developing a new drug from scratch is that the existing drug has already shown itself to be safe in the context of the original use, so developing and obtaining marketing authorisation for new treatments can be relatively speedy and cost-effective.

The benefits of repurposing were recently shown in relation to COVID-19 where studies identified a number of existing drugs with beneficial effects, including Dexamethasone, a cheap steroid, that has saved at least a million lives and rheumatoid arthritis drug Tocilizumab, which reduces the risk of death in hospital patients[i].

Patents for second medical uses

In European Patent Convention countries (including the UK), patents are available for second medical uses provided that the idea of using the drug for the new therapeutic purpose is both novel and inventive. Such products may also attract an additional year of data exclusivity. Second medical use patents may be infringed by the intentional supply or manufacture of the drug for the new purpose. However, they can be difficult to enforce in practice, especially if the original drug is freely available as a cheaper generic option and can be used off-label for the new purpose. In this situation the ability to obtain sufficient return on the investment may depend on whether the repurposed drug involves a different formulation or dose requiring differences in manufacture and packaging.

A missed opportunity

If no patent is available (or it cannot be enforced), there may not be sufficient incentive for research-based life sciences companies to develop repurposed drugs. This represents a significant missed opportunity for health systems, especially as modern computational and other methods have much improved the ability to identify candidates for repurposing. There is currently also little incentive for generic companies to progress repurposing, although some have expressed an interest and would be in a good position to do so. The NHS England Medicines Repurposing Programme is considering suitable direct incentives for generics to take repurposing forwards, so this is a space to watch.[ii]

[i] The Guardian, 20.04.21

[ii] Opportunities to Repurpose Medicines in the NHS in England, Recommendations of the Medicines Repurposing Programme Board 2019/20 and Proposed Forward Work Programme 2020/21 – 2022/23

SUPPLY AGREEMENTS

Supply agreements can come in various guises and, in the case of pharmaceuticals, may take the form of manufacturing services agreements, pure "supply of products" agreements, or a hybrid of the two.

At the outset of drafting the terms of a supply contract, it is of course important to be clear about whether the supplier will be providing a finished product to the customer, or whether the commercial agreement will be more akin to a manufacturing services arrangement. Beyond this, important considerations for both parties may include:

- **Raw materials** – Who will supply the raw materials such as the active ingredient or the packaging? Will the customer require that these are purchased from its nominated third-party supplier, and who will bear the risk of the third-party failing?
- **Filling** – Is the customer's requirement for a bulk supply, a supply to fill containers or finished product supply? In the case of bulk supply or filled containers supply, have the parties considered a tolerance for shortfall?
- **Packaging** – If the arrangement is not for the supply of a finished product, will packaging, wrappers and leaflet insertion be required by the customer? If so, which party will source these?
- **Pricing** – Is a fixed price contract, cost-plus contract or another fee arrangement most suitable in the circumstances?
- **Type of outsourcing** – Is the arrangement a complete outsourcing by the customer of production, packaging and delivery (known as contract manufacturing) or will the supplier be responsible only for the processing of raw materials or semi-finished products into finished products (known as toll manufacturing)?
- **Warehousing and logistics** – Which party is responsible for these and where does the risk pass?

Ordering process and capacity issues

The recent dispute between the European Commission and AstraZeneca relating to the COVID-19 vaccine highlighted the issues suppliers face where demand for product demand exceeds supply. For more information, read our article about the case here.

To minimise the risk of these problems arising, there are a number of important points for life sciences businesses to consider before entering into supply contracts, such as how customers will be prioritised in the event of the supplier's shortage, ensuring the contract addresses availability and lead times, at what point (if at all) a customer's orders become a binding obligation on the supplier, as well as the consequences for breach.

Exclusivity

In the context of a supply agreement, a customer may wish to secure the exclusive right to the supply of a product, usually within a certain territory. Where this is the case, a supplier may seek to impose minimum purchase commitments on the customer to ensure the arrangement is commercially viable.

Minimum purchase commitments

Whilst more likely to be found in exclusive agreements, any supply agreement can stipulate minimum purchase commitments. Considerations for both parties before agreeing to such commitments include:

- Is it binding or non-binding, and what is the penalty for failure to meet the purchase commitment?
- Does the minimum purchase amount refer to a certain number of units or a monetary value? If the latter, should the amount increase over a period of time and, if so, should this be calculated according to actual price increase or by a mechanism such as the RPI?
- Is there an option for the customer to retain exclusivity by "buying out" all available product in the event that the supplier does not produce sufficient product for the minimum purchase commitment to be met by the customer?

- Conversely, can excess volumes purchased by the customer be "carried over" to the next period?

Best endeavours?

In addition to the issue of when orders becoming binding, the supply agreement should address whether the supplier has an obligation to accept a customer's orders. If so, this could take the form of a strict obligation or an "endeavours" based approach. The latter may be particularly relevant where an agreement contemplates the supply of product in numbers beyond those forecast at the outset.

When drafting the agreement, it is important to be aware that interpretation of terms such as "best endeavours", "reasonable endeavours", "all reasonable endeavours" or "commercially reasonable endeavours" can differ under English law and change the weight of the obligation.

