
## Overview of the Program

- The program is designed to provide insight into the issues that an animal health company needs to manage when considering an in-license or an out-license.
- There are three main topics that we will cover and we will do so as steps:
  - Step One: How to self-evaluate to ensure that the company has positioned itself correctly for a licensing deal and understanding how the regulatory landscape will impact a license
  - Step Two: What are key licensing terms and the implications of those terms
  - Step Three: What are the negotiation pitfalls to be aware of and how to avoid them when negotiating a license

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## Types of Licensing Arrangements

- Generally licenses fall into one of two general categories in the life science market, a traditional license and a "soft" license
  - A "soft license" is typically a co-promotion arrangement or a co-development arrangement. We will not really be focusing on these types of licenses although much of what is being discussed in this presentation could be extrapolated to those arrangements
  - 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
    - The asset is removed form the control of the licensor
    - Involves a long term commitment between the licensor/licensee

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## Step One: Self-Evaluation

- 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
  - Make sure that senior management knows how to present the targeted asset ***and*** understand the regulatory stage of development of the asset
  - Distinguish the asset from others in the market – market positioning is critical in the terms and negotiations

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## Step One: Self-Evaluation

- Have an understanding of what recent similar deals have priced at in the market place
- If you know that the licensee/licensor has recently done a licensing deal in the animal health arena, 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 a 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 – know your bottom line
- Be prepared to walk away

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## Step One: Self-Evaluation

- Understand the regulatory position of the asset and understand where your products fall within the regulatory framework of the FDA (and in some instances USDA), as that will make a difference on time to market which means cost to get the product to market
  - The FDA has primary jurisdiction to regulate animal drug, animal feed and feed additive products
  - Its worth noting that the FDA has stated publicly that DSHEA does not apply to animal products functioning as supplements however the agency believes that the majority of these products fall in to the feed, feed additive or drug category
  - Market entry is regulated by the FDA and with the exception of drugs post market regulation may be deferred by the FDA to the FTC or the USDA

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## Step One: Self-Evaluation

- Understand the path to market entry through the regulatory system – this allows the milestone and royalty expectations to be managed correctly in any license deal:
  - Be mindful when setting the valuation that your competitor's product could be a human drug which may be prescribed under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) – this allows veterinarians to prescribe approved human and animal drugs for extra-label uses in animals under specified conditions
  - If a food additive, understand that a Food Additive Petition must be filed with the FDA in order to gain market entry. This petition must be supported by composition data, manufacturing data, draft labels, data on intended effect, safety data and tolerances - to name a few - so the science must be done before a petition is considered.

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## Step One: Self-Evaluation

- If a medicated feed, these are likely to be regulated pursuant to the Animal Drug Availability Act of 1996 which established a new category of drugs known as Veterinary Feed Directive Drugs (VFD) – prior to distribution the Centers for Veterinary Medicine within the FDA must be contacted
- If an animal drug, a Veterinary Master file must be place with the FDA. These files contain confidential information about the animal drugs from a specific sponsor. There is also an Animal Drug User Fee Act (ADUFA) which must be complied with either, in terms of paying fees for a filing or qualifying for an exemption and/or waiver of those fees. Further to obtain approval to market as an innovator product, a New Animal Drug Application (NADA) must be filed.

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## Step One: Self-Evaluation

- NADA are submitted to the CVM. This can be submitted two ways, at once with all the modules included or as a phased review process known as an Administrative NADA.
- In a phased review, sections of the required filing are submitted for review while the investigation of the new animal drug continues. There are eight technical sections: chemistry, manufacturing and controls; effectiveness; target animal safety; human food safety; environmental impact; labeling; freedom of information summary; and all other information (such as the FDA forms and patents). As each section is reviewed and determined complete, the filer will receive a "complete letter" from the FDA.
- This phased submission process is voluntary

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## Why is the Regulatory Process Important to Understand in a Licensing Arrangement

- For purposes of valuing a license, it is important to understand what regulatory pathway a product falls under and then to identify where the product is in that pathway
- This allows a licensor to determine the cost to bring the product to this point in the license process and therefore what it needs to "recover" as part of the licensing process
- It also sets realistic expectations as to the additional time and costs going forward that will be incurred in positioning the product for approval as well as market entry
- This is much of the information you will need to approach a licensing partner and to position the deal to meet with a successful signing of a license

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## 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 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 particularly important for innovator products not yet approved for market. If not clearly defined, it can lead to litigation as to ownership of the improvement or new invention.

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## Step Two: Key Licensing Terms

- Key terms
  - 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 or not understood at all. A representation concerning the pending approval is never advisable. Avoid “absolutes” and overbroad terms.

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## Step Two: Key Licensing Terms

- Key terms
  - 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.
  - 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.
  - 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 form making, using or selling . The license needs to expressly deal with this type of situation.

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## Step Two: Key Licensing Terms

- Key terms
  - 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 has substantially the same terms

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## Step Two: Key Licensing Terms

- Key terms
  - 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: marketing materials often include the label as well as “leave behinds” or package inserts in the case of drugs. Two different types of liability can arise here:
    - first, improper messaging can lead to mislabeling claims
    - second, product liability claims (failure to warn, duty to warn, lack of controls on safety of ingredients or API)

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## Step Two: Key Licensing Terms

- Key terms
  - 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 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.

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## Step Three: Negotiating and Avoiding 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 therefore not being able to let go of the asset to the licensee – the need for overwhelming control
    - Approaching the negotiations with a "winner take all" attitude – the inability to compromise means no negotiation
    - Have an internal mechanism for monitoring the license arrangement, this can lead to early issue spotting
    - 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 – get consensus on other important terms as that will drive the dollars
    - Understand the issues critical to the other party – give ground where it does not cost anything

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## Step Three: Negotiating Pitfalls

- Pitfalls
  - 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
    - 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 available
    - Account for publication rights and public statements. Have a nondisparagement and confidentiality provision included

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## Step Three: Negotiating Pitfalls

- Pitfalls
  - 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
    - Make sure that the licensor includes a "right to use" provision
    - Don't try to account for every situations which could possibly arise during the life of the license. This can create liabilities and obligations where there was no intent to do so
    - Make sure the license terms do not inhibit the ability of either party from capital investments or other deals

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## Conclusion

- 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.

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## Questions?

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