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The Ins and Outs of In-Licensing

In the research, development and design of new products, an increasing number of startups are turning to “in-licensing” technology from universities and other institutions as a means of getting products to market quicker while reducing both risk and cost in the early stages of development.

Rapid progress in product development also allows for financing opportunities beyond what is possible for most technology startups. An increase in capital, in turn, can help support more aggressive development of novel technologies (both internally and by way of additional in-licensing arrangements).

While in-licensing can result in a successful “marriage” between licensor and licensee, it’s important for the parties to recognize that – just like in any marriage! – they often come to the table with different (and at times conflicting) experiences, incentives and goals. Therefore, a better understanding of key issues involved in structuring and negotiating the in-licensing arrangement will help the parties better establish a clear framework for a mutually beneficial relationship.

Drilling Down

As with any strategic transaction, in-licensing arrangements are typically more successful when both parties enter the relationship well-informed and with eyes wide open. Identifying risks and other "red flags" through the due diligence process – and working together in addressing and trying to resolve those issues – will go a long way in ensuring that the parties start the relationship off on the right foot.

In addition to general business and economic considerations, a licensee will want to drill down on certain technical and legal matters in determining the value of a prospective in-license arrangement, including the following:

- What is the track record of the licensor and its development team in supporting successful commercialization of technology?
- Have all members of the licensor's development team and other personnel duly assigned all rights to the technology to the licensor?
- Will the licensee have access to key members of the licensor's development team? Are they willing to provide the licensee with information regarding their development efforts?

- Are there any existing research and development, joint venture or other arrangements restricting the licensor's use or license of the technology? Do any third parties hold patents or other rights that could block the use of the technology the licensee proposes to in-license?

- What do the licensor's patents and patent applications actually cover? Will the licensor (or the licensee, if associated rights are granted) be able to effectively prevent others from competing with the licensee?

- Are there any regulatory considerations that should be disclosed? What is the risk the licensee will not get regulatory approval for products containing the technology? Has the technology the licensee intends on in-licensing already been used in an approved product?

Bridging the Value Gap

Generally speaking, the more likely it is that the product containing the technology will be commercially successful, the more favorable the financial terms will be to the licensor. A number of factors need to be considered in assessing the likelihood of success, including existing and prospective competition, expected demand for the product, the need for

additional capital/investment and the nature of any required regulatory approvals.

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The following are among the most common financial features of an in-license arrangement:

- Upfront Payment
  - Paid to the licensor upon or shortly after signing the definitive license agreement
  - Often treated as an advance on royalties
  - Typically expected in situations where the technology is well-developed (resulting in less risk to the licensee)

- Milestone Payments
  - May include payments due upon events such as the licensee obtaining financing, the successful completion of clinical trials, the product receiving regulatory approval and/or some other mutually agreeable milestones
  - Allow the licensee to extend payments over the term of the license as the product achieves commercial or other success

- Royalty Payments
  - Typically expressed as a flat rate per unit sold or a percentage of sales/profits
  - Often a difficult point of negotiation
  - "Customarily" ranging from 3% to 8% of sales
  - Often subject to adjustment over the term of the license upon the occurrence of certain "trigger events" (e.g., an increase in the sale price of the product, an increase in licensee's costs in supporting the product, the expiration or invalidity of the patent(s) covering the licensed technology, etc.)

It should be noted that licensors and licensees often have different notions of what it means for a product to be a "success" when considering commercial and other milestones. For example, a large pharmaceutical company may establish certain commercial thresholds before advancing a new compound into the final stages of clinical development (e.g., projected annual revenue of at least $200 million). These thresholds may be much higher than those that a startup or emerging company may look to establish in determining "success."

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Furthermore, as the primary focus for an early-stage company is typically enterprise value (rather than revenue), a successful clinical trial (or achievement of some other “non-commercial” milestone) may be of more relative value to the early-stage company than it is to the larger company that is more concerned about its bottom line and share price.

To negotiate successfully, it is important for each party to recognize the other party’s goals and incentives and find a way to “bridge the gap” between the values placed on the technology and the product at the various stages of the in-licensing transaction.

Papering the Deal

The definitive license agreement should accurately reflect the commercial terms as agreed upon by the parties, with appropriate representations, warranties, covenants and conditions to account for the results of due diligence and allocation of risk between the parties.

The scope of the license and the definition of licensed rights and technology are arguably the most “material” provisions of the agreement. The licensee will want to ensure that the license includes all rights it needs – both now and in anticipation of future growth – to produce and sell the products. The licensor will want to ensure that the scope of the license is not overly expansive (potentially resulting in an inadvertent grant of rights to technology or other intellectual property

[IP] that is not necessary for the production of the products or violation of the terms of an existing agreement it has in place with a third party).

As the licensor owns and may continue to develop the licensed technology, it is important for the licensee to ensure that the scope of the in-license extends to all new technology/IP that is derived from the original. The licensee may also create new IP based on the licensed technology (i.e., derivative works), and while it is common for the licensee to maintain ownership rights in this new IP, the licensor may be granted rights or a "grant-back" with respect to this technology.

As with other commercial agreements, termination rights will typically arise upon breach of the in-license agreement by either party. In addition, both parties will want the right to terminate the relationship in the event regulatory approval is not obtained or obtainable within a predetermined period or upon the occurrence of any other event that makes the commercialization of the product containing the technology impracticable.

Express Licenses

In an effort to support local entrepreneurs and startups (many of whom lack the time and resources to negotiate the terms of a "customary" in-license), a recent and growing trend among universities is to offer "express licenses" – a predefined template license designed for startups

with a rapid and streamlined review process. The associated license fees are typically deferred (or substituted with a convertible note), and while the terms of these licenses are not subject to negotiation, a startup can get access to technology within a relatively short period (often as little as 30 days).

About the Author

David Schaffer is a corporate partner with the law firm of Wiggin and Dana LLP and a member of the firm's Emerging Companies and Private Equity Practice Group. He counsels foreign and domestic clients in a broad range of corporate and commercial matters, including licensing and distribution arrangements, mergers and acquisitions, debt and equity financings, joint ventures and other strategic transactions. David is based out of Wiggin and Dana's Stamford and New York offices. You can contact him at dschaffer@wiggin.com.