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Business Development & Licensing Journal

A Look Back at the 16th IPLS Annual Conference p.04

The Rise of Inorganic Growth in Pharma p.07

The Tax Implications of Licensing IP p.18

CONTENTS

03 Editor's Welcome
Umaima Ahmad | Editor

04 A Look Back at the 16th IPLS Annual Conference
Adam Collins | NGA Events

07 The Rise of Inorganic Growth in Pharma
Muhammad Mustaqim | AstraZeneca

18 The Tax Implications of Licensing IP
Oliver Pumfrey | FTI Consulting

Welcome

Change is abound at the PLG, and this issue begins with a warm welcome to Andrew Dean who took on the role of Chair of the PLG UK in September 2022. Andrew has served on the PLG Board for 5 years and brings with him networks, experience, passion and a new perspective, and we're excited to see what he has planned for the PLG in its next phase.

At the same time, a huge thank you is due to Kay Tait, who will continue to serve on the Board though has stepped back from the Chair role that she has held for a magnificent 5½ years while closing a raft of multi-billion dollar deals at AstraZeneca. We've seen much progress during Kay's tenure, including diversification of the PLG's offering, and membership levels reaching their highest ever in its 39 year history.

In this issue, we recap on IPLS Brighton, a brilliantly-organised event with 225 attendees that made full use of its seaside location, and share plenty of photos (**page 4**).

We talk about inorganic growth strategy in pharma and take a comprehensive look at the key drivers behind value in contemporary deal-making (**page 7**).

We also hear from an international tax expert on the tax implications of licensing IP (**page 18**), looking at the whole suite including withholding taxes, corporation tax losses, indirect tax, Patent Box and R&D incentives.

Finally, we bid farewell to seasoned PLG aficionado, Sharon Finch, who stepped back from the board in December 2022 to allow her to enjoy a very well-earned retirement. We know how treasured Sharon has been over the years to many of our members, and the grapevine reveals that a special farewell party is in the works, with more to be revealed in the coming weeks.

Umaima Ahmad
Editor

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A Look Back at the 16th IPLS Annual Conference

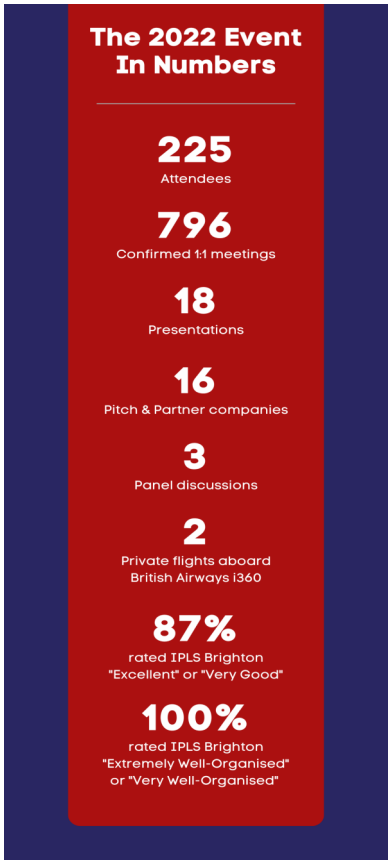
Adam Collins | NGA Events

2022 saw the welcome return of in-person attendance at the 16th IPLS annual conference held in Brighton, UK from 18-20 September 2022. The 3 day event began with the first of 796 confirmed one-to-one partnering meetings that attendees had arranged prior to arrival using the online partnering system.

Professor Kevin Fong, Consultant Anaesthetist at University College London Hospital, pre-hospital doctor for Kent/Surrey/Sussex Air Ambulance and general space enthusiast, set the tone for the event with his keynote speech receiving rave reviews; 'super entertaining and very thought provoking', 'Prof Fong was excellent', 'Professor Fong was fascinating' and 'Kevin Fong was amazing'.

Across the 3 days attendees heard directly from companies including Amazon, GAIA, IQVIA Jefferies, PwC and YouTube providing analysis of deal data from 2021, innovation in digital health therapeutics, private equity deal structures, medicinal cannabis and much, much more.

