Valuation Of BioPharm Intellectual Property: Focus On Research Tools And Platform Technology

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The valuation of intangible assets typically covers selected economic theories behind valuations, including the well-known Market, Cost, and Income approaches. In an effort to educate biopharmaceutical professionals on the details of intangible asset appraisals, we focus here on two areas within the biopharmaceutical field that create special problems for assigning an accurate value to technology – research tools and platform technology. How should an appraiser value these types of technology?

For this, it is critical to understand the basic concepts of valuations and then to design valuation methodologies so that they address the uniqueness of biopharmaceutical technologies. Although the biopharmaceutical industry subscribes to the same economic principles as other industries, it is sufficiently different to require special modification to standard valuation procedures. Market, cost, and income approaches will always apply to this industry because they reflect economic theories; however, for conducting a specific valuation, these general approaches should be modified to reflect the realities of the biopharmaceutical industry. In this industry, there is significant uncertainty in the successful conversion of technologies into final commercial enterprises; moreover, technologies must pass many governmental regulations. These factors dictate the design of unique approaches to capture the uncertainties in the commercialization of biopharmaceutical technologies. These approaches include (a) the royalty rate, (b) Monte Carlo approach, and (c) probability analysis combined with the income approach.

Before understanding the mechanics of valuation and the aforementioned approaches, it is important to understand certain elements in order to arrive at a good conclusion of value. In the past, appraisers assumed that a technology could not be separated from its associated business, so they conducted the valuation of the business and then concluded that the technology component must be equal to the value of the business. Now, we recognize this to be a false concept in that there is more value in the business (vis-à-vis sales and marketing, as well as manufacturing) than in the value of the technology. So, to value a technology, it is necessary to extract the contribution of the technology from the total value of the business.

A. Valuation Basics

The most important element in a valuation is to understand the context of valuation. The appraiser needs to know the purpose of the valuation exercise when determining the value of a specific bundle of technology. In other words, is the value of the technology stemming from internal development using in-house business know-how and manufacturing capabilities, or through a joint venture partner with the necessary complementary assets, or for a pure licensing opportunity? Although the technology bundle is the same, the dollar value of the technology could be significantly different depending on the specific context in which the technology is leveraged.

The second step is to identify the technology bundle in need of valuation. Often a valuation exercise is started when the client gives the appraiser a set of patents. Then, subsequent interviews with R&D personnel indicate that significant know-how, trade secrets, and trademarks are critical to the success of the business. So, valuing the technology bundle from the standpoint of patents only versus patents plus additional intangible assets will result in different values.

The third step is to identify whether the technology bundle being valued represents a key technology or an incremental improvement to an existing technology. A key technology is that which can create a stand-alone business around itself, while an incremental improvement represents an enhancement to an existing product and/or process. This concept is critical because, in an incremental valuation, one calculates the additional review expected from the improvement, whereas a key technology represents the total revenue from the market application or profitability arising from the sale of the associated product.

Valuation is basically an attempt to measure the impact of the technology on the total business. Simply, technology impacts a business in two general ways: by reducing costs or by generating additional revenue. Further complexity comes out of the details. For example, if a technology reduces costs, how exactly does it do this? Does the technology improve yield so that a company can avoid building another plant? This sce-

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nario is very common in the electrical generation industry. Or does the technology allow the company to use cheaper raw materials, resulting in improved profits per each unit of product produced?

However, if the technology increases revenue, then detailed follow-up questioning should be directed toward how this additional revenue is generated. Does the technology create a stand-alone business generating completely new revenue from new products? Alternatively, an improvement to a product may result in an increase in market share. Everyone is familiar with "new and improved" slogans that are put on products to correspond with a company's developmental improvements. Examples of this notion include liquid detergents and fabric softeners within a controlled release capsule. Alternatively, a technology could maintain the same market share but lead to an increase in price. This is typical in the electronics industry, where continuous improvements are necessary to keep the prices high. For example, Palm Pilot puts additional functionalities on its products and then charges higher prices; likewise, in the computer industry, innovation is retained so as not to lose market share.

In other words, the technology can contribute to market volume by selling more or by offering enhanced properties for which the customer is willing to pay a higher price or by allowing the product to be manufactured at lower cost. All the above scenarios have a positive impact on profit and result in enhanced revenue to the owner of the technology.

B. Valuation Variables

Having set up the problem and decided upon the approach to be followed for determining the value of the technology, it is important to look at the information necessary for determining the value of the technology. The factors used for this determination are discussed in detail below.

Valuation variables are boundaries applied to the valuation exercise so that one can arrive at a reasonable assignment of value. These boundaries include the following:

- Valuation period
- Market size and growth
- Revenues projected for the business enterprise
- Analyses of the probability for commercial success of the technology
- Risk and discount rates
- Royalty rates

Once these variables are derived through research, they may be used in different valuation approaches in order to give the best representation of value.