Sale and purchase terms

The commercial terms applicable to the sale and purchase of products under the supply agreement will also need to be addressed either in the supply agreement itself or by incorporating appropriate sale and purchase terms. These can address items such as liability, warranties, timing, intellectual property ownership, risk, and retention of title, prices, Incoterms, clearances and other allocation of responsibilities.

SPECIFIC PERFORMANCE

The dispute between the European Commission and AstraZeneca regarding supply of the COVID-19 vaccine prompted a look a specific performance as a remedy. AstraZeneca faced production delays, resulting in a demand by the European Commission that AstraZeneca must use UK manufactured products to supply the EU. AstraZeneca argued that it was prohibited from doing so due to the terms of its contract with the UK.

In April 2021, the European Commission commenced legal action against AstraZeneca in Belgium. While we have not seen the legal papers, we understand from press reports that the Commission sought an injunction requiring AstraZeneca to deliver 120m vaccine doses by the end of June 2021.

Such mandatory injunctions are relatively unusual. In what circumstances can a contractual party seek a court order for the ongoing supply of a product rather than, or as well as, damages or compensation for breach of contract?

Specific performance is a recognised remedy under English law. An order for specific performance will oblige a party to perform its positive contractual obligations. It is a discretionary and exceptional remedy and can be awarded where damages alone would not be adequate.

Often in commercial cases for the supply of goods, an order for specific performance would not be appropriate as the same or a similar product might readily be obtained elsewhere. In such a case, damages for breach of contract would be an adequate remedy. However, where a product is unique and not easily obtained from another source, specific performance can be ordered.

While unusual, specific performance can also be ordered in cases concerning the provision of services. For instance, it may be possible to seek an order for specific performance in the context of collaboration, marketing and distribution agreements. One such case, where our

firm successfully obtained an order for specific performance, involved an agreement for the sale, co-promotion and distribution of a pharmaceutical product. The defendant owned the rights to the product. The claimant promoted the product and formed part of the supply chain and was paid commission.

There was not an intense or close day-to-day relationship required for the provision of the services. The relationship proceeded positively until the defendant purported out of the blue to terminate the contract. We were able to show that the alleged grounds for termination were not merited and a court order that the defendant should permit the claimant to continue promotion and distribution of the product in accordance with the contract was granted.

The case concerned commercial arrangements made between independent companies involving the employment of no named individuals and where the services being provided were not personal in nature. Damages were considered not to be adequate because of the relatively unique nature of the product and where that sat within the claimant's suite of products. Effectively the court order preserved the status quo.

However, specific performance cannot be ordered in certain circumstances. An example might be where a dispute arises under a contract that is highly personal in nature, such as an employment contract, or circumstances that would require constant supervision or monitoring to enforce the order made.

T:

TELEMEDICINE

Whilst efficiency, convenience and access to healthcare may be improved by telemedicine, regulation in this area can be a minefield.

COVID-19 has altered our lives in many ways, one of which being the significant increase in accessibility and use of telemedicine and, more generally, telehealth services. Telemedicine is the practice of medicine using technology to deliver care at a distance, whereas telehealth is the umbrella term encapsulating all healthcare services provided remotely using technology. For example, telehealth also includes online education or video conferencing between healthcare professionals.

During the pandemic, the NHS has increased its use of remote medical consultations to minimise contact and consequently the risk of infection. It is unsurprising that during one of England's national lockdowns, seeing a general practitioner (GP) remotely became the default position and the number of GP appointments taking place virtually rose from around 25% to 71%. According to the Digital Healthcare Council (which represents British telemedicine firms), this shift has meant that digital providers are rushing to meet demand.

Even though there has been a global increase in the use of telemedicine, there is a lack of coherent legislative frameworks in this field. This can create additional difficulties for businesses when navigating the already complex domain of telehealth.

UK regulation

Despite the healthcare industry being heavily regulated within the UK, there are currently no specific laws addressing telehealth. Some regulatory bodies such as the General Medical Council (GMC), which oversees medical education, registration and revalidation of doctors within the UK, and the General Pharmaceutical Council, the regulator for pharmacists and pharmacy technicians, have issued guidance on the provision of remote consultations and online pharmaceutical services respectively.

All healthcare providers based in England are regulated by the Care Quality Commission (CQC). Helpfully, the CQC has produced guidelines on compliance for telehealth providers in England. However, the situation becomes unclear if medical practitioners in a different country provide telemedicine services within England.

Location of services

One of the biggest questions in telemedicine is whether the location of services for regulatory purposes should be determined by where the practitioner or the patient is based. For example, if a patient is receiving healthcare advice in the UK from a medical practitioner in Germany, is the service being provided in the UK or Germany?

Unfortunately, there is no clear-cut answer to this in the UK. Some countries take the approach that the patient's location determines where the services are provided. For example, the United States generally requires providers to be licensed in the state in which the patient is receiving the services. In the example above, this approach would mean that the German medical practitioner would need to be registered in the UK and obtain a UK licence in order to practice telemedicine, despite being based in a different country. While this could be a sound approach from a regulatory perspective, it may be unnecessary, inefficient and difficult to achieve in practice. A report by Europe Economics commissioned by the GMC noted that where a doctor outside the UK provides remote medical services to a patient within the UK, the GMC cannot require registration of that medical professional.

