Appraising Inventions: The Key to Technology Management

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ABSTRACT

The process of developing a commercialization strategy for an invention begins with evaluation of its commercial potential at its current state of development. The evaluation includes assessments of technical feasibility, patentability, and marketability. Further appraisal of risk and time factors, costs, and estimated revenue yields a risk-adjusted present value. A hypothetical septic shock treatment provides a model of an appraisal that includes estimates of market demand and penetration, royalties and income.

INTRODUCTION

When an organization seeks to maximize the value of an invention through development or licensing, the commercialization process begins with an appraisal that includes analysis of technology, patentability, and marketability, as well as calculation of the expected value through the term of the patent. Technology managers allocate limited human and financial resources to inventions in their portfolios on the basis of rational assessments of factors such as anticipated risk, cost, time, and revenue.

The hypothetical case in this article presents a greatly simplified example of RCT's approach to technology appraisal.

TECHNICAL ASSESSMENT

The technical assessment defines the inventive concept, its theoretical basis and scope, as well as potential commercial applications and technical value.

A broad, objective review of fields in which the invention may have an impact requires unbiased research by an individual who understands the technology from a scientific perspective.

Resources available to the assessor include the inventors, their academic and industrial contacts, and searches of published technical articles and patents. Inventors often recognize their colleagues' technical publications but they rarely investigate patents. Often, industrial contacts provide useful information despite their biases and potential conflicts.

A vision of potential products results from an understanding of the invention's technical limitations. The assessor must identify other technologies required for commercialization, unprecedented products or markets, potential for circumvention of the patent, difficulty of detecting infringement, potential users of the technology and their motivations, and the

costs and benefits of adopting the technology in comparison to available or anticipated functional equivalents.

PATENTABILITY ASSESSMENT

An assessment of patentability provides a basis for formulation of patent strategy and an understanding of the strategy's strengths and weaknesses in relation to potential markets for defined products. An initial investigation reveals any bars to patent rights due to publications or failure to meet requirements for utility and enablement. Licensable claims must adequately cover the envisioned products.

A monopoly advantage enables the seller to induce and protect investments in product development. If a monopoly is unavailable, then a dominant patent position yields more value than a subservient position. The ability to either dominate follow-on technology or block current technology will provide value and leverage in licensing.

Geographic breadth of patents in countries where the invention will be practiced protects both licensee and licensor in their efforts to exclude competition for a time and maximize return.

Practicality and economic feasibility determine the capacity to enforce patents. Consider, for example, a new, unapproved use for a drug that is currently marketed for an approved use. Physicians could infringe patent claims for the new use by writing prescriptions for the unapproved use of the drug. Such infringements prove difficult to detect and costly to prosecute case by case.

Finally, infringements of patent claims to a process for making a product obtainable by other means may prove difficult to detect, unless the product bears traces of the claimed process. Alternatively, an unpatented process may circumvent the contemplated patent. Consideration of all these factors permits a determination of a patent's value to the licensee.

MARKET ASSESSMENT

The goals in market assessment include determination of the technology's expected value in marketable products, identification of potential licensees, and development of a commercialization strategy. After identification of optimum and secondary commercialization paths, the licensor can estimate appropriate royalty rates. While royalty rates bear directly on value, we need not repeat here the many published techniques for their determination. Rates and calculation theories vary among industries and technologies, based in part on their impact upon the final product's value.

Other factors that may require consideration include exclusivity, developmental investments, start-up companies, marketing costs and environment, competing technologies or products, and the target industry's receptivity to new ideas and willingness to invest in them.

FINANCIAL ANALYSIS

A financial analysis estimates the present value of a technology, an important value for planning decisions such as whether to allocate resources to commercializing the invention, and how to structure and value investments. While technical, market, and patentability factors impact analyses, true value determinations also consider risk factors, costs, time, and revenue.

A naive analysis would set the present value of an incremental improvement to a technology-say, a cure for a disease-based on the erroneous assumption that the market equals current expenditures for treatment of the disease.

The more sophisticated analysis modeled below values a product for the interdiction or treatment of septic shock. Septic shock results when patients with systemic bacterial infection experience circulatory collapse, a severe drop in blood pressure with its associated complications. This blood pressure drop generally occurs rapidly, does not respond well to the usual pressor agents, and often leads to death within 24 hours. Each year in the United States and Europe, one million people develop sepsis and 35% die of the disease.

Rather than an intervention in the infectious cause of septic shock, this technology merely allows maintenance of blood pressure, prolonging the period during which the bacterial infection can be treated. The data in this example offer only an illustration rather than an exhaustive analysis.

The analysis begins with the patent's filing date, in this case of a GATT patent that will expire 20 years from that date. This determines the period of time during which revenue can accrue.