In determining the valuation (time) period, one needs to assign two end points, the ending date and the beginning date. The ending date is easy to assign for a biopharmaceutical technology. It is usually the last day of a patent's life or any extensions due to the Hatch-Waxman Act, which accounts for delays due to the approval process of the specific product (e. g., drug). This extension could be up to five years.

On the other hand, for a biopharma-ceutical technology, it is difficult to assign the beginning date on which the product starts to generate revenue. Considerable uncertainty in the success of the technology through human clinical trials and delays due to governmental approvals make it difficult to assign a starting date. As a result, one usually looks for and examines technologies that are similar or comparable to those being valued in order to get an understanding of the time it took for these comparable technologies to be initially commercialized. This information is readily available in the biopharmaceutical industry. So, although one could argue that the specific technology being valued could take longer to commercialize, it is reasonable to assume that it will require a similar or even shorter time to commercialization, since the current managers of the technology could learn from others in the industry and complete the commercialization process faster.

The analysis of market size and growth is one of the most misunderstood concepts in the bio-pharma-ceutical industry. We have reviewed many business plans for solid, innovative technologies and, in almost every case, the author of the business plan addresses the market for the specific technology as the total market available because it is assumed that the technology will solve problems associated with the whole disease. So, a typical business plan statement is, "this technology is very critical to oncology study and addresses the multibillion dollar worldwide market for cancer ailments." However, investigations of the technology and the related patent literature reveal that the technology is mainly effective for skin and lung cancer and not for all other forms of cancer. That is, the market is no longer the multibillion-dollar market for all cancer therapeutics, but rather it is specific to the market for skin and lung cancers.

The next step is to examine the growth rate of these diseases for the past few years, from which it can be reasonably assumed that similar growth could be anticipated in the future. If the treatment cost per patient is known, then the revenue (i.e., the market for the technology) can be calculated.

For every industry, appraisers must determine different elements of risk for the revenue that a company expects to generate. In general, these elements include country risk, industry risk, company risk, and technology risk. In the pharmaceutical industry, a technology's development stage is one of the critical elements in assigning risk. That is, in early stages, such as drug discovery or preclinical testing, a new pharmaceutical is at greater risk than when it is in Phase II or Phase III clinical trials. However, in assessing early-stage risk, there are enough data and statistical studies to aid in measuring the probability of success for any pharmaceutical technology at any of the required development stages.

Once an appraiser determines the expected revenue, it is critical to determine how much money is necessary for a company to develop the technology all the way to commercialization. In other words, how much of the total revenue will a company retain at the end? If we know that a specific company is implementing the technology, then this exercise is simple – the specific company's profit margins and their tax rate are used. However, if the company is a hypothetical organization or the company is not sure which specific licensee will be commercializing the technology, then a proxy market approach must be used. This approach entails that a large number of companies existing in the same industry or possessing similar technologies be analyzed; moreover, it is essential that these companies are public so that one can find public information on their financial performance. This analysis relies on two key assumptions: (1) in an efficient market, everything levitates toward equilibrium, resulting in similar performance, and (2) the management of the current technology will perform similarly to that of other companies in similar circumstances.

Once the variables of the technology are determined, then all pieces of the puzzle are in place to assemble the final valuation and, hence, determine the value of the technology.

C. Valuation Approaches

In the biopharmaceutical arena, three main approaches are most used. These approaches are (1) the Income approach, (2) the Probability Analysis approach, and (3) the Royalty Income approach.

Many appraisers typically rely on the "cost" and "market" approaches. Although these are generally applicable in valuation, they are rarely used in biopharmaceutical valuations. The Cost approach is usually used when the application is at such an early stage of development that its market application is still unclear.

In the biopharmaceutical industry, a company practicing a technology will typically develop that technology on a global scale and will rarely license it to competitors using a known market number for the sale of that technology. As such, the "market" approach is rarely used for biopharmaceuticals. This runs contrary to what is observed in other industries, such as the chemical sector. For example, in this industry, the costs of manufacturing and shipping of polyethylene and polypropylene are so high relative to profit margins that one single company cannot muster the financial resources to supply the entire world's needs of these commodity chemicals.

The biopharmaceutical market is different altogether. In fact, if a company cannot have access to the global market, in many cases, it would not develop the market, since (1) the costs to bring inventions to market are prohibitively high, and (2) pursuing a global market is the only way a company can support its growth.

