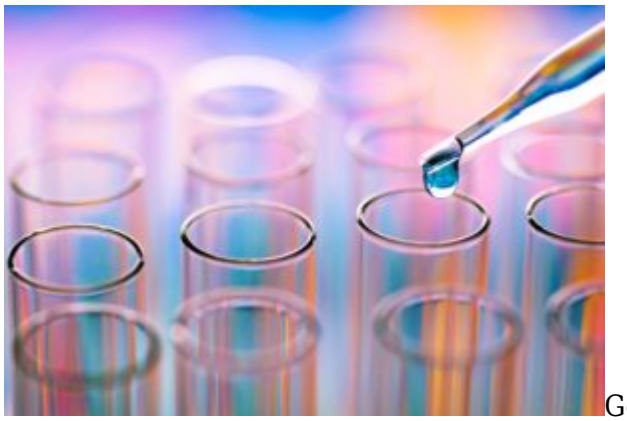
Decision Time: The Unified Patent Court Begins in 2023

 The Unified Patent Court ("UPC") is set to begin on June 1, 2023. Under the UPC framework, a single court proceeding could result in simultaneous revocation of European Patents across multiple European Union ("EU") countries, including France and Germany.

A three-month "Sunrise Period" is set to begin March 1, 2023. If a request is filed during the Sunrise Period, patent owners can "opt-out" specific patents from the UPC, such that they never become subject to the UPC unless the patent owner decides to withdraw the opt-out. However, the opt-out procedure is not necessarily straightforward. Importantly, if not done correctly ***and*** completed within the Sunrise Period, any patent challenged by a third party within the UPC will irrevocably be confined to the UPC's jurisdiction. Given the high stakes, patent owners should begin assessing which patents they would like to opt-out of the UPC and ensure that the necessary parties are involved in the opt-out procedure. Parties to license agreements, collaboration agreements, and the like should evaluate their existing agreements to see if they are UPC ready. Further, parties to future agreements should take the UPC into account when drafting those agreements.

Read the client alert **here**.

Restructuring and Insolvency in the Life Sciences Sector: Q&A

 Goodwin's Financial Restructuring partner Simon Thomas and counsel Oonagh Steel, with contributions from Life Sciences partners Sophie McGrath, Andrew Harrow and Tim Worden, have recently published a piece of thougtht leadership titled "Restructuring and insolvency in the life sciences sector: Q&A"

The Q&A discusses the sector-specific issues and risks that restructuring and insolvency (R&I) practitioners should be aware of in the life sciences sector, including:

- Sector characteristics and current trends that may impact the level of distress and insolvency in the sector.
- Legislation relevant to R&I in the sector.
- Managing R&I risk in the supply chain.
- Sector-specific considerations for buyers to be aware of in distressed M&A transactions.
- Key considerations when approaching a restructuring or insolvency process in the sector

For more information please read the Reuters article **here**.

European Life Sciences Deal Trends

In Europe, life sciences deals increased over the last few years with a strong acceleration in 2021. As a result, the market wonders whether this is just a pick or rather a steady trend which will impact our market in the future as well. Analyzing the reasons of such growth and comparing it with more mature markets such as the U.S. comfort us in thinking that it is just the beginning for continental Europe.

The U.S. life sciences market has been very strong over the past decades and is seen as very mature. The level of venture investments, which are now very much standardized, licensing, M&A and IPOs is very high, both in volume and in number.

For the last ten years or so, the life sciences UK market attracted U.S. investors and an increasing number of growth funds. After a first step of development through venture investments, such companies are now ready for licensing, M&A and IPOs. This is also the trend that we anticipate for the European market even if each country or region still has its own specificities (in particular UK, Germany, France and the Nordic Countries).

Read the **client alert**.

Getting Over The Hurdle

 Companies often use equity incentives to reward key members of their workforce and attract and retain the best talent. In the UK, companies have typically granted EMI options (a government-backed, tax-advantageous share option) or unapproved options. However, where a company is unable to grant EMI options (for example, because the company is not sufficiently 'independent', the company's gross assets exceed the relevant threshold when the option is to be granted or the individual is not an employee of the company) and it does not want to grant an unapproved option, then growth share schemes can be used as an alternative.

The principle behind growth shares is that they only participate in the growth of the company from the date they are issued and the right to receive a return on exit in respect of the shares is only triggered if the value of the business increases above a 'hurdle' threshold. Growth share schemes can be tax efficient and attractive for companies and individuals, if they are structured in the right way.

With regards to implementation, the company's articles of association will be amended to create a new class of growth shares, which are then issued to the individual. Key considerations for the company include what rights should attach to the shares (for example, whether the shares will have the right to vote and/or the right to receive dividends) and where the hurdle should be set (ideally, backed by a third party valuation). In many cases, an individual will sign a growth share subscription agreement with the company, containing details of the hurdle and bespoke vesting or leaver provisions.