Data protection

Telemedicine businesses must also consider data protection legislation, regulation and protection. This will vary depending on where the service provider and the patient are each located, and how/where the business processes personal data.

Under the UK General Data Protection Regulation (GDPR), it is likely that patient data will be considered special category data and high-risk. If this is the case, the steps required for compliance with the GDPR are more stringent than in other circumstances, including a requirement on the business to conduct a Data Protection Impact Assessment.

Given the lack of congruent laws across different countries and broadly inadequate legislative frameworks, coupled with the risk areas of patient safety and data protection, telemedicine businesses must venture cautiously.

TRADE MARKS

Trade marks are extremely important in the life sciences sector.

A strong brand name can endure, and sustain a market leading position, long after a patent has expired. However, due to the nature of the sector, trade mark protection is highly regulated with brand names having to satisfy the requirements of both trade mark offices and health authorities.

Choosing a name

When branding a new product pharmaceutical companies face a long, challenging and expensive process. This usually begins three to four years before a product launch with names creation. The active ingredient of a pharmaceutical product will have an international non-proprietary name (INN) which is considered public property and which no one can monopolise. A trade mark in the sector must not be too close to or derived from an INN.

A pharmaceutical trade mark must also not make an overt claim as to the effect of the product, nor be misleading as to its effects or composition. The made-up word can have positive connotations as to the product (for example the Pfizer–BioNTech COVID-19 vaccine is named "Comirnaty" which intentionally references the ideas of "COVID-19", "mRNA", "community" and "immunity") but the absolute grounds for refusal of trade marks should always be borne in mind. A trade mark will be refused registration if:

- It is deceptive
- It is devoid of distinctive character
- It consists exclusively of an indication or sign which may designate the kind, quality, quantity, intended purpose, value, geographical origin or the time of production of the goods or of rendering of the service, or other characteristics of the goods or service.

Clearance

Once potential names have been identified, the next stage is to carry out searches of trade mark registers around the world to assess whether there are pre-existing trade mark rights that may be confusingly similar to those names. Often, 50 to 70 potential names are taken through to the clearance stage. The key Nice Classification classes for clearance of pharmaceutical trade marks are Class 5 (medicines) and Class 10 (medical apparatus and instruments). There are some goods outside these classes which trade mark offices may consider "similar" to pharmaceutical products, such as cosmetic products which fall within Class 3.

When considering whether the similarity between an existing trade mark and a potential trade mark may cause a likelihood of confusion in the minds of the consumer, trade mark

offices will take into account the relatively high level of attention consumers pay to Class 5 and Class 10 goods. This would generally lessen the likelihood of confusion. However, pharmaceutical companies will take a cautious stance since the overriding concern is always patient safety. Even if a mark may make it through trade mark office examination, health authorities will take a much more conservative approach to whether there is an unacceptable likelihood of confusion with another medicine based upon a similarity in names.

To manage the costs of the clearance exercise, pharmaceutical companies often take a cascade approach to clearance searching, starting in key jurisdictions then taking viable names further through the process. A significant challenge in this is making a similarity assessment when taking a multi-jurisdiction approach which encompasses various languages. The process will usually result in a consolidated clearance report which rates names by level of risk.

Marketing and safety research

Generally, around 15 names will still be on the table when marketing and safety research is carried out. This involves prescription simulation studies which seek to assess the risk of dangerous confusion between medical brand names when health professionals prescribe products. Such studies will look at written, verbal and computerised simulations of how the name may be used; and will take into account the practices of health professionals in different countries.

Names will also be cross-checked against common medical terms and abbreviations, and screened for any inappropriate, exaggerative or promotional claims in various languages, taking into account pronunciation and slang terms.

Medical and health agencies

The final hurdle in the process of branding a pharmaceutical product is obtaining regulatory approval of health agencies, such as the Medicines and Healthcare products Regulatory Agency, the European Medicines Agency or the US Food and Drug Administration, whose remit is to address any public health or safety risks and to protect the INN stems. Health agencies will review potential names to ensure that they are not confusing with the common or scientific names for any medicines and that they are in general acceptable as a name for a medicine. They tend to be conservative in approach, particularly the European Medicines Agency which must take into account differences in national practices and languages across all member states of the EU.

Non-traditional trade marks

In additional to a strong brand name, many pharmaceutical companies use non-traditional trade marks as part of brand protection strategies. Depending on the jurisdiction, non-traditional marks can include colour, shape, sound, trade dress, scent and moving images, with colour and shape marks most commonly utilised for medicinal products. For example, Pfizer owns registered trade marks for the 3D diamond shape and the blue colour of Viagra pills. However, seeking registration of such marks is not as straightforward as for word or figurative marks. For instance, Glaxo has tried and failed to register a particular shade of purple in respect of its inhalers and asthma treatments, with the EU courts finding that such a mark lacked distinctive character and had not, despite survey evidence submitted by Glaxo, acquired distinctiveness through use. Glaxo has also failed in the English High Court to prevent competitor Sandoz from using the colour purple on its rival inhalers.

In summary, therefore, the path to market for pharmaceutical product names is a complex one and, more so than in any other industry, requires careful planning and consideration.