The Income approach is calculated by determining the total revenue that could be generated from the anticipated sales of a product. In this approach, the net income (or, more accurately, the cash flow that could be generated from this revenue) must be calculated. This requires that all costs associated with the generation of revenue must be subtracted from the total predicted revenue. Such costs include the costs of production, sales, marketing, R&D, and regulatory approvals, as well as, of course, taxes. The anticipated future revenue is then discounted at a special discount rate. In the Income approach, the discount rate is the most critical variable, since it captures all of the important elements of risks, namely, the country, the industry, the company, and the technology.

The Probability Analysis is a refinement of the Income approach. A biopharmaceutical technology can experience several outcomes and take a number of different paths, which generate a number of "go/no go" decisions during the course of a biopharmaceutical's development. Thus, it is often worthwhile to do probability analysis for biopharmaceutical valuations.

In this analysis, the appraiser conducts an income calculation at the last successful step of each of the different paths or steps in development. Then, using statistical probabilities through research, the appraiser reduces the value based on the probability of passing from one stage to the next.

If the unknown in the probabilities does not reside in moving from one step to the other but rather in variables such as sales price, cost of production, degree of market penetration, etc., then it is possible to conduct a Monte Carlo analysis of all the variables, in which case analysis software will conduct enough iterations to obtain a most probable value. But, like any valuation approach, the quality of input (to capture the ranges of all the variables) is critical to deriving a logical and accurate value.

In most industries, one royalty rate is usually used to calculate the royalty income; however, in the biopharmaceutical industry, the situation is different. The long development time of a biopharmaceutical and the prevalence of "development-stage" companies that concentrate on developing technologies up to a certain phase have made it necessary to offer milestone payments until a commercial product is produced. Then, at the time of commercialization, a royalty rate kicks in to capture a return based on the revenue from product sold.

These milestone payments are usually paid by large pharmaceutical companies at the beginning of each phase. For example, upon successful completion of its pre-clinical testing, a company would receive $2.5 million at the beginning of Phase I clinical testing from a co-development partner so that its technology can be developed to Phase II clinical testing. Then, the company would request another milestone payment to proceed to the next phase. Such milestone payments, along with royalty rates, represent one specific example. A wide range exists for milestone payments and royalty rates that could be charged, depending on the strength and the size of the market, the availability of competitive technology, and the corresponding stage of development. In general, if a company asks for large sums of milestone payments, then royalty rate at the end would be lower; alternatively, if milestone payments are low, then royalty rate would be high. So, one must look at the whole package in its entirety to determine the availability of profit margins remaining for the final producer of the products.

So far, we have outlined the most popular valuation methodologies used in the valuation of biopharma technology. Each of these methods can be used to determine the value of a technology; however, depending on the purpose of the valuation, one method is invariably favored over the other. Although this selection is not absolute, Probability Analysis and the Income approach are used in combination when valuing technology for the purpose of raising capital (e. g., first or second round funding, initial public offering (IPO), or even mergers & acquisitions).

If the client is interested in licensing the technology, then the Royalty Income approach is used. In many instances, the appraiser should conduct both of the above approaches to determine if any large discrepancies exist. If so, then, the assumptions in the models must be revisited. Typically, our experience shows that the assumptions are internally consistent when the different valuation methods yield values that are within 80-90% of each other.

D. Specific Examples

In the biopharmaceutical field, two areas create special problems for assigning an accurate value to a technology – research tools and platform technology. How should an appraiser proceed to value these types of technology?

i. Research Tools

Research tools, in general, could mean developed methods and reagents and /or data compilation used by scientists to develop therapeutically useful medications. From a business point of view, research tools should be defined as innovative approaches permitting scientists to do their job better, cheaper, and/or faster. Better could mean a more accurate analysis of an assay from, for example, better imaging software or higher resolution in a diagnostic tool. Cheaper could mean cost reductions from using cheaper equipment or labor or less expensive raw materials to produce a medication. Faster means progressing from one phase to another faster or delivering end products more quickly to the marketplace than could be done before.

In all of the above definitions, one must determine if the research tool solves the rate-determining step in development. That is, if a research tool can increase the speed of a step, but that step is not the slowest in the process, the total impact of the technology cannot practically be measured because there is another step that is slower and rate-determining. In those instances, being faster, although interesting, does not impact the total value because it has no impact on the delivery of the final product.

However, if it is a key step, then it will have a major impact on the total value of the technology. For example, in the mapping of the human genome, several technologies were developed to screen larger numbers of genes faster, and the final impact was that final results were delivered ahead of schedule. So, the tools that were developed had an obvious impact on the rate-limiting step. In such a case, value is measured by the reduced costs of delivering the final results. That is, what would have been the cost of developing the database of the human genome using old versus new methods? In this case, the impact may be measured in labor, material and equipment. In conducting the valuation, the income approach would be used for each technology; then, the two values for both technologies would be subtracted from each other to yield the Net Value, which represents the impact of the faster research tool.