Whilst such schemes do not need to be approved by the UK tax authority (HMRC), tax is still a key area to consider, for both the company and any holder of growth shares, including how they are taxed on issue and any tax that is payable at exit, such as an IPO where the growth shares would convert into ordinary shares. Tax and legal advice should therefore be sought before implementing any growth share scheme.

Q&A with Goodwin's Andrew Harrow: Exploring the Pharma Deals Outlook in 2021

 COVID-19 put into perspective the importance of the pharma industry to the global economy. Goodwin London Life Sciences partner **Andrew Harrow** reflects on 2020's impact on the pharma sector, particularly biotech, and discusses what 2021 might look like for industry deals and investment. Full article **here**.

Pressing the Accelerator on Growth

 **What is an accelerator**? An accelerator is an entity that provides a fixed-term, cohort-based program designed to accelerate growth and support disruptive and innovative early-stage businesses. They can be generalist or specialist and are located all around the world.

Who are they? Probably the most well-known accelerator is Y Combinator (US), which is active in most sectors, including life sciences. Other particularly active biotech and life science accelerators include JLabs (US), Startup Health (US), BioCity (UK) and Illumina (US). Closer to home of the authors are Accelerate@Babraham (Cambridge, UK) and Start Codon (Cambridge, UK), which debuted its first cohort in 2020. Not all accelerators are the same though, so it is important to do the research to ensure they are the best 'fit' for the business (stage, location, specialism, oversight and financing level).

What do they do? There are many reasons why founders are attracted to an accelerator program. They provide an intense and immersive education in the life of a start-up, covering strategy, sales, marketing, communication, risk management, finance and legal matters. Perhaps the most popular reason is mentorship from experienced practitioners, investors and entrepreneurs, whose advice and relationships can be vital as the company grows. Although the level of financing is not normally substantial, it is nevertheless welcome and participation in a program can sometimes make future fundraising easier, as supported by the statistics. Therefore, it is crucial to maintain and leverage new connections with angel and institutional investors during and after the program.

Why are they important? Starting any business is difficult and can be isolating. As a result of lockdown and social distancing measures, isolation is a key concern for many and so building a

business and developing relationships is even more challenging. Accelerators do not guarantee success and are not the only route, but they can provide valuable access to a community of entrepreneurs and mentorship and drive a business forward in a protected environment.

Is Prescription Support Software Classified as a Regulated Medical Device in Europe?

…the essential criterion for being classified as a medical device is the software's medical objective…

Background

Relying on an unregulated app or piece of standalone software to provide a diagnosis or recommend treatment could have potentially life-threatening consequences. In June 2020, the UK's medical devices regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA) updated its **guidance** to help software and app developers in the medical field identify whether their products should be regulated as medical devices.

In particular, the MHRA endorsed the European Court of Justice (CJEU) ruling of **Snitem v Philips France C-329/16** from December 2017. This case considered whether prescription support software which used patient-specific data to detect drug interactions and excessive doses, constituted a medical device.

The CJEU's Judgment

The CJEU held that the prescription support software was a medical device under EU law for the following reasons:

- the software cross-referenced patient-specific data with the medicines that the prescriber had contemplated prescribing;
- the software automatically provided the prescriber with an analysis intended to detect possible drug interactions and excessive dosages; and
- the manufacturer intended the software to be used for one of more medical objectives specified in Article 1(2)(a) of the **Medical Devices Directive 93/42/EEC** (MDD), which include the diagnosis, prevention, monitoring, treatment or alleviation of a disease.

The CJEU further held that it is irrelevant whether the software acts directly or indirectly on the

human body. According to the court, the essential criterion for being classified as a medical device is the software's medical objective, examples of which are mentioned above.

Practical Implications

The MHRA guidance provides further certainty that prescription support software and other decision support software in the medical field may be classified as medical devices and thus need to comply with the requirements under the MDD.

As a final point, the MDD is due to be replaced by the Medical Devices Regulation on 26 May 2021. A key implication is that the risk classification of a significant proportion of existing medical device software could change which would mean manufacturers will soon need to obtain regulatory approval to market such software in the EU.

Territorial Licensing in Collaboration Agreements

Life sciences companies often turn to geographical licensing to realise the maximum value from their assets, and to ensure their products reach markets worldwide, particularly where they do not have a global footprint.

In the context of a collaboration agreement, the owner of certain intellectual property rights may collaborate with a licensee to develop a product, and grant such licensee the exclusive right to further develop and commercialise the product, but only in a specific territory. The licensor may reserve for itself the right to develop and commercialise the product in another territory, usually where that licensor has a presence. In certain cases, usually after much of the development of the product has taken place, the licensor may also grant additional licences limited to *other* specific territories to third parties, further dividing up the territory it had reserved for itself in the initial collaboration agreement.