TRANSPARENCY

The relationship between the pharmaceutical industry, healthcare professionals and healthcare organisations plays a vital role in the development of medicines. However, there is also increased industry as well as general public demand for clearer and objective reporting on the research, clinical trial/testing, distribution and advertising practices involved in bringing pharmaceutical products to the market and administering treatments.

Two developments reflecting this shift towards increased openness and transparency around industry practices were the publication of:

- The Code of Practice published by the Association of the British Pharmaceutical Industry (ABPI), on which we provided a general overview here, and
- The yearly report by the Medicines and Healthcare products Regulatory Agency (MHRA) on the regulation of medicines advertising to promote transparency.

ABPI code 2021

The ABPI code, which took effect on 1 July 2021, enshrines transparency as a core fundamental principle applicable to all industry stakeholders. The Prescription Medicines Code of Practice Authority (PMCPA) is the self-regulatory body established by the ABPI to administer the code, and is tasked with enforcing these transparency obligations and investigating any related complaints made against pharmaceutical companies. The PMCPA may conduct compliance audits on pharmaceutical companies, publish public reprimands or advertisements in the medical, nursing and pharmaceutical press, and report to the ABPI Board requesting a company's suspension or expulsion from ABPI membership.

One example of the APBI's increased focus on promoting industry transparency is the "Disclosure UK" database, which is part of a Europe-wide initiative to increase transparency between pharmaceutical companies and health professionals as well as organisations it works with. Disclosure UK is also the means by which UK pharmaceutical companies are meeting their obligations under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code and provides the public with a searchable database recording any remuneration and benefits in kind made by pharmaceutical companies to healthcare professionals and healthcare organisations. Disclosing the terms of these relationships openly and transparently seeks to instil greater confidence in patients regarding the supply and administration of their treatments and emphasise that sharing knowledge to improve patient outcomes is the industry's key priority.

MHRA initiatives

The MHRA's annual report highlights its focus going forward on ensuring that companies comply with industry guidelines on advertising medicines, as well providing tailored regulatory advice to self-regulatory bodies and individual advertisers.

In addition to its Blue Guide, the MHRA publishes substantial public and industry-tailored guidance to promote greater transparency across different areas within the pharmaceutical sector, including:

- Reporting and registration requirements in connection with clinical trials
- Conformity and registration requirements governing the supply of medical devices
- Import/export obligations on pharmaceutical companies and healthcare product providers

- The wider legislative requirements that apply to medical and pharmaceutical products

Similarly to the PMCPA, the MHRA enforcement group also investigates complaints made against companies relating to medical products and devices, seeking to facilitate dialogue between members of the public and industry actors and act as a central registration and reporting facility.

Businesses and individuals engaging with this sector should familiarise themselves with the guidance and resources available to stay informed and benefit from the drive towards greater transparency.

U:

UNIFIED PATENT COURT

As a tool for protecting innovation, patents are an important asset for research-based life sciences companies - high-stakes and high-cost litigation in multiple jurisdictions is common where "blockbuster" drugs are concerned.

What is the Unified Patent Court?

The Unified Patent Court (UPC) system aims to streamline patent litigation in Europe and avoid forum shopping between different national courts, radically bringing down the cost and reducing the uncertainty of patent litigation in the EU. It involves fundamental changes to the European patent litigation system for participating states. The court goes hand-in-hand with a new Unitary Patent (UP), a single patent which provides protection for a patentee across all participating EU states, much as the existing EU trade mark (EUTM) does for trade marks.

Which countries are taking part?

At the time of writing, 24 of the 27 EU Member States have signed the UPC agreement which establishes the new court. So far 17 have also ratified, but all the signatories are expected to ratify in due course. Of the countries which have not yet signed up, Spain has indicated that it does not intend to sign whereas Poland and Croatia are expected to sign eventually.

How does the UPC affect UK patent owners?

The UK is not participating in the UPC. This means that European patents[i] designating the UK are not subject to the jurisdiction of the new court. Nor is the UK participating in the UP. However, businesses rarely own patents in one country alone. All businesses (including UK businesses) owning patents or supplementary protection certificates (SPCs) in participating EU Member States will have automatically become subject to the jurisdiction of the new court unless opted out of before the court went live on 1 June 2023. This is also relevant to licensees and parties to research, collaboration and joint venture agreements.

What are the advantages and disadvantages of the new system?

Advantages of participating in the new system include that patentees should be able to save the costs of litigating in multiple European jurisdictions and to obtain pan-European injunctions and other pan-European remedies. So, staying in the system will potentially put patentees in a very powerful position. However, there is also a major risk - just one action in the UPC could result in the revocation of the European patent in all participating countries. This, coupled with the fact that this is a new, untested system involving many procedural differences, including in relation to the presentation of evidence, and that there is a fear that some judges will be inexperienced, means that many patentees are wary of being among the first to use the system.

Opt-out can be withdrawn

An opt-out lasts for the life of the relevant patent. However, it does not have to be forever. It can be withdrawn at any time up to the end of a transitional period (see below).

When is the deadline for opting out?

