Evaluating Inventions from Research Institutions

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ABSTRACT

The patenting strategies of research institutions are based on three key decisions. The first involves whether or not to file a patent. This decision must be based on sound information about the market, the uniqueness and usefulness of the invention and/or technology, the likelihood of being able to obtain patent protection, factors related to the inventor, and the potentially paradoxical impact of patenting on the institution's social and humanitarian responsibilities. The second decision involves whether to market the invention to established companies or to develop a spinout business. The third involves how much to charge for a license. Related to all of these decisions is the key question of whether patenting is the most effective route to global access. Negotiating licensing agreements that are fair to the research institution, the private company, and developing countries can be challenging because research institutions may have difficulty determining fair market values. In addition to outlining a process for obtaining these values, this chapter offers some rough numbers for guidance. In general, the author concludes that it is far better to conclude a deal than to wait for the best agreement while fighting interminably for perfect financial terms.

1. INTRODUCTION

This chapter discusses how to evaluate new inventions arising from research at universities and other research institutions. It considers early, "university-stage inventions" arising out of basic research, rather than development projects. Most of these university-stage inventions will require substantial investments in both money and time to develop them into marketable products. Such investments will usually be very risky; neither the practicality of the technology nor its ultimate market acceptance will be known with any certainty.

It is assumed that the research institution's interest is primarily in the social functions of technology transfer: bringing new medicines and other useful products into public use, enhancing the competitiveness of industry by encouraging the use of new technology, and enhancing economic development and job creation. Revenue from royalties is assumed to be a secondary consideration. (Even in the United States, the Bayh-Dole Act, which gave U.S. research institutions the right to own and license out inventions from government-funded research, was enacted in the cause of economic development-not as a mechanism for funding the institutions. Twenty-five years later, the revenue produced, though useful to the institutions, makes up on average only a small percentage of their research budgets.)

2. THE EVALUATION PROCESS

Technology transfer offices evaluate early-stage inventions in order to make three decisions:

1. whether or not to file a patent on the invention

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- 2. whether to market the invention to existing companies or try to do a spinout
- 3. what to charge for the invention

Fortunately, these three decisions do not usually have to be made at the same time. And, of course, if the answer to the first question is no, then the other two questions are moot.

2.1 Decision 1: Whether or not to file a patent

It is assumed that money for filing patents is available but limited. The decision to file a patent should take into account answers to the following questions:

- Is this invention likely to get awarded a patent with broad enough claims to protect a product or a product line—not just a minor variation of an existing technology?
- 2. If patented, will this invention likely attract a licensee or investment for commercialization that will produce enough of a return to the institution to justify the patenting expense?
- 3. Is patenting the right route to maximize social access to the technology?

The answer to the first question on patentability is fairly easy to determine with relative (though not absolute) certainty. If time allows, a search of the literature that includes past and published pending patents will reveal prior art. When possible, this search is best done by a professional search librarian working side-by-side with one of the inventors. If potentially important prior art is found, a patent agent may be called in to evaluate its significance and the likely claims to be achieved by patent filing. The prior art search may also turn up dominating patents that may have to be taken into account.

The second question—will the technology attract investment for commercialization if it is patented—is far more difficult than the first to answer with any certainty. Market research studies take both time and labor. If the technology transfer office receives many invention disclosures (at the Massachusetts Institute of Technology [M.I.T.] we receive about 450 disclosures per year), there will not be enough resources to perform a market research study on every one. In addition, there may not be enough time for such a study before publication (particularly in academic institutions with a policy against delaying publication for patenting or other commercial reasons). The requirement for confidentiality before patenting also limits the depth of any market research study.

Finally, it must be realized that the more innovative the invention, the harder it is to get good market feedback. Potential users of new technology cannot easily judge the value of something they have never thought about before. Business histories are replete with gross underestimations of the potential of innovative products (for example, photocopy machines and home computers). Innovative inventions from basic research in universities should expect to suffer similar challenges.

