Negotiating Pharmaceutical Licensing Deal Structures: Confrontation or Common Ground?

By Michael J. Martin

Start your engines and look for the checkered flag! Lets's face it, product and technology licensing negotiations between pharmaceutical and biotechnology companies are challenging, difficult and protracted. From initiating a transaction to ultimate contract, it can take more than a year, numerous term sheets and many contract drafts! The process is wearing. Negotiations involve a myriad of financial, regulatory, supply, development and operating hurdles which have to be addressed and not to speak of the personal egos involved. Further, this does not address the internal approval process which adds anxiety to the negotiations. The Business Development Officer engages in a diplomatic joust between these internal and external pressures.

The purpose of this article is to focus on the key "Deal Breaker," the "Almighty Buck!"–or in licensing vernacular: valuation and allocation thereof. More specifically, the article discusses key financial issues and provides a methodology to identify and resolve such conflicts. These conflicts will be discussed in the context of who has the negotiating leverage. For brevity, key contractual negotiating issues such as Field of Use, Intellectual Property Issues, Territory and Termination Provisions are excluded from discussion. No, this is not designed to be a "cookbook" process to resolve various negotiation differences, but to provide a framework to guide discussions which may lead to resolution and reduce confrontation. The key points which will be discussed are:

- Valuation
- Deal Structure (Allocation of Value)
- Resolving Disputes in Valuation
- Understanding Specific Financial Disputes and Suggested Remedies
- Key Financial Contractual Issues.

Valuation: Where You "Sit" Determines Where You "Stand"!

A key negotiation question is, how much is the license worth?

The value of the license is tied to a myriad of business factors such as uniqueness, strength of the intellectual property, proximity to market approval, regulatory approval scope of geographic rights, competition, targeted markets, product cost and development time, risks and costs. In evaluating the product or technology, not surprisingly, companies inevitably arrive at two different valuations based upon the parties relative negotiating positions. Nonetheless, the valuation of the opportunity can be determined by three different approaches:

- Net Present Value of the Cash Flows—this is the most common method used to determine the value of a licensed product by projecting a revenue stream, development costs and cash flows discounted at an appropriate discount rate to determine the net present value of the asset.
- Comparable Value—what is the value of a like transaction?
- Liquidation Value—rarely used as a proxy for value but has some relevancy if the technology is in-licensed subsequently developed, sub-licensed and or out-licensed at another stage.

Unfortunately, these valuation approaches suffer from various shortcomings.

- First, at the very base of disagreement, is the perception of the risk-reward tradeoff. As discussions progress, the negotiation teams will marshal the facts to reinforce their views. The licensee will emphasize the risk and conversely, the licensor will accentuate the reward. More specifically, because products usually takes several years to develop, companies will rarely agree on the product sales potential, development costs, market introduction, competitive advantages, and appropriate valuation methodology.
- Second, there are a variety of qualitative factors which can affect valuation amount and how the deal value is allocated between partners.

Breaking Valuation Deadlocks

Suggesting the following specific process may be useful in arriving at a mutually accepted value or perhaps a value with a smaller dispersion of values. Briefly there are two steps:

1. Financial Issues: Each party independently develops a financial forecast with net present value of the product or technology exclusive of deal terms of in an attempt to arrive at a high, low and base case for valuation. The negotiating parties would be expected to provide a sales forecast, estimate of development costs, expected product indications and

product launch expectations. Invariably two different valuations will emerge, but the exercise will serve several useful purposes:

- Identify critical product risk factors which would provide a basis for identifying development milestones that should trigger payments.
- Mutually agree on product uses or indications which are critical for commercial value.
- Determine product differentiation and competitive advantages, thereby determining market penetration.
- Earmark critical development costs: size of the clinical trials, risk and duration.

2. Valuation Mediation: While there is likely to be no mutual agreement on value, the valuation exercise will narrow the absolute differences and invariably lead to some narrow range of values. In short, both companies arrive at relatively different product values and there is a value gap which represents a difference between the two parties which should be allocated as contingent payments in a deal structure.

Allocating Value Between Partners-Breaking the Deadlock

Assuming one can agree at a tight dispersion of value, an interesting approach to allocate value is to use a Value Allocation Grid as depicted below. Please note that allocation of Value is not designed to be a dogmatic tool to allocate value between the partners, but a discussion guideline which will frame and lead to a mutually agreed upon dispersion of value.