During an initial seven-year transitional period (which may be extended by another seven years) the UPC system will run in parallel with the "old" system of national patent courts, allowing patentees and others to choose which system to take action in. However, the rules provide that once a patent has been litigated in the UPC it may be locked into the UPC, and vice versa. Many patentees are expected to opt some of their patents out of the UPC as soon

as possible to avoid the danger of being locked in in this way. This would allow them to see how the system beds in and then withdraw the opt out later.

V:

VACCINE LIFE CYCLE

The COVID-19 pandemic has put the spotlight on vaccine development in recent times, with the public showing a great amount of interest in the development and roll-out of COVID-19 vaccines. Vaccines have for a long time been pivotal in curbing the spread of infectious and often highly dangerous diseases, saving millions of lives each year. Behind the scenes, the stages involved in taking a vaccine to market are wide-ranging and complex, often spreading beyond the remit of one single company and involving numerous contractual arrangements between a number of different parties.

As is the case with other drug development, numerous stakeholders will contribute certain intellectual property (IP) that will feed into the development of a vaccine, ranging from patents, which typically protect the key components or active ingredients of the vaccine itself as well as know-how and confidential information, both of which are key for the production process. Parties seeking protection of these vital IP rights is a common theme throughout the contractual arrangements involved in the vaccine life cycle. The key stages of vaccine development and the relevant contractual arrangements are discussed below.

Research & development (R&D)

This is the initial stage of vaccine development and refers to a specific project targeted at developing a new vaccine. R&D commonly involves collaboration between two or more industry or higher education institutions that enter into research or collaboration agreements. Collaboration agreements will commonly cover the ownership and exploitation of any IP rights arising from the R&D, as well as confidentiality provisions in relation to technical information generated prior to and during the project.

Licensing

To aid vaccine development, parties will often enter into licensing arrangements, under which an inventor or proprietor (the licensor) grants a customer (the licensee) either exclusive, sole or non-exclusive rights to use its patents or know-how. These arrangements allow a party to commercially exploit its IP rights and tend to be complex arrangements containing multi-tiered payment structures and provisions governing the use of the licensed IP by both the licensee and third parties.

Manufacturing

The manufacturing stage of vaccine development is extensive. At the outset of the manufacturing pilot, batches of the product are made at a scale large enough for the relevant stability and quality testing to be carried before larger-scale manufacturing takes place. As many companies do not have the ability or resources to manufacture vaccines at the scale required for commercial use in-house, third-party manufacturers are widely used.

Development and manufacturing agreements are used to govern the terms of these third-party arrangements. Such agreements set out in detail the vaccine manufacturing specifications and pricing, clarify which party shall be responsible for sourcing the raw materials required for manufacturing, and specify storage and delivery terms. Once wider-scale manufacturing has commenced following the clinical trial stage, some companies will

also enter into arrangements with third parties for the storage and distribution of the product, the terms of which are usually governed by a separate distribution and warehousing agreement. At a time where supply chains around the world are under a great deal of pressure, the negotiation of these types of agreements is becoming an increasingly important aspect of the vaccine life cycle.

Clinical trials

The clinical trials stage is key to getting a vaccine to market safely and, as a result, is heavily regulated. Before commencing work on any clinical trial, the relevant parties should enter into a clinical trial agreement. As is the case throughout the vaccine life cycle, the protection of IP rights is of vital importance to pharmaceutical companies to safeguard the significant investment in their vaccine.

The vaccine developer will want to ensure it retains ownership of its pre-existing background IP as well as any foreground IP created during the clinical trial. Meanwhile, the institution running the clinical trial will often seek ownership rights in any foreground IP created and the right to use any know-how developed in future trials, meaning negotiations can be lengthy in order to strike a commercially balanced position that protects the interests of both parties.

Regulatory approval

The final stage before marketing a vaccine for use in the public is the regulatory approval stage. Following Brexit, the relevant body for granting approval in the United Kingdom is the Medicines and Healthcare products Regulatory Agency (MHRA). Often with the support of regulatory lawyers, a vaccine developer will submit an application to the MHRA which will then assess the safety, quality and effectiveness of the vaccine using the results from the clinical trials before, where deemed appropriate, granting approval.

VALID CLAIM

We consider the role of “valid claim” wording in patent licensing arrangements.

Patents are risky assets

Patents play a crucial role in protecting innovation in the life sciences sector and are often essential to attracting investment and funding for new medicines and treatments. However, despite rigorous examination and opposition procedures at patent office level, a large number of invalid patents make it onto patent registers in Europe and worldwide. Estimates differ widely, but some suggest that up to 60% of granted patents are invalid. So, the risk of invalidity cannot be disregarded by parties entering into patent licensing and other patent-heavy commercial arrangements.

How do commercial parties deal with the risk of invalidity?

Even where a patent is believed to be weak, in practice it may be better for third parties wishing to use the invention to take a licence rather than go the expensive route of challenging the patent. However, whether the patent is weak or strong, the licensee will wish to avoid a situation where it is paying royalties for technology that its competitors can use for free, as this will put it at a competitive disadvantage.