So what is a technology licensing office to do? Below are some questions to consider. They will be answered, for the most part, through discussions with the inventors, some library work perhaps, some discussions with potential users or investors maybe, and the experience and judgment of the technology transfer staff.

2.1.1 The market

It will be important to try to answer these questions about what the market for the invention might be:

- What need does this invention satisfy? Is this a major, well-recognized need or a minor one?
- How is this need being met now? Or is it satisfied at all?
- What size is the market? Huge, large, small, miniscule? (As will be discussed later under pricing, more precision here is not usually needed by the patent holder, although much more precision will be needed by the licensee or investor.)
- Is the market already established, or will it need developing?
- Is this a growing field or a dying one?

2.1.2 The technology

The institution will need answers to these questions about the new and existing technology and how to develop the invention:

- How would this technology change how the market presently addresses the need?
- Is the new technology not only different from what is already available, but better? If better, what are the major benefits it offers?
- How certain is it that the technology will work? Can this be demonstrated to a potential licensee or investor?
- How long and how much money will it take to develop the invention into a commercial product?

2.1.3 *Likely degree of patent protection*

Answering the following questions will help decision makers determine whether obtaining a patent is worth the expense:

- Did the prior art search (or what is known about the state of the science) indicate that broad claims are likely?
- Is the invention at such an early stage in product development that the patent will expire before products reach the market? (Sadly, many have seen their patents expire just as the market began rapid growth.)
- Is the field moving so quickly that patents are irrelevant? By the time the patent issues, will the invention be obsolete? (This is not uncommon for software patents in the United States.)
- Can practice under the patent be detected, thus allowing for patent enforcement against infringers? (It may be impractical to enforce the patent if the manufacturing method is simple and requires no special materials, and the invention is not evident in the final product.)

2.1.4 The inventor

Inventor participation in the development of university-stage technology is usually critical. The inventor is most familiar with the technology and is most likely to have a vision for its use. Some inventors (particularly students or research associates) may wish to leave the research institution and join (or help form) a company. Most professors or senior researchers, however, will probably choose to stay at the research institution, although they may consult or work part time for the company developing the invention.

On the other hand, if the inventor has no interest in seeing the technology developed and will not help to market the patent, these tasks can be hopeless.

The following questions should be considered to decide how effective the inventor might be in finding a licensee or investor for the technology. As we shall see, not all of the findings should be documented!

- Is the invention in the inventor's major field of research? If not, is he or she at all familiar with the market's needs for the invention?
- Does the inventor have business connections in the field of the invention?
- Is the inventor famous? (It's a lot easier to market a patent with a Nobel Laureate's name!)
- Will the inventor be cooperative in meeting with potential licensees or investors to share his or her vision of the invention's potential and the means of developing it?
- Does the inventor have realistic expectations about the magnitude and uncertainty of the development task and the potential financial returns?
- Can relationships with investors or companies proceed reasonably or is the inventor too naïve or overly paranoid?

2.1.5 Social responsibility

In terms of public policy, patents are two-edged swords. They can protect investments very effectively. Moreover, the licensing of university patents has been shown to stimulate much earlier investment than the placement of inventions in the public domain. They can also bring muchneeded revenue to research institutions (although the revenue potential of university-stage inventions has been much exaggerated). On the other hand, patents can limit investment in new technologies when the patent holder (or exclusive licensee) does not invest in all of the fields that can use the patented technology. Patents can also sometimes be used to maintain high prices on necessary products by excluding competition.

As a side note, patents are particularly paradoxical in the development and distribution of drugs and vaccines for diseases in developing countries.1 Indeed, if effective drugs and vaccines for all diseases in developing countries existed and could be manufactured at low cost, a social philanthropist might wish that no patents existed, since in theory the absence of patents would allow competition, leading to lower prices and wider availability. But in the absence of effective drugs and vaccines, patents may be necessary to ensure profits for pharmaceutical companies, thus encouraging commercial investment in the research, development, and clinical testing of new drugs and vaccines. This paradox puts a special burden on technology transfer professionals. When licensing health- and agriculture-related patents from nonprofit research institutions, technology transfer professionals must try to patent strategically to protect profits in developed countries and encourage commercial research and development. At the same time, they must use mechanisms to assure that the poor can access the final products.