A networking reception was held aboard the British Airways i360, offering 360 degree views across South Downs National Park and the English Channel from 138 metres high, before guests sat down for a gala dinner.



Organised by national member groups across Europe and Canada, IPLS events offer attendees the opportunity to network, partner and learn through presentation content, formal partnering meetings and informal social events. Amsterdam will host the 2023 event to be held Tuesday 19 - Thursday 21 September 2023. Please **save the date** in your diary and look out for details of early booking rates.

Attendee Comments

'Fab variety of companies'

'Right blend of networking/business sessions – well done'

'Great place to meet new business partners – great keynote speakers – fantastic overall organisation'

'Right size, right location, good opportunity to meet and excellent level of speakers'

'Great mix of F2F, presentations and social'

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The Rise of Inorganic Growth in Pharma:

the productivity problem, contemporary deal-making and value drivers

Muhammad Mustaqim | AstraZeneca

The pharmaceutical industry, as exemplified by the recent Covid-19 pandemic, is a core industry with implications for global society.

It has been steadfast in providing healthcare solutions and a model for business productivity. However, the industry is facing several challenges associated with declining research and development (R&D) productivity as well as financial performance (Goldsmith 2017).

Long gone are models of internally sourced assets and innovation taken through commercialisation as the norm. In fact, the industry standard now is collaboration and growth through inorganic means. These inorganic paths to growth take the form of mergers and acquisitions (M&A) (Ornaghi 2009), divestitures and frequently licensing transactions. In addition to acting as a mechanism to source innovation, inorganic growth models can also help to re-align pharma portfolios and unlock revenue or cost synergies; for example, after three years, Takeda's acquisition of Shire was expected to deliver $1.4billion in savings due to organisational synergies and complementary portfolios.

Recent technological innovations have accelerated advancements in pharma. However, the pace of innovation has faltered and several experts argue that the decline in research and development (R&D) productivity is one of the main challenges facing the industry right now, thus driving a change in the business model (Pammolli et al, 2011). The blockbuster model of pharma generated substantial returns with strong intellectual property (IP) rights for their makers ensuring their reign. This traditional "closed innovation" model (Chesbrough, 2006), whereby all innovation is developed in-house is no longer profitable. Instead, an open innovation model in pursuit of new technologies has evolved to enable pharma to fill the gaps in their pipelines.

Additionally, the industry's financial performance is being affected by upcoming patent expirations, replacement with and increasing prescription volume of generics, higher commercialisation costs and constrained health care budgets (Garnier, 2008). Deloitte's 2021 report on declining return on investment (ROI) in R&D year-on-year since 2014 highlights this well.

Kinch et al's 2021 study illustrated that the number of companies that had at least one FDA approved drug had reduced from 331 companies in 2004 to 145 companies in 2019. Notably, the industry has seen a degree of consolidation amongst the players, though the rate of venture investment is at an all-time high.