Next the appraiser determines the number of septic shock patients that could benefit from the treatment, how many will be treated, and how that number might change with time based on the expected date of product marketing and the percentage of market that would be captured if this were the sole available treatment. A treatment price provides the basis for an approximate calculation of sales and income, assuming a royalty rate reasonable to the industry.

Table 1 shows a financial analysis that employs these factors to calculate a present value for the royalty stream of about $23 million, calculated at a discount rate of 12%. Costs of patenting, development, and marketing are excluded in this table.

Table 1. Market for Septic Shock Treatment

Year	Patients (thousands) Sepsis	Shock	Market Penetration (%)	Treatment Market ($K)	Royalty at 5% ($K)
1995	1,000	500	0	0	0
1996	1,010	505	0	0	0
1997	1,020	510	0	0	0
1998	1,030	515	0	0	0
1999	1,041	520	0	0	0
2000	1,051	526	0	0	0
2001	1,062	531	30	47,768	2,388
2002	1,072	536	65	104,533	5,227
2003	1,083	541	80	129,943	6,497
2004	1,094	547	90	147,648	7,382
2005	1,105	552	90	149,124	7,456
2006	1,116	558	90	150,615	7,531
2007	1,127	563	90	152,121	7,606
2008	1,138	569	90	153,643	7,682
2009	1,149	575	90	155,179	7,759
2010	1,161	580	90	156,731	7,837
2011	1,173	586	90	158,298	7,915
2012	1,184	592	90	159,881	7,994
2013	1,196	598	90	161,480	8,074
2014	1,208	604	90	163,095	8,155
2015	1,220	610	90	164,726	8,236
				Present Value at 12%:	22,736

The model assumes that the invention occurred in 1994, no divulgation created a patent bar, and a provisional patent application was filed in 1995 to gain a year toward a formal filing and start of the clock toward patent expiration. For simplicity, this example assumes that one worldwide patent application was filed and that all patent actions

occurred on the first day of the year. The patent therefore expires at the end of 2015, together with the right to collect royalties.

We also assume that one million people in regions covered by patents will contract sepsis in 1995. Estimating conservatively, the patient population increases 1% per year. Half will experience septic shock, including the symptoms of circulatory collapse described above for which the product is appropriate. Nearly all patients who experience shock will be treated. The cost of the treatment is set at $300.

The model further assumes that a product will achieve development, FDA approval, and marketing by 2001. During that first year of product life, the treatment will capture 30% of the potential market, ramping up to 90% over three years and maintaining that level for the life of the patent.

We can now calculate the market size and the royalty return based on a royalty rate of 5%. Calculating a present value at a discount rate of 12% yields $22.7 million.

The large present value of the royalty stream predicted by this best-case scenario seems to call for commercialization of the invention. However, this model does not account for the risks associated with developing the product and bringing it to market. The present value falls to $98,000 after adjustment for the risk factors summarized in Table 2.

Table 2 Impact of Risk Factors on Present Value

Risk Factor	Probability	Risk-Adjusted Present Value
Patent issues in strength and geographic breadth desired	80%	$18,189,000
Patent survives future legal challenges	90%	$16,370,000
Company licenses project in current state of development	10%	$1,637,000
Regulators grant final approval	1%	$164,000
Public accepts product	100%	$164,000
Public prefers product	60%	$98,000

Selection and quantification of appropriate risk factors results from extensive experience, research, and debate. These numbers, while inexact, provide a framework for rigorous critical analysis of a project's value, trackable over time as the probabilities of factors change.

At the time of most technology appraisals, the patent has not been filed. Additionally, despite the inventor's knowledge about his scientific competitors, the appraiser must conduct adequate industrial research to gain a sense of the anticipated patent's ability to dominate competing technologies. This perspective permits prospective licensees or investors to gauge potential returns.

The geographic breadth of patents also directly influences the ability to collect royalties. We could further assign a probability of patents issuing in each geographic region of importance and include a factor for each patent's strength. All of these risk factors change fluidly as additional information becomes available.

If we multiply the probability of obtaining a patent, set at 80%, by the probability of its surviving legal challenges, set at 90%, the overall probability of patent success falls to 72% at present. Because anticipated patents issue in all important areas, the 80% probability of issuance rises to 100% and ceases to negatively impact value, while the probability of surviving legal challenges may also change.

Similarly, each stage of technical development merits assignment of a degree of risk. University-derived technologies rarely permit easy assessment of the value of final products. Usually years of high-cost research precede product definition, development, and introduction.

The non-risk-adjusted value in the model assumed an existing product. Realistic risk factors include the project's attractiveness at its current state of development to a prospective licensee. This factor is influenced by performance of additional research to reduce the risk perceived by the licensee.

A more difficult assessment to control, the ability of a licensee to produce a marketable product, varies according to intensity of motivation, availability of capital, and influence of the product champion in driving the development process.