When deciding whether patenting a new invention is in the public interest, the following issues, among many others, should be considered:

- Is this technology self-evidently useful without substantial further investment in development? Will it be widely used even if it is not patented but put in the public domain?
- If the answer to the previous questions is yes, can the patent-holding institution nonetheless devise a nonexclusive licensing strategy that allows revenue to be generated without impeding the use of the technology?
- If the technology requires substantial highrisk investment, and therefore patenting and exclusive licensing is warranted, should patents be foregone in developing countries to encourage generic competition? (This approach is reasonable, under some circumstances, for health and agricultural patents.)
- Can the patent holder require sublicensing of other mechanisms to promote low-cost

manufacture and distribution in the public sector of developing countries?

- If the drug or vaccine is expected to be used only in developing countries, with little or no market in developed countries, will market aggregation through patenting and limited licenses create a sufficiently profitable market that will encourage development and clinical testing?
- Should the patent holder carve out free use of a patented research tool for nonprofit research institutions?

2.1.6 Local considerations

The decision to patent depends, to some extent, on the institution and its geographic location. For example:

- In under-developed regions (of both developed and developing countries), technologies well-suited to local industry and the technology skills of the region, especially, may be promoted to create jobs and strengthen the local economy.
- Public institutions, more than private institutions, may emphasize technologies that will enhance local economic development—particularly if technology transfer is one of the metrics that legislators use to decide how generously to fund a given institution.
- Medical institutions may decide to patent a product with a relatively small market, because of the potential benefit to patients.

In all, this set of challenges is formidable. For any given invention, most of the answers will be guesses at best; still, these should be *educated guesses*, and the judgment of the technology licensing office may be all that is available. Both the technology licensing office and, even more importantly, the senior administration of the institution must realize that a decision to file a patent is a decision to take a risk. Patents are expensive, and patent budgets are limited. Nonetheless, decision makers must realize that although it is easier to say no than yes, the sin of *omission*—not filing a patent on a technology that later becomes important—may be worse than the sin of *commission*, the filing of a patent that is never licensed. Decision makers should consider that if the requirements for patenting are too stringent, then only a few of the inventions submitted to the technology licensing office will be accepted for patenting. This will be discouraging to researchers and will result in fewer inventions reported in subsequent years.

2.2 Decision # 2: Whether to market the invention to existing companies or license to a spinout

Licensing to an existing company has many advantages over licensing to a spinout (a new company specifically formed to develop the licensed technology). An existing company already has its infrastructure in place, including management. The company usually has sufficient funds to develop the invention, and its financial health often can be readily assessed. The company also usually has distribution channels, and its brand name and market access will make final distribution of the product easier and more effective. From the research institution's point of view, the license agreement is much easier than spinout agreements, and potential conflicts of interest are far less likely.

This is not to say that licensing to an existing company has no difficulties and disadvantages. For one, it is difficult to get the attention of an existing company (particularly a large one) with new but unproven inventions. Existing companies have already set their research agenda and priorities, and a new technology needing development could cause disruption. It is also difficult to find within a large company a "champion" who will enthusiastically support a new technology that is not his or her own when it runs into the inevitable problems in development.

The single biggest disadvantage of licensing to an existing company is the risk that the company will lose interest in the technology, or, perhaps worse in the case of an exclusive license, that it will retain some interest in the invention but that the project will be given less priority and inadequate resources. When things do go wrong, it is often difficult for large companies to identify the right person to provide information or to negotiate a change in the license agreement.