The above deal structures raise many complex issues of coordination between the parties. Some of these issues in relation to geographical licensing in the context of collaboration agreements are:

1. **Product development**: if multiple parties are conducting activities in their own territories to develop a single product, high levels of coordination between those activities are required. No party will want the activities of another party to damage the value of the product being developed. Sharing results of development activities between the parties could avoid

duplication of work, and help to ensure compliance with regulatory obligations. However, development results are costly to produce, and some parties may not be willing to disclose this information freely. The development work may also give rise to intellectual property rights, and the licensor will need to consider the degree of access it will need to those intellectual property rights.

2. **Regulatory authorisation and compliance**:
    a. **Pre-approval submissions:** the collaborating parties will also need to coordinate their submissions to regulatory authorities in relation to the product being developed. Inconsistent statements between such submissions must be avoided in order to protect the value of the product worldwide and ensure timely regulatory approvals can be granted.
    b. **Post-approval submissions:** once the product is on the market, each of the parties involved in its commercialisation will have reporting obligations to the regulatory authorities in their own territory. The parties will likely need to share information relating to safety and regulatory matters. If any additional licensees have been brought into the mix, the licensor will also need to consider whether all regulatory information should flow through the licensor, or whether it should flow directly between these licensees.

3. **Intellectual property management:**
    a. **Patents:** licensees who are taking an exclusive licence under certain intellectual property in a territory – particularly if they are developing improvements to such intellectual property under a collaboration agreement – are likely to want control over the prosecution, maintenance, enforcement and potentially the defence of such intellectual property in their territory. Although this may relieve the licensor of the cost of maintaining the intellectual property in such territory, prosecution of patent applications, and defence of patents, must be coordinated worldwide to avoid inconsistent statements or actions. Such inconsistencies could impede the prosecution of a corresponding patent application, or diminish the validity or enforceability of a granted patent, in another territory.
    b. **Trade marks**: if a licensor licenses rights in a centralised trade mark to various licensees, care also needs to be taken to ensure licensees are restricted in their use of the mark. Licensees should be prevented from acting in ways that could damage the value of such trade mark.

The above issues are tricky to navigate in a collaboration agreement, particularly where significant development of the product remains to be carried out, and the identity of any future additional licensees remains unknown.

A carefully considered term sheet at the beginning of negotiations can help to ensure that all relevant issues are raised and discussed as part of an overall package, as well as avoiding any key issue being missed which could potentially derail negotiations at a later stage.

Life Sciences Crowdfunding Considerations

 In recent years, equity (or investment-based) crowdfunding has been growing as an alternative source of funding for early stage biotech companies. This is due to the increasing availability of capital and willingness of the general public to invest in innovative companies, the potential speed and efficiency gains for companies compared to other sources of funding and the positive marketing and media exposure associated with a successful crowdfunding campaign, which can then generate more follow-on funding for companies.

Although early stage biotech companies will often need many millions before a product can be launched to the market, equity crowdfunding can be (and has been for some) an important source of capital at the start of that journey, when venture capital or other institutional investors may otherwise be less inclined to participate in that stage of funding.

According to a recent report tracking equity crowdfunding campaigns in the UK, whilst there was a slight decline in the number of campaigns and amount raised during Q2 2020 (with the market uncertainty resulting from Covid-19 likely having an impact), more investors are backing crowdfunding campaigns than in previous quarters, the crowdfunding market remains strong and there is an expectation that investors and companies will continue to utilise this source of funding. In addition, an interesting market trend is the growing number of purpose-driven companies, including those that qualify as “Certified B Corps” and actively commit to balancing profit with social and environmental impacts. Such companies can generate additional public interest, and this can be particularly relevant for life sciences companies which are often engaged in activities that have the potential to benefit the public in general.

This article explores 5 key considerations relevant to any equity crowdfunding campaign, including those in the life sciences sector.

Size of the crowd

Equity crowdfunding involves a high number of individual ‘crowd investors’ investing into a company through an online platform, such as Crowdcube or Seedrs, which continue to dominate the overall equity crowdfunding market – according to a recent report, during Q2 2020, approximately 95% of all campaigns took place, and money was raised, on Crowdcube and Seedrs. There are also specialist life sciences equity crowdfunding platforms, such as Capital Cell, which was the first of its kind in Europe and launched in Barcelona, Spain and Cambridge, UK.

There can be hundreds or thousands of crowd investors (and potentially more if multiple campaigns are completed over time). Individually, each crowd investor will hold a very small proportion of the company’s share capital, but together, the crowd investors may hold a more meaningful proportion. As a result, companies should consider how the crowd investors will align with its existing shareholder base and, if necessary, what protective wording needs to be included in the company’s equity documents (including those set out below).

