The Activities and Roles of M.I.T. in Forming Clusters and Strengthening Entrepreneurship

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ABSTRACT

This chapter describes the structure, policies, and operations of the Technology Licensing Office at the Massachusetts Institute of Technology (M.I.T.). The chapter emphasizes the licensing office's role in generating spinout companies and considers the importance of the biotechnology cluster within the state of Massachusetts and it's surrounding regions. Also discussed is M.I.T.'s approach to ensuring that licensing procedures maximize access to medicines and vaccines arising from M.I.T.'s research.

1. INTRODUCTION

The Massachusetts Institute of Technology (M.I.T.) is probably not a direct model for universities and research institutes just beginning their technology-transfer activities, whether in the United States or in developing countries. Instead, the institute is an example of what can be achieved by a mature organization that has built its patent portfolio and technology-transfer skills over the course of half a century. We, at M.I.T., live in an entrepreneurially advanced city, where technology-based companies originating from university research inventions have become an important part of the Massachusetts area's economy. M.I.T. and the other major research institutions in the area, such as the Whitehead Institute for Biomedical Research, Harvard University, Massachusetts General Hospital, Brigham and Women's Hospital, and Boston University, have helped to build this entrepreneurial cluster and have benefited from it.

Nevertheless, other organizations can learn from our experiences, and M.I.T.'s Technology Licensing Office[1] is both honored and pleased to help in the *transfer* of technology-transfer practices.

1.1 *History and mission*

M.I.T.'s Technology Licensing Office is one of the most active university patent and licensing offices in the country. M.I.T. has had more than 1,500 issued U.S. patents in its portfolio, many with foreign counterparts.

M.I.T.'s technology licensing endeavors follow the mandate of the U.S. Congress who, in 1980, gave to universities title to inventions developed with federal funds through the Bayh-Dole Act. Technology licensing from universities was greatly accelerated by Bayh-Dole, which allowed universities to own the patents arising from federally funded research, to grant exclusive licenses, and to charge royalties that could be shared with inventors. Since nearly 90% of the basic research funds in U.S. universities comes from U.S. federal funds, the new law drastically changed the face of university technology transfer.

The theory behind the law's application to university research was based on Congress'

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understanding of the embryonic nature of university discoveries and inventions. Since universities do not develop products, early investment by industry is needed to turn university findings into commercial realities. Typically, such investment involves high risk, since neither the practicality of the inventions nor their market utility has been proven. Patents, and particularly exclusive licenses, can be used as incentives for *first mover* companies to make the investment: if the product were to succeed, the patent would protect the initial investor from competition for a period of time, rewarding the initial risk taking.

Finally, the law provided an economic incentive for both universities and their researchers to patent their inventions and to participate in the technology-transfer process. Although the royalties gained from technology transfer are only a very small contribution to university budgets (averaging about 3% of university research budgets for U.S. universities), there is enough economic return to support the process—and considerable incentive for individual researchers. More importantly for the biotechnology industry, the technology-transfer process is an organized, effective method of transferring university findings via protected IP for the purpose of forming a protected technology dowry for new companies. Investors in most technology companies—and certainly in such high-risk/high-investment fields as biotechnology—must have proof of the exclusive rights to patents and other forms of IP by the company before they will invest.

Consequently, we use licenses to our IP to stimulate the development of our inventions into products that serve the public good. Through our patenting, licensing, and copyright protections, we encourage companies to take the necessary risks to develop our inventions into products and/or services that benefit humanity. Royalties derived from licenses support further research and are shared with inventors. These, in turn, provide incentives for further innovation.

Each year, more than US$1.2 billion in sponsored research is conducted on the campus of M.I.T., at the Lincoln Laboratory, and at the Whitehead Institute for Biomedical Research. This research leads to more than 500 new inventions per year. These inventions and software are marketed through M.I.T.'s Technology Licensing Office. The core of this office is a group of technically trained and business-oriented people. They work with industry, venture capital sources, and entrepreneurs to find the best ways to commercialize new technologies.