Recently, several products designed to interrupt the physiological progression in sepsis leading to circulatory collapse failed to gain regulatory approval following clinical trials. In light of this experience, we estimate the probability of licensing success for the product in its current state of development at only 10%. The potential licensee might view this as the probability of successfully obtaining regulatory approval. This probability would increase as additional data demonstrate the safety and efficacy of the treatment.

The likelihood of final regulatory approval might not exceed 1% based on industry experience with technologies at an equally early stage. If the compound proves effective in acute-care settings when administered for short time periods, long-term toxicity and safety issues may not arise. If these issues became significant, the estimate of probability of success would decrease. The compound must complete pre-clinical trials and Phase I, II, and III clinical trials. In this case, investigators can easily measure the uncomplicated end points for clinical trials: blood pressure or mortality. We anticipate low toxicity based on available information. At any point in the regulatory process, failure will drive the probability of success to zero along with the present value of the technology. Conversely, this probability increases upon achievement of regulatory milestones.

Public acceptance generally follows approval by regulatory authorities. In this case we define the consumer as the prescribing physician. In Table 1, a market penetration of 90%

represents knowledge of the need for intervention and recognition of a particular treatment. We assume a probability of acceptance by physicians of 100%. Note that this factor differs from market share as discussed below.

Patients could, of course, refuse treatment despite the advice of their physician. Recent products that encountered consumer resistance despite regulatory approval include genetically engineered tomatoes and milk produced using hormones.

Ability to differentiate the product relates to consumer preference. Although we have identified no competitors so far, some probably will appear eventually. The risk factor for competition depends on how users view this technology's differential utility, such as decreased side effects or increased benefits.

The model assumes that the product will reach the market first, capturing significant market share and recognition as an effective treatment. Assuming that competing products reduce this preference by 40%, we set the factor for product differentiation at 60%.

We calculate the probability of achieving success by multiplying together all of the assigned probabilities. For our example, this probability approximates 0.04% or 1 in 2,000. Based upon past experience with technologies at a similar stage of development and risk profile, this probability proves sufficient to attract investment interest compared to most university-derived technologies.

Alternatively, to value an investment in the technology or to sell it outright, we could multiply the probability of achieving the present value derived in Table 1 by the probability of attaining successful introduction (the product of all of the probabilities in Table 2). This yields a value of about $100,000 for the invention at its present state of development.

This estimated value should achieve accuracy within an order of magnitude if it employs reasonably accurate risk factors. Frequently, errors arise from inclusion of the same risk in more than one factor or from over- or under-estimating requirements for commercializing the invention. Naturally the accuracy of estimates increases as a product approaches realization.

How can we apply these estimated values? In addition to the previously mentioned determination of selling price, the estimate permits allocation of constrained resources to maximize value. Valuing technologies allows prioritizing of development efforts.

Additionally, we can examine the impact of alternative actions on value. For example, the value added by experiments that the inventor might do to reduce risk can be estimated against the cost in dollars or equity ownership. Similarly, an investor who funds successful experiments may expect to receive an increased share of equity in return for the investment. Alternatively, the investor withholds funding if the cost of a particular step outweighs an increase in value.

Time rules the commercialization process, particularly revenue production. Although we can license a patent application, we could not enforce it against infringement prior to issuance. Thus we seek a licensee who will commercialize the invention as quickly as possible to generate royalty income over the longest possible period until patent expiration. For our case study, royalties could reach $20,000 per day in the best-case scenario. Each day lost reduces income once the patent clock begins to run down.

An exclusive licensee will demonstrate high motivation to maximize return on investment by marketing a product as soon as possible, particularly if generic products promise to reduce market share and product price upon the expiration of the patent. Licensees of pharmaceuticals may experience difficulty in strengthening a monopoly position during the life of the original patent with new patentable material. Regardless, the licensor probably will not share in revenue derived from such additional patents.

Costs of developing and maintaining the technology also negatively impact the revenue stream in a number of ways. The licensor's cost of obtaining and defending patents is not included, because it probably will approximate the cost for similar pharmaceutical projects.

Likewise we excluded the licensee's development cost, which would figure into such revenue calculations as the amount of pre-royalty payments likely to be extracted. We included these costs indirectly in setting the probability of obtaining a license and gaining regulatory approval. A licensee performing this same exercise would balance its calculations of cost to license and develop product against expected profit. A licensor can take these into account when determining the type of licensee capable of affording the development of a technology.

This model, modified as needed over the life of a technology, guides allocation of resources, pricing of deals, and valuation of equity and investments. Much experience and research must inform the selection of the numbers entered into the simple spreadsheet and probabilities assigned to the risk profile. This effort affords a rational basis for making decisions about the value of a technology and the factors affecting its commercialization.