

# Four keys to successful technology in-licensing

In-licensing can allow companies to take advantage of outside knowledge and technology without bearing excessive costs or risk. A well-thought out agreement and thorough due diligence are crucial to its success

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In designing new products and services, companies may consider licensing technology as a means of getting to market quickly while reducing risk at the development stage. This type of transaction, known as ‘in-licensing’, also allows companies access to the ideas of scientists and engineers who specialise in the necessary technology, enabling them to undertake innovation that transcends the business and intellectual constraints of their organisations.

Although in-licensing can result in a successful arrangement for the parties, a number of issues must be addressed before an agreement is executed. Licensees and licensors must have a clear understanding of how the technology will be used, as well as the risks associated with its development and use and how the finances of the deal will work.

Properly navigating key issues and decision points along the path to an in-licensing programme will help parties to avoid setbacks and get optimal benefit from the transaction.

## Start on the right foot

As in any transaction, success depends on

identifying risk early in the process, then determining whether – or how – to proceed based on your ability to manage potential setbacks. Thorough due diligence for in-licensing transactions will cover technology, legal and business aspects of the arrangement.

## Technology due diligence

Prior to significant discussion of business terms, it is important to know as much as possible about the technology being licensed. At the least, thorough technology due diligence will uncover answers to the following questions:

- Who developed the technology? What is the reputation of the inventor, development team and/or licensor? Do they have a track record of licensing technology and supporting successful commercialisations of technology?
- At what stage of development is the technology? Does it comprise more than just patents? Have models or samples been built? Has testing occurred? Are the test results available?
- How well documented is the technology? Are there detailed instructions on how to build and use it? Have problems that have been identified and resolved been well documented?
- Will you have access to key development personnel? Are they still with the licensor? Are they willing to provide you with background information on the development effort?

## Legal due diligence

Understanding the IP legal landscape early in the in-licensing process is vital to your success.

A first step should involve reviewing the licensors’ patents and patent applications to determine what they really cover, whether you really need a licence and – especially in

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an exclusive licence – whether the licensor will be able effectively to stop others from competing with you.

While a licensor may have a significant portfolio of IP in a particular field, you may not need access to all of it. You must perform a thorough analysis of the IP rights on offer and identify that to which you need access. Further, you must decide whether you need an exclusive (if available) or non-exclusive licence to make the relationship successful. While an exclusive licence can help to protect the in-licensor in the marketplace for its products, it is generally more expensive to obtain and can be difficult to keep.

While understanding what IP rights you can get from the licensor is important, it is equally important to be aware of rights held by third parties in the field of the technology. Due diligence should determine whether another company holds patents that block the use of the technology you intend to in-license. An oversight in this regard could result in your inability to use the technology.

### Business plan due diligence

Once the technology and IP landscapes are understood, other risks in commercialising the technology must be identified. Understanding all of these risks is necessary in developing a business plan for use of the in-licensed technology.

Before moving forward, ask yourself the following questions:

- Is there a risk that you cannot make the technology work for your application? This is where thorough technical due diligence can help. Fully understanding how the technology works and knowing what, if any, help is available from the licensor should give an indication of how well you can transition the technology.

- Is there a risk you will not get regulatory approval for products containing the technology? This issue arises particularly in the fields of biotechnology and medical technology but can arise in others as well. The risk of regulatory rejection may be lower in situations where the technology you are in-licensing has already been used in an approved product.
- Are there economic risks for the product or technology you are developing? Factors to weigh in relation to the product or technology include competitive landscape, cost drivers, projected demand, likely margins and potentially disruptive technologies making their way into the market.

### Establishing the financial terms

This is where the negotiations will often get difficult. As a general rule, greater risk to the licensee of failure in the licensing transaction should lead to a lower royalty on the improved product. A number of factors are subsumed by the term “risk”, such as how much investment the licensee will have to make to commercialise the product, how many competitors already exist in the field, demand for the improved product and whether regulatory approvals are required. If most of these hurdles have already been crossed by the licensor or other licensees, then the royalty may be higher.

Typical licensing structures may include terms for:

- Upfront payment when the licence is signed (which may or may not be treated as an advance on royalties).
- Payment upon achieving financing for the company based on in-licensing the technology.
- Payment when the product receives regulatory approval.

- Royalty payments on sales of the products.
- Technical assistance fees.
- Trademark usage fees.

#### Upfront payment

In arrangements involving well-developed technologies – and where there is little risk to the licensee – the licensor will expect payment when the licence agreement is executed (or shortly thereafter) of an amount that is significant to the licensee. This is to ensure that the licensee is motivated to get the technology into product and start creating royalties for the licensor.

In some cases this payment is characterised as a “licence access fee” and the licensor never has to repay or credit the licensee for this amount with respect to future royalties. Other times, the payment is characterised as pre-payment of royalties and the licensee may take credit for the pre-payment against future royalty payments. Generally, the more mature and stable the technology, the more the licensor will expect upfront.

#### Royalty payments

While upfront, lump-sum licences are sometimes offered, the more usual model involves payment of royalties to the licensor. Royalties are typically expressed as a flat rate per sale or event (eg, one euro on the sale of a blood test kit), or as a percentage of the sales price of a product or service (eg, 5% of the value of a blood test kit).

In establishing terms for royalty payments, it is critical to define clearly both the triggering event for payment of the royalty and the basis for payment.

#### Setting the royalty rate

Setting the initial royalty rate can be one of the most difficult aspects of reaching a licensing deal. Unfortunately, these types of agreement are generally kept confidential by the parties, leading to a dearth of publicly available information.