The advantages and disadvantages of licensing to a spinout are almost the reverse of those for licensing to an existing company. At the beginning, at least, the spinout will be dedicated to developing the invention as its first priority. It will also usually be working very closely with one or more of the inventors; moreover, the research institution itself knows the people involved. The financial arrangements of the license may include both shares of stock and royalties, giving somewhat more assurance that the institution will get at least some return from its license. And, if the company's strategy does diverge from the original technology (or the technology doesn't work), although there will not be any royalties on the patent, the equity shares may become liquid and reward the research institution for its role in starting the company.

Spinout companies represent a substantial risk of conflict of interest, which can be on the part of the inventor/researcher or on the part of the institution itself. Frequently, both the inventors and the institution will own stock in the company. This can lead to an unhealthy interest in the company's fortunes-the parties involved may encourage the institution to make concessions on future IP, to sequester data from publication, or to misuse institutional resources or staff time. The situation is exacerbated if the institution also invests its own funds in the company. Thus, research institutions need well-crafted and well-enforced conflict of interest policies if they plan to engage in spinning out companies around their technologies.

Spinout companies are also fragile. They must find management talent and raise investment money. They are highly dependent on the talent of the management team, and a bad hire can set the company back for a year or more. A spinout company often has difficulty in marketing and developing distribution channels. In hard economic times, further investment may be very difficult to attract, and the research institution's equity shares may become valueless due to a down round of investment or a low-price sale to an acquiring company, made in desperation. And, because of the complexity of equity investments, the technology transfer agreement is likely to be considerably more difficult to negotiate than a conventional license.

The advantages and disadvantages of conventional licenses and spinouts will be different for different inventions. A spinout may be preferred when the following criteria are met:

- The invention is a *platform technology* that may lead to not just one but many products. It is difficult to justify the risk of a spinout when only a single product is envisioned. Also, a spinout company is more likely to try to exploit the full range of potential applications of the technology, while an established company will more likely focus on a single addition to its existing product line.
- There is no existing industry making similar products. It is difficult for a new company to compete in an established market unless the technology is overwhelmingly superior.
- The market is large enough to justify the risk. This is particularly true for technology requiring substantial investment in development. Since the failure rate of spinouts is often high, investors expect a very large return on their investments from the winners. A small market, therefore, will not be sufficient.
- Strong intellectual property (IP) protection exists in the country in which the spinout exists and/or in the major markets to which it intends to export. Patents are the primary protection for small companies against larger companies that enter a market after a technology is proven successful. Without them, the market strength of a large company that is the second to enter the market can overpower the innovating small company.
- At least one credible inventor will join the company as founder, consultant, and/or employee (the most important criterion). Without this *human technology transfer*, it will be almost impossible to raise investment money and much more difficult to develop the technology.

In reality, the choice between a conventional license and a spinout often is made for the technology transfer office. If the inventor is not interested in contributing to the spinout, it is unlikely to be successful. On the other hand, if the inventor wants to form a spinout and there are no clear reasons why this is impractical, then it is not advisable for the technology transfer office to "take the baby from its parent" and give the job to an existing company. Such an act would likely cause political problems in the research institution and could also discourage future inventors from reporting their inventions.

2.3 Decision #3: What to charge for the invention

Although research institutions may engage in technology transfer primarily for social benefit, most nonetheless expect to reap a reasonable financial return from those licenses. The company expects to make a profit from the product with the proviso that concessionary terms may be appropriate for critical public goods where the markets are small, or the ability to pay is very limited.

Under the usual (profit sector) conditions, how does a technology transfer office decide what is a reasonable return from licensing a particular invention? Unfortunately, all too many technology licensing offices spend far too much time trying to evaluate the total value of embryonic inventions in some supposedly scientific manner. Calculators are kept running on Net Present Value calculations and other more abstruse formulae, when the major inputs to the formulae-cost of developing the technology, cost of manufacture, the market adoption cycle, and the ultimate market size-are all unknown and cannot even be reasonably estimated. Thus, the calculations often fulfill the "garbage in/garbage out" axiom, producing largely meaningless results.