The Technology Licensing Office at M.I.T. began its operations many decades ago as the Patent, Copyright, and Licensing Office. It was reorganized in 1986 and became the Technology Licensing Office. It is administered by the Vice President for Research/Associate Provost and is now part of the academic arm of the university. Its mission statement declares that:

The mission of the M.I.T. Technology Licensing Office is to benefit the public by moving results of M.I.T. research into societal use via technology licensing, through a process which is consistent with academic principles, demonstrates a concern for the welfare of students and faculty, and conforms to the highest ethical standards.

This process will benefit the public by creating new products and promoting economic development.

It will help M.I.T.:

- show tangible benefits of taxpayers support for fundamental research
- attract faculty and students
- generate industrial support of research
- generate discretionary income
- generate new job opportunities for graduates

We will continue to be a world-class model of excellence in university technology licensing.

1.2 *Staffing*

The Technology Licensing Office is staffed by:

- Director Lita Nelsen, chemical engineering background (BS, MS, MBA) with 20 years experience in industry in the fields of medical devices, membrane separations, and biotechnology

- Associate Director Jack Turner, electrical engineering background (BS) with 18 years of experience in industry
- seven technology licensing officers, all with degrees in engineering or science, each with one to two decades of industrial experience; each is responsible for one of the seven technology areas: biotechnology, chemistry, medical devices, semiconductors, communications, software, and nanotechnology
- four technology licensing associates, all with BS degrees in science and little or no other experience; associates assist the technology licensing officers
- legal personnel: one corporate attorney, one junior lawyer, and one legal assistant; these staff members provide advice on licensing and particularly on corporate structure, manage outside attorneys for litigation, and manage M.I.T.'s trademark and end-use software licensing; patent prosecution is handled by outside attorneys and patent agents
- financial and computer systems personnel: one financial manager, two accountants, one programmer, and one desktop support administrator
- office management and clerical support: office manager, compliance manager (government reporting), three secretaries, a receptionist, a files manager, and a file clerk

1.3 *Numbers of patents and licenses*

M.I.T. currently holds about 1,500 active U.S. patents and many corresponding foreign patents. About 150 U.S. patents are issued to M.I.T. each year. We have about 600 active licenses and issue around 100 new licenses every year.

The gross annual revenue of the office is about US$40 million. Net revenue is about US$10 million (after patent expenses, personnel expenses, and distribution of a portion of royalties to inventors).

The majority of our licenses are to existing companies—both small and large. But about 25% of the licenses are to new spinout companies, which are specifically formed to develop a licensed technology.

2. THE ROLE OF THE TECHNOLOGY LICENSING OFFICE IN THE BUSINESS COMMUNITY

2.1 *The "virtual incubator" for spinouts*

Twenty to 30 new companies are *spun out* from M.I.T. each year. All of them are based on M.I.T. inventions and are built upon licenses to our patents and software. The companies based on our biomedical inventions form an important part of the biotechnology cluster in the Massachusetts area (see section 3 below).

Our formal role in starting up new companies is confined to filing patents and negotiating license agreements with the companies, and although we will often take equity shares in the company as partial payment of royalties, we do not take board seats on the company or any management role. The purpose of these restrictions is to keep the company clearly separate from the university. We believe this separation is necessary for the university to concentrate on its mission of basic discovery research, dissemination of knowledge, and education. Through these policies, the management of technology transfer essentially becomes a by-product of the academic process and will not distort the long-range mission of the institution.

We can only achieve this mission through clear and transparent conflict-of-interest policies and procedures (see Box 1). The conflict-of-interest rules may seem unusually strict, but this careful approach is necessary because of the very large number of companies spun out (more than 250 since 1987). Management that allows exceptions to the rules would not be possible given this large number. Our task is not to use these rules as deterrents but to efficiently and creatively craft arrangements within the rules. Put differently, our operating motto is "*A firm wall between university and industry—but a wall with many doors.*"

We do not formally incubate these spinouts; we do not invest M.I.T. money in any of these companies; we do not allow the companies to use M.I.T. laboratory facilities; and we do not write their business plans nor do we participate in their management.