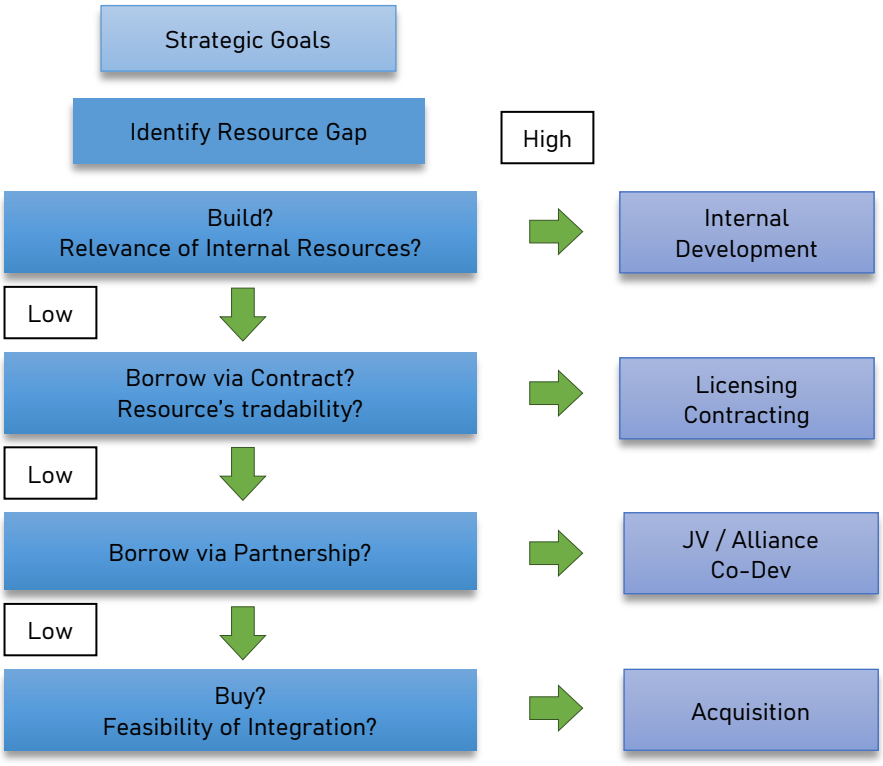
Biotech more than doubled its capital raise in 2021, $34 billion versus $16 billion in 2020, suggesting deeper factors at play. Pammolli et al (2011) analysed over 28,000 compounds since 1990 and proposed that the declining productivity may be due to riskier projects being pursued. Another factor may be the increasing complexity of the modality of drugs, deeper disease examination to exploit unmet therapeutic needs, as well as technological advancements making it difficult for Pharma to have all the technologies available. Scannel et al (2012) called the inefficiency in R&D productivity "Eroom's Law" (a play on Moore's Law), leveraging data from Munos and co that showed the cost to develop a drug has been increasing almost exponentially since 1950 to, in today's terms, costing billions of dollars (Schlander et al 2021).

To determine the most suitable inorganic growth pathway, companies typically employ a resource-based view when considering how to establish the necessary capabilities. A conceptual understanding can be visualised through Capron and Mitchell's resource pathway framework (Figure 1). In this model, strategic goals are developed and resource gaps identified. Subsequently, four key dimensions are assessed against time regarding the company's internal capabilities. Should the company build this new capability in-house, and does it have time to do so?

If the internal resources are relevant, then in-house development is a strong possibility. If internal competencies are not highly relevant, the manager asks whether these capabilities should be borrowed or traded via contracting or licensing arrangements. The third question assesses whether it is better to go it alone or with a partner, and finally the fourth asks whether the firm should simply buy the capability and integrate. Each mode has its pros and cons and must be assessed within the context of the firm's strategy, competencies, commercial feasibility and the competitive landscape.

Figure 1

Resource Pathway framework contextualised within a pharmaceutical setting.
(as adapted from Capron & Mitchell's finding the Right Path, 2010)



Given the eclectic nature of the industry and the high commercialisation costs, large pharma is well-positioned to power the costly late phase development and commercialisation of drugs. Smaller entrants typically bring innovation into the space, facilitating an "open innovation" model (Chesbrough 2006). Here, companies fill gaps in their pipelines and product portfolios from external sources such as smaller biotechs. Acquiring or in-licensing assets enables pharma to selectively choose the product, avoid full development costs and de-risk the investment. These collaborations provide the biotech companies with access to pharma's immense capabilities and expertise, which they often lack, particularly in manufacturing, clinical, regulatory, marketing and commercialisation. In return, pharma obtain access to proprietary technologies, scientific expertise, and the innovators behind them (Reepmeyer 2006). From the perspective of a young biotech, these collaborations are often win-win situations. Corporate transactions in the form of licensing arrangements, co-developments or joint ventures can play a pivotal role in a young companys' growth trajectory and strategy. As the seller effectively gives up their decision-making rights in return for cash, there must be a balance against the commercial potential of the asset, timings of cash inflows to the seller and obligations on the buyer so as not to cause disincentives. These transactions may be structured to ensure the economics incentivise both parties to commercialise the drug, whether derived from obligations and diligence towards achieving key goals or financial incentives structured against milestones, royalties or payments on net sales. These licenses of rights and inheritance of obligations include an agreement on a host of factors that each party must agree on based on the fundamental drivers behind the deal.