A common solution is to provide that royalties under the licence are only payable on licensed products that would infringe a “valid claim”. “Valid claim” is defined as one for which invalidity has not been formally and finally established. It should be noted that in an international licence, the claim wording in equivalent patents may differ slightly between countries and the law on validity may also be different, for example the rules on equivalence differ between European countries even though the European Patent Convention applies

throughout. In such licences, it is possible that the licensee will be paying royalties in some countries but not in others.

A mechanism to avoid dispute

This approach to "valid claims" promotes certainty between the parties and avoids the parties arguing about validity in a contractual dispute under the licensing agreement. If the licensee is confident that the patent is invalid but there has been no final invalidity decision, the solution is to institute revocation proceedings to invalidate the patent as a separate matter.

Can the licensor prevent the licensee challenging the patent?

Depending on the nature of the project the licensee may be in the best position to challenge the patent because it is working with the technology and knows it well. The licensor will wish to prevent the licensee from using the knowledge obtained under the licence in this way. From the perspective of competition law, such "no-challenge" provisions are a controversial issue. The application of competition law will always depend on the circumstances, but under both UK and European competition law, no-challenge clauses will generally be unenforceable in both non-exclusive and exclusive patent licences. In an exclusive licence it may, however, be acceptable to include a provision whereby the licensor is entitled to terminate the licence if the licensee challenges the patent. This puts the licensee under pressure as failure to invalidate the patent will result in infringement.

W:

WAREHOUSING

With an ever-increasing need for efficiency, alternative routes to market and access to new geographies, the life sciences industry is undergoing an accelerated supply chain transformation. Market participants would be remiss not to keep in mind the warehousing and logistics processes fundamental to such transformation.

What is warehousing?

Warehousing constitutes a critical step in a business' supply chain and refers to the process of storing physical goods in a warehouse (dedicated or shared) or other storage facility before they are sold or further distributed.

Whilst warehousing services can strictly refer to the provision of storage space, many industry providers are likely to provide a more expansive storage and distribution service. As such, governing contracts may cover:

- Storage of goods
- Picking and packing
- Order fulfilment processes
- Transport logistics

Reducing the risks

Warehousing plays a pivotal role in the overall supply chain of pharmaceuticals and can greatly affect the final product to its advantage or detriment. When handling pharmaceuticals, the nature and lifespan of the products warrants the following considerations:

- Temperature control throughout the storage, packaging, transportation and delivery stages
- Speed of service
- Transport handling, including mitigation of theft, spoilage and contamination risks
- Customs clearance, especially in territories with complex regulatory requirements

Pharmaceutical companies rely heavily on the smooth execution of these processes and face a multitude of risks when entrusting their products to third party service providers. To mitigate such risks, the process is often closely monitored.

For example, the Medicines and Healthcare Products Regulatory Agency (MHRA) regulates the standards and licensing for the manufacture, assembly and wholesale distribution of medicinal products under UK legislation.

Businesses wishing to participate in the manufacture, transport and/or storage of medicinal products for human or veterinary use may be required to procure process licences from the MHRA that capture both customers and suppliers of warehousing services.

Upon application for a licence, the MHRA will conduct inspections both at the outset and at regular intervals to ensure any manufacturing or distribution sites comply with the good practice standards.

Distribution sites must ensure compliance with good distribution practice (GDP), ensuring as a minimum "that medicines are obtained from the licensed supply chain and are consistently stored, transported and handled under suitable conditions, as required by the marketing authorisation or product specification".

Standard contract terms

Given the high-risk levels inherent within global pharmaceutical logistics, hauliers, carriers and other logistics service providers generally seek to limit their potential liability where something goes wrong during the warehousing and distribution processes.

For context, parties engaged in the provision and utilisation of logistics services typically enter into contractual arrangements based on terms and conditions recommended by reputable industry bodies, including:

- The UK Warehousing Association (UKWA), whose Conditions of Contract may be used by members to inform warehouse arrangements between the service provider and customer.
- The Road Haulage Association (RHA), whose Conditions of Carriage 2020 may be used by members to inform contractual arrangements between carriers and customers.

While such industry standard conditions generally adopt a pro-supplier stance in relation to liability where products are lost or damaged during the provision of the services, the following terms are typically excluded:

- The supplier's liability for indirect or consequential losses
- Any loss of profit or revenue
- Liability for any lost or damaged products (or this is typically limited by a cap of £X per tonne of product replacement value)

Pharmaceutical businesses seeking to incorporate these standard terms should remain cognisant of how they may apply within their specific circumstances and negotiate edits to such terms as appropriate. For example, whether it is appropriate to agree to a liability cap calculated with reference to product weight for the goods in question, when those goods are likely to have a higher value-to-mass ratio than those in other industries.

Commercial parties to a warehousing and logistics arrangement are not governed solely by their contractual relationship. The Convention on the Contract for the International Carriage of Goods by Road (CMR), for example, establishes a framework for liability onto carriers which cannot be contracted out of for international carriage of goods for damage, loss or delay.

Parties should therefore carefully consider the negotiation and drafting of warehousing and/or logistics arrangements even where the margins may be low for the service provider.

WHISTLEBLOWING

The recent conviction of Elizabeth Holmes in relation to fraudulent activities at biotech company Theranos reminds us of the impact that whistleblowing has had in the life sciences sector. Dr Li Wenliang's attempts to raise the alarm in relation to COVID-19 in 2019 is another high-profile example.