Box 1: M.I.T.'s Conflict-of-Interest Rules for Spinout Companies

(Last Revised February 2005)

1. Faculty member may consult but not be a line officer in any company. Consulting activities should not use university resources and should not use students.

2. Faculty member must distinguish direction of research at university from responsibilities at company in which he/she owns equity.

3. The university will not accept sponsored-research grants from the company if the faculty member owns equity.

4. No confidentiality of research results (anytime). All research must be publishable.

5. Only patents, copyrights and tangible property can be licensed for compensation (no *know-how* or *trade secret licensing* can be done since this would preclude open publication).

6. Faculty members may not conduct the license negotiations (nor attend the negotiations).

7. Consulting is *third-party*, between the faculty member and the company. No tie-in with the license.

8. Only very minimum commitment of future inventions (those dominated by previously licensed patents). No pipelining of *improvements*.

9. Faculty member/founder who holds equity signs Conflict Avoidance Statement promising:
   - Not to accept research support from company
   - Not to suppress dissemination of research findings
   - Not to use students on company-related work at M.I.T.

10. Arm's length relationship between the university and the company
    - No M.I.T. monetary investment in the company
    - No board seat
    - Equity managed by Treasurer of M.I.T.—*not* the Technology Licensing Office

11. Technology Licensing Office enforces diligence terms, payment of patent costs, other license obligations *just like any other company*. No special status for M.I.T. spinouts.

12. Yearly departmental overview of faculty outside professional activities.

Common sense: Emphasis on the spirit (not just the letter) of the rules, administered by people with judgment and authority.

Our informal role, however, is much broader. We call it a "virtual incubation" function, which encourages and accelerates the formation and growth of our spinout companies. The initial license agreement itself includes contract terms that help. Our financial terms are quite generous for the first few years of operation, reflecting our understanding that new companies are often cash poor. Similarly, our royalties on products are low, because we know that the company will have to make substantial investments and develop and contribute substantial IP of its own before the product can be successfully commercialized.

An important part of the license agreement—both for us and for the company—is that which defines the *milestones*, or *diligence terms*. These require companies to raise minimum amounts of capital and achieve progress in product development. Milestones related to raising capital assure us that the outside market finds the company worthy of investment and that sufficient capital will be raised to fund product development.

Our virtual incubation incorporates many other functions. We meet with inventors, helping them to define the direction of the company and their own career aspirations. We introduce them to consultants, potential executives, and other advisors who can help them formulate their business strategy and write business plans. And, because of our long relationships with sources of investment capital, we can introduce inventors to venture capitalists and angel investors who may be willing to invest in the new companies.

2.2 *The role of students in entrepreneurship at M.I.T.*

The admission criteria for prospective M.I.T. students, particularly those for undergraduates, contribute to the entrepreneurial spirit at the institute and the ultimate impact of our graduates on the economy. In evaluating candidates for admission as undergraduates, we look not only for academic achievement (such as high grades and strong standardized test scores), but also for a certain quality of potential leadership—an intensity and focus that fosters achievement and also influences others. Young people who are strong potential leaders often possess a self-confidence that allows them to think unconventionally and take risks—including the risk of joining (or forming) an entrepreneurial company.

Our education of these students (and of their "big brothers and big sisters" in graduate school) stresses the fundamentals of science, rather than short-term applications. The students are involved in leading-edge research projects early in the course of their studies. We seek to produce graduates who will have leadership capabilities based on a solid grounding in science and a familiarity with the state of the art.

Role models in business are an important influence on these students during their years at M.I.T.. Many of the professors and many alumni who visit campus—and not a few of the students' friends—have started companies based on M.I.T. technology. These entrepreneurs expose students to entrepreneurial thinking. The presence of strong role models is important for developing an entrepreneurial culture; the plethora of such role models at M.I.T. and in the Boston/Cambridge area leads others to think that "*I can do it too*"—and offers resources for advice and strategy.

Finally, our culture at M.I.T. stresses that risk taking is necessary for achievement. And, importantly, that "*failure is a learning opportunity—not a black mark*." We assume that our students are good enough to take risks and succeed. They have sufficient talent, energy, and self-confidence to recover rapidly from failure and to learn from failure to become more effective in their next endeavor. A willingness to take risks and the ability to learn from failure are critical for entrepreneurship.

