

Spotlight on Licensing: Avoiding and Limiting Risk in Agreements

Michael R. Annis, Partner, Husch Blackwell
Diane J. Romza-Kutz, Partner, Husch Blackwell

HUSCH BLACKWELL

Overview of the program

- The program is designed to provide insight into the issues that a company seeking to engage in a licensing arrangement will typically confront and how to negotiate terms which do not create liability or risk, but minimizes it
- Three main topics:
 - **Step One:** How to prepare for negotiations to ensure that the company has positioned itself correctly for a licensing deal and understands the value of the to-be-licensed asset;
 - **Step Two:** What are key licensing terms and the implications of those terms; and
 - **Step Three:** What are the negotiation pitfalls and how to avoid.

Types of Licensing Arrangements

- Generally licenses fall into one of two general categories
 - a traditional license and a “soft” license
 - A “**soft license**” is typically a co-promotion arrangement or a co-development arrangement;
 - A **traditional license** is for a time certain and has some key markers such as it is typically based:
 - on a market valuation based on its current developmental/regulatory stage or its market position such as first in kind;
 - asset is removed from the control of the licensor; and
 - involves a long term commitment between the parties

Step One: Preparation

- **Have a plan to license**

- Establish a profile for what a licensee should look like;
- Check the claims on your intellectual property – understand the breadth of the claims structure for patents and where there are no patents in play, establish how you have protected the asset;
- If the license is for a trademark make sure you have the freedom to use the trademark
- Make sure that senior management knows how to present the targeted asset particularly if the asset is science or technology based;
- Distinguish the asset from others in the market;

Step One: Preparation, cont'd

- Have an understanding of what recent similar deals have priced out at in the market place;
- If you know that the licensee/licensor has recently done a licensing deal, try to understand what the terms of that deal were in order to prepare yourself;
- **Be realistic** in how the asset is valued internally
 - the farther along in development the product the better opportunity for an larger upfront payment and quicker to milestone or royalty payments – be reasonable in equating the value of the license to the stage of the asset's development or if market ready to reasonable market share;
- Internally **establish realistic expectations** as to the terms you want and be prepared to justify those terms;
- **Be prepared to walk away**

Step One: Preparation, cont'd

- If the asset is still in the development stages or requires regulatory approval to enter the market, understand the time it will take to be market ready and to begin to generate ROI as that will make a difference on time to market which means cost to get the product to market.
 - If the asset is subject to state of federal regulatory approval, then make sure there is someone on the negotiating team who understands not only the approval process but the post market regulatory restrictions;
 - If the asset is technology based, make sure that not only is there someone on the team that understands the technical aspect;
 - Often technology driven assets are trade secret driven or have a trade secret aspect of protection – understand what this means for the license and how to protect your trade secrets from being the subject of future litigation;
 - Understand the competition in the market place or if possible who is prospectively entering the market.

Understanding market positioning is critically important to your deal

- Licensing monetizes assets and therefore a key term of any license is the licensing payment. Payment structures within a license should reflect not only the market space the asset will occupy but also the realistic revenues to be generated;
- Understand the cost to bring the product to this point in the license process and therefore what the licensor needs to “recover” as part of the licensing process; and
- Time to market and market value will dictate reasonable terms but without advance preparation it may be difficult to align expectations of the parties – lack of alignment leads to disputes and litigation.

Step Two: Key Licensing Terms

- Know what key terms are critical to your company and the parameters of those terms and get agreement internally on those terms and parameters of those terms before you sit down to negotiate;
- Key terms to think about:
 - **Scope of the license:** know the claims in your IP and understand what claims are being licensed or whether the entire asset is being licensed. It is often difficult to parse out claims across various licenses and therefore not desirable. Indication splitting is difficult and will under value the asset.
 - **Improvements and New Inventions:** This is a particularly important for innovator products not yet approved for market. If not clearly defined, can lead to litigation as to ownership of the improvement or new invention.

Step Two: Key Licensing Terms, cont'd

- Key terms, cont'd
 - **Enforcement rights** against infringers or against patent challenges: Controlling the outcome is critical. Controlling the litigation will effect the products market space.
 - **Responding to Agency actions:** Same as enforcement rights. The terms need to define who is in control as well as a cooperation clause for the party not controlling the responses to the agency.
 - **Representations, Warranties and Covenants** going forward: these are often misunderstood terms and not understood at all. A representation concerning the pending approval is never advisable. Avoid “absolutes” and overbroad terms.

Step Two: Key Licensing Terms, cont'd

- Key terms, cont'd

Valuation provisions: these include payments upon execution of the license (upfront payments – less likely to get in the present day market), milestones for products still in development and royalties from sales once the product is on the market – be prepared to ask for gross sales at a lower percentage. If it is net sales, define what it is deducted from the gross sales to reach a net number under the license.

Exclusive or Nonexclusive license and define the territory with specificity: typically exclusive licensors will want or will be deemed to have a beneficial ownership or right to prevent others from making, using or selling so the license needs to expressly deal with this type of situation.