Transactions on crowdfunding platforms are also generally structured for compliance with UK financial promotion regulations. Companies should ensure, and potentially seek confirmations from

the platform, that all necessary financial promotion regulations have been complied with by the platform in respect of the offer to the new crowd investors.

Nominee structure

Crowdfunding platforms often use a nominee structure, whereby the nominee holds the legal title (including the right to vote) and the underlying crowd investors hold the beneficial title (the economic interest) to the crowd shares. This can provide enhanced protection to investors, simplify the administrative burden on the company and make it easier to manage the equity going forward on both sides.

Crowd investor rights

Deal terms will vary but, generally, although crowd investors will receive the same economic rights as other investors that hold the same class of shares, the non-economic rights afforded to crowd investors will not be the same as those typically given to institutional investors in the company. For example, it is normally the case that crowd investors do not: (a) conduct extensive due diligence into the company; (b) receive business warranties or extensive information rights from the company; or (c) participate in consent matters or receive other contractual rights, such as the benefit of restrictive covenants from the founders of companies. Companies should evaluate if, and to what extent, crowd investors should receive pre-emption rights on new issues of shares, rights of first refusal over transfers of existing shares and / or co-sale rights. Crowd investors and the nominee will also not typically become a party to a company's shareholders' agreement and so their rights will be set out in the company's articles of association.

Decision-making

Companies should consider how decisions in respect of the shares are made by the crowd investors and/or the nominee and reflect this in the investor terms and conditions that will apply between them and the company's articles of association. In some cases, a decision is effective if approved by the majority of the crowd investors that respond to a request from the nominee. In other cases, the nominee can act in its discretion (without any vote), so long as it acts in the best interests of the crowd investors. Given the number of crowd investors, companies should try to avoid having to obtain consent from each crowd investor.

The articles of association should also clarify how shareholder offers, notices and communications are shared with crowd investors. It is customary to allow them to be sent to the nominee only, to avoid the company having to also distribute the same to each crowd investor.

Share transfers and exits

Companies may consider restricting the ability of the nominee and each crowd investor to transfer the legal or beneficial title (respectively) in shares to limited scenarios, such as permitted transfers, board approved transfers, tag-along transfers and compulsory transfers. These restrictions would be set out in the articles of association and referenced in the investor terms and conditions entered into between the nominee and the crowd investors. This will help avoid a secondary market in the shares, given the size of the crowd and the known split in the legal and beneficial title to the shares. It is important that, wherever beneficial ownership is transferred, the nominee remains the legal owner of the shares.

It is also important that companies understand how an exit can be implemented in respect of the crowd shares. Companies will want to avoid relying on the consent of each crowd investor to

implement the exit, given how many there may be. This can be achieved by relying instead on nominee consent (subject to various protections) and ensuring the nominee and the crowd investors are capable of being 'dragged' with other shareholders under the drag-along provision in the articles of association.

Conclusion

Equity crowdfunding is distinct from other forms of crowdfunding, such as reward-based crowdfunding on Kickstarter, donation crowdfunding on Crowdfunder or loan-based crowdfunding on Funding Circle. It is also distinct from other sources of capital from angel investors, venture capital funds, corporate venture companies or sovereign wealth funds. It presents a unique set of issues and challenges that should be evaluated to facilitate the effective management of the crowdfunding investment, beyond the initial campaign. It can, however, provide an important source of capital for life sciences startups, particularly at the start of their journey.

Tranched Investments in Troubled Times

Investments in early stage life sciences companies often provide that payments are tranched over time, subject to satisfying agreed milestones. This is normal, but in this abnormal market, stakeholders are approaching tranched investments with more caution.

As a starting point, where milestones and other completion conditions are met, the investor should be contractually obliged to invest the next tranche. To facilitate this, operational milestones should be objective tests and completion conditions should involve clear deliverables for the company. However, unforeseen events may challenge the tranched structure that was originally agreed when the initial investment was made.

In the current climate, R&D-focused business models of life sciences companies are under pressure. Specifically, as the effects of COVID-19 crystallise, there has been an impact the ability to carry out R&D, particularly where it involves third party contractors, laboratory testing and evaluating patients during clinical trials. Where R&D is able to continue, the pace at which it is moving is generally slower. This is particularly difficult for companies that rely on tranched funding from investors linked to satisfying specific milestones.

Consequently, where companies are mid-way through a tranched investment round, parties may consider adjusting them to allow for smaller and more frequent tranches or adjust the associated triggers. In circumstances where a milestone has not been met, an investor may be persuaded to waive the milestone to invest the next tranche earlier than planned. Where a milestone has been

met, if the investor does not invest the agreed amount for whatever reason, the company may consider what the ramifications on the investor's preferential rights should be.

Tranched investments are not an option to invest. However, in these times, flexibility may be needed and regular communication between companies and investors as to what is appropriate at the time is essential.