Fortunately, technology transfer offices are almost never asked (or able) to sell a technology outright for a single lump sum. (Few companies or investors would be willing to pay any substantial sum up front for unproven technologies even if the research institution was willing to make the offer.) Thus, the full worth of an invention need not be calculated at the time the technology is transferred. License agreements and spinout agreements share the risk of this uncertainty between the research institution and the company through a combination of payments, some at the beginning of the license and others later, depending on future sales or the company's future success.

In a *conventional license to a company*, the financial components of the license may include (among possible other terms, such as sublicensing fees):

- a license issue fee: a negotiated amount payable at the time the license is executed
- license maintenance fees: annual fees, usually creditable against royalties in any year where royalties are payable (Thus, the license maintenance fees function as "minimum royalties" in years when the product is sold.)
- patent cost reimbursement: almost always required by universities
- milestone fees: usually applied only when the technology is very risky and requires significant investment (Meeting a milestone—such as approval for clinical testing or regulatory approval for sale—validates the technology, allowing the research institution to expect more rewards after the relatively low initial license fees.)
- running royalties: usually a percentage of sales (Major value is expected here, but it is contingent on the technology's success and on the market's acceptance of the product.)

In a *license to a spinout company*², the financial components may include:

- a license issue fee
- license maintenance fees
- patent cost reimbursement
- milestone fees
- running royalties
- shares of stock (in other words, equity) in the company

Shares of stock may or may not be the major source of return for the research institution. Equity in the company is certainly the riskiest component for the institution. In harsh economic climates, the company may have a difficult time reaching liquidity (that is, public stock trading status or acquisition by a larger company). In addition, if the company has to raise more money later from investors and its progress-to-date has not been good (or the economic climate for investment is bad), the company may have to accept funding in a "down round investment" that makes the initial stock almost worthless.

If both running royalties and stock are taken, then each is usually lower than if the deal were "pure cash" or "pure equity." In addition, license fees are usually lower than from a large company, since a new company will typically be cash poor and will need to use its cash to develop the technology.

The main point for both conventional licenses and spinouts is that if the technology is successful the major financial returns will be from license fees and/or equity. With both conventional licenses and spinouts, the returns are linear. That is, once a running royalty rate is set (for example, 4% of net sales), then the formula will make "appropriate returns" regardless of whether the sales of the final product are US\$100,000 per year or US\$100 million per year:

- If the sales are only US\$100,000 per year, then the company pays the research institution only US\$4,000 per year; a small but fair number, since the sales have not been high.
- If the sales are US\$100 million per year, then the research institution receives US\$4 million per year, reflecting the large success of the product.

Similarly, if the research institution takes 100,000 shares of founders stock from a total of one million shares of founders stock issued, representing 10% of the company, in exchange for the technology (the total number of shares, one million in this case, is totally arbitrary: the percentage of the total is what counts), then:

- If the share price at liquidity is US\$50 per share (reflecting a successful company), then the university will receive US\$5 million.
- If the share price is low, reflecting a "desperation acquisition" price of only US\$0.50 per share, then the research institution will get only US\$5,000. (This is not unheard of.)

It is worth reiterating that the research institution does not need to know the total value of the technology at the time of licensing/spinning out, because the linearity of running royalties and/or equity determines the amount the institution will receive. The acquiring company (or spinout), however, must have a much better estimate of the final value of the technology and of the cost of developing it, since the spinout must balance the cost and risk of developing the product within the market against expected sales and profit returns. Fortunately, industrial concerns and financial investors have better resources for making these estimates.