Importantly, Table 1 is based on the following tenets:

- Product value is a function of its proximity to commercialization, the number of alternative licensees and market potential.
- As the probability of success increases, more value is accorded to the innovator or licensor (Small Biotechnology). Conversely, the further the product is from the market more value is allocated to Large Pharma.
- The allocation of the Product Value Spilt between licensee (Large Pharma) and licensor (Small Biotechnology) changes as the probability of success increases.

The Value Allocation Grid (VAG) is for illustrative purposes and assumes that the Small Biotech Company is out-licensing a development product at the various research phases. For example, at the Preclinical or Phase I the value accorded to a project is deemed to be extremely low with a very high risk of failure whereas conversely, at Phase III or marketed the value is relatively higher.

Despite the best negotiating efforts, there will be a Value Gap between the licensee and licensor.

Identification of Valuation Conflicts

The following valuation issues usually arise regarding financial negotiations between the two parties. For illustrative purposes, the example in Table 2 assumes that the large pharmaceutical company is in-licensing whereas the biotechnology company is out-licensing. Table 2 identifies the issue and tactics to resolve the conflict. The assumptions in Table 2 are that the relative posture of either Large Pharma or Small Biotech will be determined by the relative negotiating leverage of either company.

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Who has the Negotiation Leverage? Translating Financial Negotiating Tactics and Using the Valuation Grid

The key elements which determine which party has the negotiating leverage throughout the discussions are the following: the value of the product, the number of alternative licensees and its proximity to market. For example, assuming the product is at preclinical stage, few alternative licensees and a long and risky development cycle. The Licensor will have the leverage assuming again that there are few competitive licensees. Referring to the Valuation Grid, the approximate value distribution of the product or technology should be about 70 percent to "Large Pharma" and 30 percent to "Small Biotech." In this

Table 1. Value Allocation Grid: Biotechnology Product

Product Status	Phase I	Phase II	Phase III	Pre-Market
Absolute Value:	Low	Medium	High	Higher
Probability of Product Launch[1]	10%	30%	70%	90%
Value Split: Large Pharma[2]	70%	50%	40%	30%
Small Biotechnology	30%	50%	60%	70%

1. Chances of a product being commercialized. 2. Licensee. 3. Licensor.

Table 2. Financial Negotiation Positions: Large Pharmaceutical Company vs. Biotechnology Company

Topic	Large Pharmaceutical Company (In-license) Negotiating Positions	Biotechnology Company (Out-license) Negotiating Positions	Comments or Resolution
Absolute Value of License	Low-high risk	Higher-potential of commercialization	Recognize value difference and reslove through milestones tied to commercial success, i.e. sales milestones.
Payment Structure	Back loaded	Front loaded	Negotiated-key determinant: Investment spent/risk of commercialization
Upfront Payments	Low: why? Emphasizes future risk and development cost burden.	High: why? Sunk development costs should be recouped.	Use comparable deals to resolve
Contribution to Commercialization	Development costs and regulatory expertise	Provides development guidance and clinical supply	Negotiated
Future Payments	Tied to tangible events leading to value added product commercialization	Tied to events which Biotechnology Company has control	Contract definitions: clarity about event triggers for payment is necessary.
Type of Future Payment	Preferences for royalties on sales vs milestones - why? Royalties shift payment tied to commercialzation	Preference for earlier milestones not associated with commercialization	Negotiated-use comparable deals as a guide
Financial Reporting Constraints	Minimize effect on parent income statement	Desires to report sales or co-promotion payments not royalties	Negotiated and structured
Commerical Role	Control of product pricing sales and marketing	Commercial involvement	Co-promotion product rights to Biotech Co.

case, Small Biotech can expect to receive a more back loaded compensation transaction structure with many of the financial milestones tied to future regulatory or commercial events. Alternatively, for late stage projects which have significant value which are essentially 'de-risked,' small biotech would have the negotiation leverage. Large Pharma can expect to receive an estimate of 30 percent of the value with approximately 70 percent of the value allocated to Small Biotech, Small, Biotech could expect that the deal structure would be more "front loaded" with relatively higher upfront payments, a significant sales and marketing role, comparative larger milestones and royalties.

In summary, valuation is a function of size of the opportunity, proximity to commercialization and the number of licensees interested in the product or technology. Deal Structure, or the allocation of valuation between each company, is a function of the relative negotiating leverage of each company which is also related to the value of the technology. Late stage and commercially proven technology or products are deemed less risky or conversely more valuable and accord the owner more negotiating leverage in the licensing discussions. For early stage products or technologies, financial compensation is usually back loaded reflecting relative commercial uncertainty. Conversely, for late stage products, financial compensation tends to be front loaded. ■