But what are the legal issues arising from whistleblowing? Of course, these can be viewed from both the individual whistleblower's and the business' perspective.

Individuals

In the UK, whistleblowers making "qualifying disclosures" may well be protected from suffering a detriment or unfair dismissal under employment law under the Public Interest Disclosure Act 1998, the Employment Rights Act 1996, and any applicable specific protections for whistleblowing (e.g. protections for the Data Protection Officer under data privacy law).

Whistleblowing can give rise to allegations against the relevant individual of wrongdoing, including breach of confidence, breach of duties of confidentiality in contract, defamation or breach of public law duties of confidence (e.g. under the Official Secrets Act 1989). Threats to blow the whistle may also be viewed as extortion.

For the individual therefore, it is important to tread carefully in relation to whistleblowing, and to ensure that an appropriate procedure is followed, particularly if that individual is looking to rely upon protection under the law.

Businesses

For businesses, while it is not mandated in the UK, it is typically advisable to have some form of whistleblowing policy in place. This can assist in shedding light on problematic practices within the business and to manage these issues appropriately, ideally before they proliferate.

Having a whistleblowing policy can be an important part of a functional compliance programme, and may have direct benefits for the company (e.g. as a defence to allegations of failure to prevent bribery, or giving rise to a reduction in fines levied for competition law infringements).

X:

EX PARTE

There is a general principle that a court order in England and Wales should not be made against a party without it having an opportunity to respond. However, there are exceptions to this principle and it may be possible to make a "without notice" or "ex parte" application in a limited range of circumstances. Sometimes an ex parte application is made on notice to your opponent, but they do not attend the hearing.

One of the exceptions may arise for life sciences applicants who wish to challenge the decisions of public bodies through Judicial review. Judicial review can be a lengthy process and if the applicant is at risk of suffering significant damage while the application for Judicial Review is pending, applying for an urgent injunction at the outset can be an effective way of swiftly protecting the applicant's interim position.

The meaning of ex parte

Ex parte is Latin for " for one party". The term is often used to refer to legal proceedings that are conducted without notice to other parties affected by the proceedings. Generally, ex parte proceedings are only permitted when a party requires relief that is so exceptionally urgent that there is not enough time to inform the other party and provide it with an opportunity to respond.

When to make an ex parte application

In England and Wales it is possible to make an ex parte application where permitted by a provision of the Civil Procedure Rules, Practice Direction or court order (CPR 23.4(2)).

The court may grant an interim (or temporary) remedy on an application made without notice if the court considers that there are "good reasons" for not granting notice (CPR 25.3(1)). Typically, good reasons can be categorised as follows:

- Giving notice could defeat the purpose of the application (for example, freezing injunctions or search orders).
- The respondent is not on the court record at the time of the application (for example, applications to extend the time for serving a claim form (CPR 7.6(4)(b)), or for permission to issue an additional claim under CPR 20 (CPR 20.7(5)).
- The respondent cannot be identified by name (this may occur in intellectual property claims).

It is generally recognised that for the court to consider an application for an injunction on an ex parte basis, it must be clear that:

- Giving notice to your opponent is likely to cause injustice through delay or action that the respondent or others may take before the order can be made.
- Any damage suffered by the respondent as a result of complying with the injunction order may be compensated by the applicant's agreement to compensate for any such damage, or the risk of the respondent suffering "uncompensatable" loss is outweighed by the risk of injustice to the applicant if the order is not made.

Judicial review and ex parte applications

For life sciences businesses that wish to challenge the decisions of public bodies, such as NICE, judicial review can be a potential cause of action. Judicial review is the manner in which the courts supervise the executive by ensuring that government departments and other public bodies act lawfully and fairly in their decision-making processes.

Judicial review can take many months, by which time the applicant may have suffered significant financial, reputational or other loss. For that reason, it may be possible to seek an ex parte injunction, to protect the applicant's position immediately.

Depending upon the nature of the injunction sought, if successful, the court could order a public body to do something, or refrain from doing something, pending resolution of the application for judicial review. For example:

- An injunction may prevent or postpone the publication of NICE's decision or guidance that would be damaging to the applicant's financial or reputational position.
- An injunction may also be helpful in defending a pharmaceutical patent holder's market position when faced by a challenge from a potential generic entrant.

There are other factors to take into account when considering pursuing an injunction which are beyond the scope of this note.

EX WORKS

Transportation of goods within the life sciences sector provides unique challenges, such as critical time restraints or the requirement for specific temperatures to be observed. The terms applicable to the transportation in a manufacturing or distribution contract for medicines or medical devices are therefore crucial to get right.

Ex Works is one of 11 Incoterms rules, which are used in both domestic and international trade contracts. Incoterms rules are published by the International Chamber of Commerce (ICC) to assist traders from different countries in understanding their contractual obligations.

Ex Works can be used for a trade contract regardless of the mode (or modes) of transport selected to carry the goods. Incoterms 2020 Ex Works requires that:

- The seller must package the goods and make them available for collection at its premises or another designated location (this constitutes delivery)
- The buyer must collect from this location

Ex Works is therefore considered extremely favourable to the seller or contract manufacturer, as it is not required to load goods onto a vehicle or clear them for export. Furthermore, the buyer assumes responsibility for all costs and risks related to the goods from delivery (defined above) onwards.