Eroom's Law, becoming an established phenomenon by the 80s, paralleled a paradigm shift in R&D with pharma looking at external assets. 1978 saw the birth of the biotech industry and the beginnings of this model with Genentech's license for insulin to Eli Lilly. Soon after, Amgen licensed its rights to erythropoietin in Japan to Kirin (Arnold et al 2002). This shift was driven by a technological wave - the genetic revolution, and a stream of acquisitions, even to this day, whereby traditional small molecule pharma players sought to acquire capabilities in biologics. However, big pharma's "impoverished" pipeline and active deal-making has changed the partnering landscape with billion-dollar valuations and large upfront payments becoming the norm (Moran 2007). This has brought competition and pressure into the environment, along with vast capital from private equity. Therefore, the importance of successfully navigating a partnering deal, which often has existential consequences for the niotech, cannot be understated.

Table 1

Top five pharmaceutical licensing deals in 2020 in order of deal value.

Licensor	Licensee	Details	Upfront Value	Headline Value
Daiichi Sankyo	AstraZeneca	TROP2-targeted antibody-drug conjugate datopotamab deruxtecan for lung, breast & other cancers	$1.0 Billion	$6.0 billion
Seattle Genetics	Merck & Co	LIV-1-targeting antibody-drug conjugate for breast cancer and other solid tumours	$1.6 Billion	$4.5 billion
Genmab	AbbVie	Multiple bispecific antibodies for cancer	$750 Million	$3.9 billion
Sage Therapeutics	Biogen	Zuranolone for multiple depression types and SAGE-324 for essential tremor	$1.5 Billion	$3.1 billion
Sangamo	Biogen	Up to 11 neurological disease programs, including ST-501 for Alzheimer's and ST-502 for Parkinson's	$350 million	$2.72 billion

Biotechs with little or no revenue and unproven assets with progressively costly 10-15 year commercialisation timelines require valuation methodologies to reflect their context. Due to extended negative cash outflows, often as sunk costs, standard valuation multiples (EV/ EBITDA, P/E) are not appropriate (Koller et al 2015; Rotgen 2022). The investments may be entirely equity funded and the market dynamics with implications to revenue are constantly changing. Regulations impose upon these companies a structured development process with definite decision points and irreversible binary outcomes. The drug is efficacious in one phase of the clinic and either proceeds or fails. The therapeutic area, R&D process and market also heavily influence the valuation (Bogdan 2018). Industry research demonstrates that the risk-adjusted NPV approach is by far the most common with comparables a close second and internal rate of return (IRR) and payback period third; options pricing being the least used. Currently there is no universal consensus on the application of valuation techniques in life sciences. In part this is due to the inconsistent calculation of input parameters (Bogdan 2010) as well as the esoteric nature of the technology, infancy and volatility of markets, which for truly innovative therapies the market itself must be created. Add to that the long and risky commercialisation timelines and the dynamic nature of the clinical and regulatory pathway, and an accurate measure of value becomes a tricky endeavour indeed.

Arnold et al's 2002 study, one of the most comprehensive studies into the field of licensing shows that of the various valuation methods, "46-68%" of deals could not be accounted for by quantitative parameters alone, suggesting that the remaining "32-54%" of deal value constitutes qualitative factors. When assessing the relationship between deal value and quantitative factors of 77 deals over a 10-year period, the results of their multivariate regression did not align with the perception of value drivers held by industry leaders involved in deal-making. According to their study, six key attributes influence the financial value of a deal (Table 2).

Table 2

Contextual factors driving deal value adapted from Value Drivers in Licensing Deals – Arnold et al, 2002 .