2.3 *Interaction with the business community*

A key part of the technology-transfer function at the university is to develop and maintain a wide range of contacts with the surrounding business community and to leverage these resources to help build our spinout companies. Our model for spinning out companies depends on a mature, entrepreneurial community surrounding the university.

The geographic area of M.I.T. is the Cambridge/Boston area, which in many ways provides an infrastructure of support for spinout companies. High technology companies have been regularly spawned here for more than 40 years. As a result, there are many executives, lawyers, accountants, consultants, real estate managers, and other professionals who are experienced at working with new companies. And the community is well connected. Networking organizations, such as the M.I.T. Enterprise Forum and the Massachusetts Biotechnology Council (MBC), keep people in contact with one another.

Finally, the community has developed "knowledgeable money": investors who contribute to spinout companies not only funds, but wisdom, guidance, and connections to management talent, business development opportunities, and follow-on money. A new breed of high-technology angel investors—former entrepreneurs who founded and cashed out from successful companies—is now bringing wisdom, connections, and experience, along with money.

There are also venture capital funds that specialize in technology-based spinouts. Many even subspecialize in biotechnology and have partners and associates with MD and PhD degrees in biology who are experienced in the biotechnology industry.

3. THE BIOTECHNOLOGY CLUSTER: EXPERIENCES FROM MASSACHUSETTS

It is helpful for those who are involved in technology transfer to be in proximity to others with similar issues and challenges. The Boston/Cambridge area is one of the three main biotechnology clusters in the United States. (Biotechnology clusters are geographical regions where a disproportionately large number of biotechnology companies are located.)[2] The other two biotechnology clusters are:

- the San Francisco Bay Area of northern California
- the San Diego/La Jolla area of southern California

Many factors have led to the formation and growth of the Massachusetts cluster, with research institutions playing a critical role. This cluster of more than 280 companies accounts for almost 20% of the total number of U.S. biotechnology companies. Almost all of these companies started as small, entrepreneurial companies within the last two decades, the majority having been formed within the last 12 to 15 years. According to data from the Massachusetts Biotechnology Council, these companies now employ more than 30,000 people. In addition, there are more than 220 medical device companies in the area that employ an additional 25,000 people.

3.1 *Key elements for a biotechnology cluster*

It all starts with early fundamental support of basic research by the U.S. government. Leading research institutions make the discoveries, develop the IP, and train the scientists that form the biotechnology companies. Where the research institutions cluster, the new companies eventually form. The process continues with alliances developing between biotechnology companies and large pharmaceutical companies, which will often provide necessary testing, manufacturing, and distribution of the drugs discovered by the biotechnology companies.

For a robust cluster to form, the area needs investment capital (and experienced investors), executive talent, trained scientists, and a host of supporting professionals—lawyers, accountants, real estate professionals, and others—who understand biotechnology entrepreneurship and can help fledgling companies establish themselves. Good airports are critical, and local communities that are attractive to highly talented personnel and their families create a competitive advantage.

The Boston/Cambridge area of Massachusetts has an unusually large concentration of world-class research institutions (universities and research hospitals) funded in large part by the U.S. government—particularly the National Institutes of Health (NIH)—to perform basic discovery research in biology and biomedicine. Together, Massachusetts research institutions received more than \$2.1 billion in NIH research grants in fiscal year 2003, approximately 10% of the national total.

From this research comes much of the "feedstock" for new biotechnology companies: new discoveries, IP, knowledgeable scientific advisors for new companies, and, importantly, well-trained scientists to staff the new companies.