However, where the goods being supplied Ex Works are medicinal products, the supplier should also take into consideration its obligations under Good Distribution Practice (GDP) and the Human Medicines Regulations 2012. Paragraph 9.1 of the GDP requires a wholesaler "to protect medicinal products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport". Supplying the products in accordance with Ex Works, and passing the responsibility of transportation

onto the buyer under the contract, does not relieve the seller of its obligations under GDP and it must still ensure that it has appropriate visibility and control over the process.

Furthermore, Incoterms rules do not provide a complete contract of sale, and as such are often referred to or incorporated within a fuller set of contract terms or manufacturing arrangements. For example, they may be silent in relation to the price of the goods, method of payment, transfer of title, and the consequences of a breach of contract, which will need to be addressed within the contract itself. Incoterms can deal with the following:

- Which party to the sale contract has the obligation to make carriage or insurance arrangements
- When the seller delivers the goods to the buyer
- Risk
- Which costs each party is responsible for

The appropriate Incoterms for each manufacturing contract will depend on the commercial deal and care needs to be taken to ensure that there is no conflict with other good practice requirements or contractual terms.

Y:

WHY HAVE A WRITTEN CONTRACT?

Contracts such as research agreements, material transfer agreements and commercial licence agreements underpin the innovative, complex and dynamic collaborations between parties in the life sciences sector.

Even though contracts such as these do not always need to be in writing to be binding, there are a number of reasons why it is generally advisable for parties to enter into a written contract before embarking on a project – in particular to ensure certainty of terms and minimise the risk of disputes.

Certainty of terms

Agreements in writing provide a far greater degree of certainty over the terms of the contract than verbal discussions. At a practical level, the parties will want to be clear about what is being supplied, how much is due to be paid and when, the consequences of the parties not doing as they say and how the parties can exit the agreement.

There are many other provisions that parties usually look to agree, and certainty of terms applies just as much to what is included in a contract as what is excluded. Written contracts can include "entire agreement" clauses which make clear that the contract is limited to its written terms (and sometimes other agreed documents), usually with a view to excluding any other terms, whether written or oral, from the contract. This might then prevent a party to the contract from relying upon anything not written down, or indeed certain oral representations made between the parties.

Minimising the dispute risk

Ultimately, a written contract becomes a record of the agreed bargain between the parties. The clearer this record is, the less likely the parties will end up in dispute over the terms of their contract. For businesses in the life sciences sector, there are likely to be particular risk areas around the ownership of intellectual property rights between the parties and obligations relating to the protection of highly valuable confidential information.

Nevertheless, having a written contract does not guarantee that disputes between the parties will not arise. In some instances, the law also implies certain terms into contracts (some of which cannot be excluded), and the parties may not always be aware of these terms and their effect. This can be compounded in situations where the parties agree one thing in writing but act very differently in practice, or where an exchange of emails between the parties varies the contract terms or creates new ones.

Often therefore the intent behind the written contract is, where possible, to minimise scope for further debate on the contract terms, although there are a range of factors that influence how successful this might be, including the actual conduct of the parties.

Why might parties choose not to have a written contract?

Situations may arise in which a party considers it in its interests not to have a written contract in place. Lack of certainty of terms can work in a party's favour in some situations, including those where the terms implied by law are preferable to those it may have attained in a written agreement.

An example of this is in relation to liability, where parties may have sought to limit their financial liability to each other in a written contract. Take away the written contract and the parties are left only with the limits and exclusions that the law provides – a position that may

favour the buyer or customer. Parties may also dispense with a written contract because there are industry-standard terms that govern their relationship, more formal than a purchase order.

But beware…

Avoiding using a written contract comes with a health warning as it is clearer to deal with the terms implied by law into the written contract itself. In any event, under English law some contracts must be in writing to bind the parties, including certain types of corporate share transfers and guarantees.

The takeaway message therefore is a simple one: written contracts aim to provide greater certainty of contract terms, are likely to assist in the event that things do not progress smoothly and may also be mandatory in certain scenarios.

OUR KEY LIFE SCIENCES PARTNERS

Charlotte Tillett
Partner and Head of Life Sciences
T: +44 (0)1483 406956
M: +44 (0)7796 010908
E: charlotte.tillett@stevens-bolton.com

Gustaf Duhs
Partner and Head of Competition and Regulatory
T: +44 (0)1483 734217
M: +44 (0)7725 912385
E: gustaf.duhs@stevens-bolton.com

Catherine Penny
Partner, Commercial Litigation
T: +44 (0)1483 734275
M: +44 (0)7557 677236
E: catherine.penny@stevens-bolton.com

Keith Syson
Senior Partner and Partner, Corporate/M&A
T: +44 (0)1483 734215
M: +44 (0)7836 786894
E: keith.syson@stevens-bolton.com

STEVENS&BOLTON

Wey House, Farnham Road
Guildford, Surrey, GU1 4YD
Tel: +44 (0)1483 302264
Fax: +44 (0)1483 302254
DX 2423 Guildford 1
www.stevens-bolton.com