However, as a starting point, accounting firms and IP valuation firms do have means of valuing licensed technology. Setting a royalty from this valuation then depends on several factors:

- How much value the licensed technology adds to the licensee’s products.
- Likely demand for products with licensed technology.
- The investment made by the licensor.
- The investment to be made by the licensee.

- Whether there are other necessary IP rights to be licensed by the licensee.
- The risk to each party related to the transaction.
- Whether the licence is to be exclusive or non-exclusive.

Typical royalty rates (when expressed as a percentage of sales) are less than 10% of the sale price of the product, with rates of 3% to 5% being the most common. In addition to the initial royalty, other terms affecting the royalty may be included in the agreement.

#### Royalty adjustments

Once the initial royalty has been set, this rate is normally retained for some period of time. However, both parties may wish to include a mechanism for adjusting the royalty rate due to changes in the marketplace. Of course, this will vary with the type of royalty being paid (flat rate versus percentage).

#### Upwards adjustments

Typically, the licensor will seek an increase to a flat-rate royalty in the event of an increase in sales price of the improved product or when there is an increase in the cost of supporting the licensee. Quite often, the royalty rate will be adjusted based on a percentage increase in a neutral index such as the Producer Price Index (PPI).

#### Downwards adjustments

The licensee will typically seek to decrease a royalty in the event that competition enters the marketplace for the improved product, support from the licensor ceases or one or more patents covering the licensed technology expire or become invalidated. The licensee may also benefit from a downward trend in the PPI.

#### Guaranteed minimum payments

Almost all exclusive licences and many non-exclusive licences will include a requirement for the licensee to pay some form of minimum royalties. Failure to pay the minimum royalties as required can result in the loss of exclusivity or loss of the licence altogether. While this is sometimes expressed as a minimum unit sales obligation, other times it is expressed in terms of an actual payment obligation. As an in-licensee, the payment obligation may be preferable as you then can merely make the minimum payment in order to keep the exclusivity or the licence, regardless of sales volume.

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#### Technical assistance fees

Frequently, the licensor will charge a technical assistance fee in order to cover the cost of transfer of technology to the licensee. This is more common where know-how is being transferred or where technical personnel from the licensor will provide assistance to the licensee in incorporating the licensed technology into the licensee's products.

#### Payment triggers

Typically, the licence agreement will enumerate a number of events that will trigger a payment obligation for the licensee. Having multiple payment triggers can benefit the licensee. By spreading payments out over these events, the licensee reduces its upfront risk and can pay required payments as it experiences success along the path to commercialisation.

Licensors normally want some payment at the signing of the deal to motivate the licensee to commercialise the technology. In cases where regulatory approval is required, an event such as successful completion of clinical trials may also trigger a payment obligation. Regulatory approval suggests that the licensee has achieved some success in incorporating the licensed technology. Finally, actual sales of products or services using the licensed technology will trigger a payment.

#### Royalty base

The matter of which sales require the licensee to pay a royalty must also be determined. If sales of a product or service increase (eg, sales of a blood anaemia drug) because of sales of the improved product (eg, blood anaemia test kit), the licensor may expect a share of the sales of both the improved product and the related product. It is therefore important to understand the total impact of the licensed technology on

the licensee's business – and to ensure that any royalty obligation on a related product is tied to increased sales occasioned by the licensed technology.

#### Document the deal

All of the foregoing activity supports an initial goal of accurately documenting the deal that both parties have accepted. The executed agreement must be an accurate reflection of the final business deal and the related legal terms. To this end, you must have your business people, financial people and lawyers talking early in the process. By including all of these stakeholders at an early stage, drafting the actual written agreement documenting can be a fairly streamlined process. Still, some issues will likely not be discussed until this documentation phase.

#### Licensed rights and technology

It is important to understand the universe of the technology and rights being offered, then carefully draft a definition for the licensed rights or technology. This definition should ensure that the licensee has all of the rights it needs to produce products now – and sufficient room for growth and expansion of the products in the future.

Forward IP ownership and licensing must also be considered. Often, the licensor continues to develop the licensed technology. It is important for the licensee, where possible, to have access to this new IP through the licence. Generally, however, the licensor will own this new IP.

The licensee will also create new IP from the licensed technology. The licensee will usually own the new IP resulting from its efforts. In some cases the licensor may ask for access to this technology.

#### Exit strategies

Typically, both parties will want a means to

exit the licence agreement gracefully if the commercialisation does not go as planned or in the event of a sale or overall failure of the business.

The licensee will particularly want an exit strategy if it cannot get the licensed technology to work with its products or if market changes make the improved product unsellable. In the case of medical devices or other products requiring regulatory approval prior to sale, failure to obtain regulatory approval should also allow for the licensee to exit the deal.

Deal documentation should lay out the terms for scenarios such as these and any others that could conceivably occur.

### Conclusion

In-licensing can be an effective way to make new products or improve existing ones while reducing associated cost and risk. However, success in such arrangements depends on having a process that leads to a thorough understanding of the technology involved – along with the business and legal landscapes.

Once due diligence has been completed and a basic understanding of deal terms has been reached, licensees and licensors can move forward with crafting an agreement that provides opportunities for each party that would not have been possible without the other. **iam**



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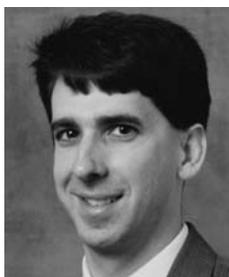
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