3.2 *The self-feeding cluster*

Even with a base of world-class university research and its resulting technology and IP, getting a cluster started is difficult—there is no simple formula for doing so. But once started, a cluster begins to feed itself in a virtual cycle. The biotechnology cluster feeds itself through:

- **role models.** These are people who have founded companies and can offer examples of success and advice to new entrepreneurs.
- **management/founders.** Often new company management is recruited from other companies in the area. People who were employees of early companies in the cluster acquire the skills and interests to become founders of new companies. New companies also can recruit other skilled personnel from the older cluster companies.
- **retention of new graduates.** A cluster of biotechnology companies in an area encourages new graduates from nearby universities to seek employment in the area, consolidating skills.
- **infrastructure support.** The area's patent attorneys, lawyers, accountants, recruiters, real estate managers, consultants, and equipment suppliers develop special skills in biotechnology as they respond to the needs of the cluster.
- **technology transfer.** As the universities and other research institutions become more experienced in dealing with biotechnology companies and biotechnology startups, they become more effective in starting new companies that strengthen the clusters. Successful technology licensing and spinouts lead to revenue, which funds the filing of more patents and more opportunities.
- **angel investors.** Local angel investors bolster the process, since they can offer their skills and experience in addition to their money. As clusters mature, founders of the early companies frequently become investors in new companies.

At some point venture capital moves in. At the start of the Massachusetts biotechnology cluster, there was little indigenous venture capital. Most venture capital money came from investment funds located in New York, California, and other states. With the growth of high-tech clusters in Massachusetts (both biotechnology and telecom), many of these funds opened new offices in Massachusetts, and many new venture funds were formed locally. Currently, the majority of new company financings in Massachusetts are led by venture funds with offices in Massachusetts.

4. CONCLUSIONS

4.1 *The importance of clusters*

Many elements contribute to the success of a biotechnology cluster. Its origin and continued health depend on a continuing source of state-of-the-art science, usually provided by universities and research hospitals funded for basic research. The source of this funding probably needs to be from government: no private institutions can afford to fund sufficient speculative basic research to sustain the flow of discoveries necessary to support a cluster's growth.

Effective technology transfer is also necessary. The legal infrastructure for transferring inventions from universities must be in place (and relatively nonbureaucratic), and sufficient funds must be available for universities to file patents and protect their IP.

The formation of new companies also requires a business infrastructure in the community. A simple legal system for company formation, consulting, accounting, and legal professionals to advise the company—as well as adequate physical space—are all necessary. Good transportation into the area is important, since investors and business partners need to visit the company. And investment capital is, of course, critical.

Most of all, the formation of companies and the subsequent development of clusters requires talented people: world-class researchers to lead the discovery, trained and talented technology-transfer professionals, entrepreneurial company founders, scientists and managers to staff the companies, and knowledgeable investors who can both fund and guide the company. All will need the support of a variety of professionals in the community. It takes a whole community to build a biotechnology cluster—but once built, the cluster can achieve a self-sustaining life that strengthens itself and the community.

4.2 *The importance of policies for ensuring the availability of products for the poor*

M.I.T. usually files patents only in North America, Europe, and Japan (though occasionally we file in China, Singapore, Republic of China, and Korea for the electronics field). Thus, the biomedicine-related patents we file are not often likely to affect the development and distribution of medicines and vaccines in developing countries.

We are, however, mindful of the issues surrounding the development and distribution of new health-related products for developing countries, and we consider both our patenting procedures and our licensing terms when working with relevant technologies. For example, it may sometimes be advisable for patents to be filed in some developing countries so that local companies in those countries can protect their investments in further developing our technology. In other cases, we may choose not to file patents in those countries and may prohibit our licensees from doing so—or we may refrain from granting exclusive licenses in developing countries unless we feel exclusivity will enhance development and access. Other agreements could require preferential pricing for the public sector of developing countries.

There are no rigid written policies guiding the way we handle technologies; instead, we leave our options open, creatively crafting agreements to maximize access. However, the number of technologies arising from our research that are relevant to neglected diseases is relatively small, since we do not have a medical school nor a school of public health. Our experience with such technologies is relatively scant, as is our experience in crafting such agreements. We discuss our approach to those technologies in greater detail in another chapter. ■

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1 web.MIT.edu/tlo/www.

2 See also in this *Handbook*, chapter 3.12 by K Viljamaa and 3.11 by PWB Phillips.

3 See, in this *Handbook*, chapter 1.3 by L Nelsen and A Krattiger.