Step Two: Key Licensing Terms, cont'd

- Key terms, cont'd

Patenting new inventions or improvements: when deciding ownership in the licensing terms make sure to include identification of the party responsible for undertaking IP protection and payment of fees related to obtaining such protection. Also it is good to get a present grant of future rights. Make sure that a cooperation clause/mandatory execution of any assignments which must be executed to protect IP is included here.

Step Two: Key Licensing Terms, cont'd

- Key terms, cont'd

Define the term of the license: this term may not be the same as what is left on the life of the patent.

- Also consider a clawback term should the licensee fail to market the product. This means either set a guaranteed “floor” for payments regardless of market penetration or sales volume targets and/or have a clawback provision wherein the technology reverts to the licensor if market penetration targets or sales volume are not consistently met.
- It is critical to have a reporting component or data tracking piece for this provision to be sustainable as in all likelihood the exercise of a clawback will become adversarial.

Sublicenses must be either expressly allowed or disallowed, or allowed upon the written approval of the licensor provided the sublicense is with substantially the same terms

Step Two: Key Licensing Terms, cont'd

- Key terms, cont'd
 - In the event of bankruptcy or insolvency: Account for what happens to the license in the even the licensee files bankruptcy or becomes insolvent.
 - Marketing provisions: Who controls? Marketing materials often include the label as well as “leave behinds” or package inserts in the case of drugs or instructions for use or comparators against similar products. Different types of liability can arise here; improper messaging can lead to mislabeling claims and second product liability claims (failure to warn, duty to warn, lack of controls on safety of ingredients or API), improper handling instructions which result in injury claims

Step Two: Key Licensing Terms, cont'd

- Key terms, cont'd

Indemnification and Hold Harmless clauses; Its all about who has the right to chose counsel, defend against any third party actions, and who pays fees, expenses and damages.

Arbitration, mediation and dispute resolution: These are provisions to resolve the issues between the parties to the license. Decide upfront if this is a mechanism to resolve disputes and whether the outcome of such is binding or nonbinding.

– Also include dissolution or **unwinding provisions**

Step Three: Negotiating Pitfalls

- Pitfalls occur in two primary ways. The first is failure to account for concepts in the license itself and the second is failing to approach the negotiations correctly.

The approach: Where and why failures occur.

- Paternalistic attitude and not letting go of the asset to the licensee;
- Approaching the negotiations with a “winner take all” attitude;
- Have an internal mechanism for monitoring the license arrangement;
- A lopsided or one-sided agreement leads to litigation;
- Focus on the asset to be licensed or its platform in the negotiation -- that will help drive the terms;
- Do not be afraid to walk away but do not let personalities dictate the tone;
- Do not make price or money the first term discussed;
- Understand the issues critical to the other party

Step Three: Negotiating Pitfalls

- Pitfalls cont'd
 - Accounting for certain concepts in the license:
 - Account for how the parties will communicate throughout the term of the license. Make sure that key communications are in writing in the event of a dispute;
 - Plan for the unwinding – No one ever wants to go into an arrangement planning for it fall apart, however, if you plan for the unwinding, if needed, it can be orderly and less likely to become adversarial;

Step Three: Negotiating Pitfalls

- Pitfalls cont'd
 - Clearly describe informal dispute resolution processes if the parties desire an escalating dispute resolution system;
 - If the licensor is a small company, realistically assess resources and do not commit to terms that require more resources than the company has in hand;
 - Account for publication rights and public statements. Have a non-disparagement and confidentiality provision included;

Step Three: Negotiating Pitfalls

- Pitfalls cont'd
 - Accounting for certain concepts in the license:
 - Do not overcomplicate the agreement. Make sure that the language is unambiguous and the roles and obligations of each party are clearly defined;
 - Define reasonable cure provisions if a party fails to perform an obligation under the agreement. Document the actions undertaken in the cure period by the curing party and if the actions are deemed insufficient to cure – be reasonable in your assessment;

Step Three: Negotiating Pitfalls

- Pitfalls cont'd
 - Accounting for certain concepts in the license:
 - Make sure that the licensor includes a “right to use” provision;
 - Don’t try to account for every situation which could possibly arise during the life of the license. This can create liabilities and obligations where there was no intent to do so; and
 - Make sure the license terms do not inhibit the ability of either party from capital investments or other deals.

Conclusions

- Licenses can be a valuable tool in monetizing assets and moving them to market.
- However, these agreements are often approached with a money first attitude and with little regard for the long term partnership that these arrangements create.
- One of the largest failures is having a real time assessment of what it takes to get a product to market, the difficulty in getting market penetration and how value ties to these concepts. This means not only following the right regulatory pathway but understanding the details and costs inherent in the regulatory process.
- Finally, it is difficult to negotiate these agreements on your own, paternalism can get in the way and the smaller company often gets “out gunned” by the bigger player. Utilize your resources to avoid these situations.

Presenter Contact Information

Mike Annis, Partner
Husch Blackwell LLP
mike.annis@huschblackwell.com
314.345.6432

Diane Romza-Kutz, Partner
Husch Blackwell LLP
diane.romza-kutz@huschblackwell.com
312.526.1569

This presentation can be found on our website:

<http://www.huschblackwell.com/businessinsights/spotlight-on-licensing-missouri-tech-expo-10-16-2014>