3. SO, WHAT ARE THE NUMBERS?

This section is a risky one to both write and read. People often ask for numbers, but the problem is that there are no *typical* numbers, because there are no *typical* deals; each one is unique. The section does, however, attempt to provide some guidance on numbers. Those presented here are all based on personal experience with U.S. and U.K. institutions and all depend on the following:

- the importance of the technology to the final product
- the type of product
- the uniqueness of the technology and the final product
- the typical profitability of that type of product and/or the industrial sector
- whether the IP is the key IP for the company or only a small piece of its holdings
- the strength and breadth of the IP
- whether the IP includes:
 - only present patent rights
 - additional know-how for which the research institution can command return (most know-how is in the public domain)
 - a "pipeline" to future technology and patents from the research institution (a dangerous precedent if the pipeline is too wide)
- whether the company will have to license blocking patents from third parties
- the state of development of the technology

- how much and how long it will take to develop it
- the cost of development in the country in which the company resides
- the state of the economy—including the state of the stock market and the investment climate in both the country of origin and, if different, the country of the licensee
- the negotiating power of the research institution relative to the company
- the negotiating skill of the research institution

The amount of equity the university gets will depend on all of the above variables, as well as on the extent to which the research institution "incubated" the technology and spinout company before the technology left the institution. For example, the amount (or percent) of equity will be lower if the university merely licenses the academic-stage invention to a newly incorporated company and higher if the university invests in showing proof of practical concept or in developing a prototype of the final product. The level of equity will be highest if the university assists in forming the company itself, devising and writing the business plan, hiring the management team, helping the company raise money, and even allowing the company to be housed in the laboratories of the research institution for the company's first year or two of life.

With those caveats, the typical ranges are given in Box 1 for license fees and royalties for a conventional license, based on U.S. experience, with the further caveat that some deals fall outside of these ranges.

4. CONCLUSION

The task of evaluating and pricing early-stage technology is more art than science. (This is true for negotiation too.) Success requires a general knowledge of product development, manufacture, and markets, plus knowledge of the pricing for comparable technologies (when the information is available), plus experience. Technology transfer offices primarily learn from their own experiences and by studying the experiences of similar institutions. If the offices can attract and retain both talented staff and commitment from their administration, they will get better with time.

No deal will be perfect. Some will fail. It is important to remember, however, that it is far better to conclude a deal with a company that will competently develop the product than to wait for the *best deal* or to fight interminably for the best financial terms. Only when the technology is developed and brought to market will the public benefit. And that is ultimately why universities and their technology licensing offices are in business. LITA NELSEN, Director, M.I.T. Technology Licensing Office, Massachusetts Institute of Technology, Five Cambridge Center, Kendall Square, Room NE25-230, Cambridge, MA, 02142-1493, U.S.A. <u>lita@mit.edu</u>

- 1 See also in this *Handbook*, chapter 1.4 by L Nelsen and A Krattiger.
- 2 See also in this *Handbook*, chapter 13.1 by A Brown and J Soderstrom.

Box 1: M.I.T.'s License Fees and Royalties (U.S. dollars)

CONVENTIONAL LICENSE (WITHOUT EQUITY)

- License Issue Fee: \$10,000-\$200,000
- Annual license fee (minimum royalties): \$20,000-\$200,000 (often beginning low and increasing by year until the amount reaches a plateau)
- Milestones (when present): \$50,000-\$1,000,000 (the latter when Food and Drug Administration approval for marketing is gained for a major drug)
- Running Royalties: 0.5%–7% (the lower range for process improvements or commodity products; the higher range for noncommodity products and patents with product claims) This may be still higher for software and for composition of matter patents on drugs.

Based on U.S. and U.K. experience, the following division of equity is typical for a spinout after it has raised \$1 million in investment. It assumes lower license fees and royalties:

SPINOUT COMPANY EQUITY SHARES AFTER \$1 MILLION OF INVESTMENT

Venture investor:	33%
Research institution's share based on IP alone:	5%–7%
(If) Research institution does extensive incubation:	10%–15%
Research institution total:	15%–22%
Employee stock option pool:	20%
Founding entrepreneurial team:	25%-32%

If no incubation was provided by the research institution, then the entrepreneurial team's share may be 40%–45%.