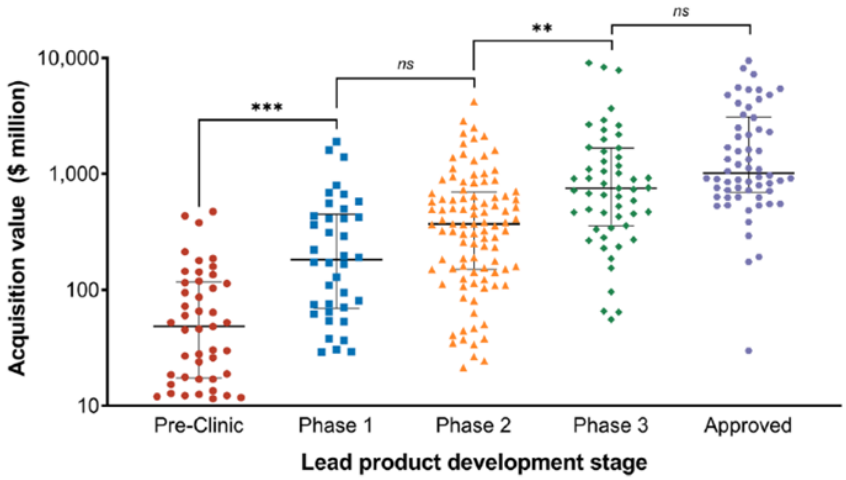
Ranking	Factors
1	Phase of molecule
2	Therapeutics Area
3	Type of Agreement
4	Scope of the Agreement
5	Type & reputation of the partner
6	Type of molecule

The results from this 2002 study are aligned with Michaeli et al's 2022 paper assessing 311 deals on the value drivers of Biopharma companies. They demonstrated that the acquisition value positively correlates with the phase of the molecule (Figure 2), the largest driver for deal value, and that the most acquired products were from Phase II. Additionally, the payment structure of deals correlated with the development process. The mean upfront payments in relation to overall deal value were 51% upfront for pre-clinical molecules and 43% upfront for Phase I products. The upfront component increased as the product moved through the clinic reflecting reduced risk; 73% for Phase II, 80% Phase III and 95% for commercial molecules.

However, it must be stated that this study focussed only on acquisitions and the split may vary in different deal structures given the change in the structure of value transfer. Michaeli also demonstrated that the type of molecule is important, with acquirers willing to pay a "37% premium" for biologics, and that higher deal frequency is seen in appealing therapeutics areas; "30%" of acquisitions in oncology and "16%" in CNS. Their study along with the Stasior (2018) paper and Schlanders (2021) review demonstrates that the valuation of an earlier stage biotech is mainly dependent on the biotech's lead product, which correlates with the drug development process and the business lifecycle of an early-stage company.

Figure 2

Acquisition value of lead products in development across different phases of the clinical cycle. As edited from Michaeli et al, 2022.



The future of deal-making will be driven by the investment themes shaping R&D today. Key areas as highlighted by McKinsey's review paper are eagerly anticipated to deliver truly innovative solutions that deliver value to pharma players and financial investors alike. Entrants developing platform technologies that form the foundational infrastructure for new therapies will benefit the most. Next-generation Cell & Gene Therapy techniques to address unmet needs and non-oncological conditions have received significant funding and the market is expected to reach $20 billion by 2026. Precision medicine has become a widely adopted strategy and the technologies enabling early detection, biomarker discovery, machine learning and population health omics continue to advance the space. New delivery methods and strategies for addressing validated but undruggable targets will also play a key role in future innovation. Deloitte's recent R&D report illustrated an uptick in R&D productivity ROI in 2021, and recent technological advancements paint an optimistic future. As challenges in pharma are being addressed through a greater degree of collaboration transforming the ecosystem, partnering and deal-making will continue to play a strong role in facilitating this growth.

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The Tax Implications of Licensing IP

Oliver Pumfrey | FTI Consulting

This article sets out an overview of the most common tax implications arising in Life Science IP licensing.