If the technology is "better," then is it improved sufficiently to expand the market or to permit a new application. One example is enhanced MRI imaging wherein computers can display slices of the brain, liver, or other organs in the body. This enhanced imaging technique will have an impact on both doctors, who will prescribe this test, and insurance companies, who will pay for it, because less accurate measurements would result in more expensive treatments for undetected cancers or other ailments that could be otherwise detected with the technology. So, the valuation calculation rests on the assumption that this enhancement will result in more support for the use of this diagnostic tool, resulting in additional revenue arising from screening more patients. In a valuation such as this, it is also important to follow how payments are done – i.e., is it a onetime fee or a per-test revenue stream?

If the new technology is cheaper, then the valuation is simple. One simply totals all of the cost savings, which will measure the impact due to a cheaper technology. The total cost savings are considered as the value if the technology is implemented internally by the company.

If the cost savings can be realized by using cheaper raw materials to produce a certain drug but the company has to invest more money into capital equipment to permit use of the cheaper materials, then this additional spending by the company must be subtracted from the total cost- saving benefits.

There are many discussions of reach-through royalty rates whereby companies who have developed research tools desire royalty rates on related, finished products because their tools helped companies identify the human genome faster. However, this is difficult to quantify, so licensors can seek but are rarely granted such rates for research tools. This reach-through is justified and appears only in patents wherein the claims cover both the tool(s) and the end product(s) that could be generated from using such tool(s).

Finally, the final value in a cost-saving scenario should be divided between both parties in a licensing deal, i.e., benefit is shared between the two parties. In a real-life situation, however, the split is closer to 25-75%, based on the costs of the complementary assets needed to commercialize the technology.

ii. Platform Technology

The other set of technologies that is difficult to value includes Platform Technology, which is defined as a new area of science that has multiple market applications. The term "platform" refers to the possibility of developing the technology into two stages. First, the basic working understanding of the technology is developed; once that is established, then, work is started on developing specific market applications.

Examples of platform technology include stem cells, superconductivity, and nanoparticles. In all of these examples, the development of a finished product depends on a basic understanding of related material science. This understanding might include novel ideas that are patented. Then, or at an earlier stage, an organization could patent different market applications from such materials.

A dilemma exists on how to conduct such a valuation. In fact, such a valuation is not difficult; however, appraisers create confusion by trying to lump both stages into one and then trying to arrive to a single number. In other words, they mix two different types of technologies into one valuation approach. In reality, there are two valuations: the first one calculates the value of the basic science, and the second values the market applications. Valuing basic science entails using Cost or Market approaches. As we have seen using a Royalty Rate approach, milestone payments are used in earlier stages of development to cover expenses and some profit. So, in the case of a platform technology, if a patent covers the basic science, then the Cost or the Market comparable approach should be applied in the valuation. If the technology is specific for a market application, then the Income/ Probability approach is appropriate. If an organization has both parts of the platform technology, then two valuations must be done and then added with special care to ensure that one portion of the technology is not double-counted into another. This approach can be illustrated using stems cells as an example.

In Figure 1, we have outlined the mechanics of stem cell biology into eight steps, each of which has associated patents. But, in reality, this scheme could be grouped into two phases. Patented technologies related to steps 1 through 5 represent the development and enabling of the platform technology, while steps 6 through 8 present the implementation of the platform technology into specific market applications.

Figure 1

The first step in valuing a platform technology is to define how it applies to each of these two phases. This will help the appraiser to decide on the best approach to calculate the value.

The first phase of the stem cell platform technology begins with a human egg, from which contents are removed. Then, a stem cell is inserted into the egg. Then, DNA from the skin cells of a patient is injected into the new progenitor cell and then those stems cells containing the DNA of the patient are allowed to grow. Up to this point, there are no market applications. So, for any patented technology on methods, tools, and procedures that apply to stem cells, it is necessary to measure the cost savings or the market value for such research versus using other comparables.

In the second phase, one can start examining the technology in terms of its impact on the patient, which translates to market applications. So, if the schematic (the stem cell process) is followed from step 5 onward, the technology begins to take shape. That is, in one scenario, the developing stem cells could be programmed to differentiate into neurons, which could be used for treating neurodegenerative diseases (such as Parkinson's disease) or spinal cord injuries. In this case, the calculation would rely on the Income approach because a number of cases can be defined for each market. Then, one can calculate the revenue generated and the profit margins, resulting in a final calculation of the income that could be produced from transforming stem cells into neurons. Similarly, one can do the calculations for the differentiation of stem cells into liver cells and heart cells, which would have their own unique medical and market applications.

In summary, it is critical to understand the basic concepts of valuations and then to design valuations so that they address the uniqueness of biopharmaceutical technologies.

Figure 1—Valuation of Platform Technology *Inavisis*