By reviewing the key components of the transaction at Heads of Terms, a number of potential issues can be ruled out, allowing focus to be applied to key aspects and the parties to agree terms when negotiations are more fluid. The concepts are covered from a UK tax law perspective however similar considerations will apply in other territories.

Companies often don't seek specialist tax advice before entering into IP licensing agreements however care should be taken as there are a number of tax-sensitive areas that may have significant impact on both licensee and licensor. There are five principal tax areas to address when in-licensing or out-licensing IP:

- Withholding tax
- Corporation Tax loss utilisation
- Indirect tax
- Patent Box incentive
- R&D incentives

These should be considered whether the agreement is between companies in the same legal jurisdiction or different jurisdictions. An overview of each of these areas is set out in Figure 1.

Withholding Tax

Withholding tax is a tax deducted in the source jurisdiction levied on royalties paid to a person outside that jurisdiction. It is essentially an allocation of taxing rights which can often be mitigated through a double tax treaty or directive. Importantly it is a tax liability of the licensor administered by the licensee.

Figure 1

Key areas of tax to consider when licensing IP

Where the licensor and licensee are resident in different territories for tax purposes, the withholding tax implications should be assessed and adequate protection built into the agreement.

To ensure that the right amount of withholding tax is paid and that, where possible, it can later be recovered, both licensor and licensee will need to exchange information. The exact requirements will depend on the specific tax law and administration in the relevant territories. The agreement should cater for this exchange of information. If withholding tax applies to any of the payments, assess what rate of withholding should be applied under the domestic law applicable to the licensee and then, if applicable, under the relevant double tax treaty.

When it is known whether withholding is likely to apply and how much, the agreement should require mutual assistance in minimising withholding and meeting compliance requirements.

Withholding tax can be a real cost to loss-making companies or where full double tax relief is not available. Companies should first determine whether it is likely to be a cost and, if it is, consider alternatives such as:

- Weightings to different categories of payment under the licence; or
- Sub-licensing to a different licensee.

Companies should try to avoid having royalty flows from several licensees under the same agreement as this will increase the compliance requirements and risk of additional tax cost. It is also important to ensure that there is suitable control over rights of assignment such that, as a minimum, it requires written approval from the licensor.

Loss Utilisation

It is not uncommon for companies to find that they have been unable to set tax losses against income streams under a licence. It is important that this is considered carefully as an oversight can prove costly. The licensor can offset receipts under the agreement against tax losses provided the income and the loss are of the same nature for tax purposes.

It is important to consider reviewing the nature of the receipt (i.e. capital vs. revenue or trading vs. non-trading, originating from IP created pre/post April 2002).

Equally, companies should review the nature of the tax losses and consider whether there are any restrictions that could apply to their utilisation. In particular, consider the timing of when the revenue will be recognised for accounting purposes.

In 2017 changes were made to the way brought forward corporation tax losses can be used such that there is a limit on the amount of brought forward losses that can be used to offset profits. A company may therefore become cash tax paying even if they have losses in excess of the receipts under the agreement.

> “Patent Box... has the ability to substantially reduce the tax liability at a corporate level”

Indirect Tax

It is important to check whether licensing costs include or exclude VAT. If VAT or other indirect taxes are chargeable, they may not be recoverable by the licensor. The anticipated VAT treatment of each component of the agreement will need to be determined. Consider whether the definition of sales and other thresholds are explicit with regard to the inclusion or exclusion of indirect tax.

If materials are being transferred cross-border, examine how the valuation and compliance is being addressed for import duty purposes. Potential duty rates should be determined and the agreement should specify which party should bear the cost.

Some territories have complex sales tax rules, e.g. Latin American countries. When dealing with such a territory, assistance may be required to understand the local rules.

Indirect tax clause(s) in the agreement should be reviewed to determine whether they are appropriate to allow for compliance and mitigation.

Patent Box

Both the licensor and licensee may want to take advantage of the UK patent box or a similar regime in another territory. The terms of the agreement may influence whether a company can benefit and the extent to which it does so. The notes below apply to the UK regime.

Qualification for Patent Box should be determined and the benefit quantified, including:

- Whether the Development Condition and/or Active Ownership tests are passed; and
- Whether any ancillary income streams under the agreement are eligible for inclusion as relevant IP income; and
- Whether the exclusivity criterion is satisfied; and
- Know the likely impact on the R&D fraction that might be applied to cut the overall benefit

The licensee may wish to ensure that sufficient evidence is available to demonstrate that they have qualifying IP rights. If patents are not granted at the time of the agreement, ensure there is a mechanism requiring the licensor to notify the licensee following grant.

To value the cost / benefit of the license, the after-tax position can be calculated taking into account the Patent Box and R&D incentives as well as other tax attributes such as tax depreciation and the availability of losses. If either party has not elected into the regime, consider whether the transaction now makes it worthwhile to elect in.

R&D Incentives

If the licensor is claiming R&D incentives, they should consider the impact of receipts under the agreement. If there is ongoing collaboration for development, any FTE reimbursement (or the equivalent) is likely to be regarded as subsidised R&D. As a consequence, the company receiving the payment will not be able to claim the more generous SME incentive on the subsidised amount but will instead have to claim under the R&D Expenditure Credit regime.

Milestones or other income could similarly be regarded as a deemed subsidy and would limit the ability to claim the UK SME relief. The terms of the agreement would be influential in deciding the treatment.

Divestment of assets

As an alternative to licensing some companies may consider the sale of IP assets. Similar to licensing, the sale of an asset can result in a double tax charge at the corporate and shareholder level. Although, as outlined earlier, patent box again has the ability to substantially reduce the tax liability at a corporate level.

The outright sale of patent rights is unlikely to generate the equivalent benefit under Patent Box as compared to license as it will only apply to the value of qualifying UK or EU patents. An equivalent license would allow rights to all patents and associated IP to qualify.

One strategy of increasing the tax efficiency is to hive the asset down to a new company. Then, upon sale, the entity can be sold. This will result in the sale being exempt under the Substantial Shareholding Exemption (SSE) meaning there will be no tax on transfer of NewCo and subsequently the asset. Other jurisdictions may have similar participation exemptions.

Conclusion

There will always be tax considerations when licensing IP whether the licence is between companies in the same jurisdiction or in different jurisdictions. Getting the right advice at the right time can prevent issues arising further down the line and protect important tax incentives and reliefs. Through the negotiations and agreements, it is possible to reduce the withholding tax implications and increase the benefit of the patent box. Additionally, it is essential to have a sound understanding of the agreement and legislation to validate if any other taxes, such as indirect tax, are chargeable and to ensure any benefit arising from prior year losses and R&D incentives are correctly taken advantage of.

Key Takeaways

IP licensing creates a number of tax considerations including:

- Withholding tax – WHT liabilities can be mitigated through double tax treaties and where not available contract drafting and sub-licensing can prove to be effective alternatives.
- Loss utilisation – Both the timing and nature of losses accrued in a business should be assed to confirm that they are eligible to be offset against an income stream to minimize the liability.

- Indirect tax – Contracts should be reviewed on a component-by-component basis to identify where indirect taxes are likely to apply and at what rate.
- Patent Box – where a license qualifies, certain regimes, such as the UK patent box regime, provide tax benefits, therefore, understanding applicability of these schemes can provide significant benefits.
- R&D incentives – Tax incentive programs, such as the SME regime, may qualify R&D as not qualifying where license payments are received in relation to the same project. It will be the terms of the agreement which determine the availability of these schemes.
- Divestment – utilisation of the UK's substantial shareholders exemption scheme can reduce the tax liability on the ultimate disposal of an asset.

Author

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Oliver supports Life Sciences clients across a range of tax matters including R&D incentive claims for large enterprises and SMEs and related transactional advice and planning. He also advises on the Enterprise Investment Scheme, licensing of intellectual property rights and Patent Box elections in regard to optimal timing and the potential benefits.

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