**Economic Decisions in Biotechnology Commercialization:
Lessons for Small Firms and Universities**

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Abstract:

The Bayh-Dole Act allows federally funded research to be commercialized and creates a viable market position for small university related firms such as the MBI. MBI fills a gap between the discovery process that takes place in Universities and Federal laboratories and the commercialization in private firms and industry. While large life science firms have the resources and infrastructure to effectively evaluate the market and value of a new technology, small firms and universities are often not equipped to perform these evaluations. This can lead to both, a lack of proper remuneration for new technologies and lack of resources to fund productive avenues of research. Thus, creating a need for a vertical linkage between the researchers/innovators and the commercialization agents.

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The face of American agriculture has been heavily affected in recent years by biotechnology. Biotechnology is a knowledge-based industry predominantly composed of small firms with close ties to universities (McMillan et al.). However, the biotechnologies that are making headlines, and affecting trade policies, are marketed by large life science corporations (e.g., Monsanto and Novartis). Biotechnology companies play a key role in transferring knowledge from universities and government supported laboratories to the marketplace. A recent survey found that sales of products developed through academic research and licensed to industry amounted to $20.6 billion in 1996 and nearly two-thirds of these licenses were to small firms (AUTM).

The nature of public-sector research and development (R&D) changed in 1980. The Bayh-Dole Act of 1980 and Public Law 98-620 of 1984 allow universities to retain title to inventions that were created with Federal funds, in effect allowing universities to compete with private industry in R&D. The Bayh-Dole Act also specifies that universities are to facilitate the commercialization of products for small and start-up firms. This coupled with current pressures on public agricultural research, including accountability to the public for expenditures and increasing privatization of research with private ownership of intellectual property rights, have resulted in public research institutions patenting or otherwise protecting their intellectual property with patent revenues used to fund additional research. These universities utilize the Bayh-Dole Act to coordinate with small and medium university-related firms (SMURFs), that often include faculty members who have made an innovation. For example, since the Bayh-Dole Act, 2,214 new companies have been formed based on protected, academic, intellectual property.

In 1997, 3,328 new licenses and options on academic property were executed, many by existing companies; 70% of these new licenses and options were reported in the life-sciences area (AUTM).

Public sector institutions are allying themselves with private-sector partners. For example, in 1998 the University of California at Berkeley reached a $25 million strategic alliance with Novartis. In this alliance, Novartis has right of first refusal to virtually all patentable genomics-based products that Berkeley produces over the next 10 years. Other universities are encouraging closer public-private alliance in a number of ways: patenting university inventions, pro-actively seeking corporate financing for research activities in return for right of first refusal on results, and supporting start-up companies through university research parks or other mechanisms.

The result of these changes in university and other federally funded research organizations is that firms producing agricultural biotechnology innovations are of two types. The first firm type is the large, often multinational corporation with expensive but well-funded research in a variety of biotechnological areas. Examples of these firms include Monsanto, DuPont, and Novartis. These 'life-science' companies maximize profits by applying biotechnology to the pharmaceutical, agriculture and nutrition industries. The second type of firm is a small, start-up biotechnology firm. These firms often arise from the inspiration and discovery of a single or a small team of scientists, and are frequently associated with land-grant or other universities (Oehmke *et al.*). These small and medium university related firms (SMURFs) are often at least tacitly vertically linked to the researcher/innovators in public research settings.

We use the case of a small, university-related firm, Michigan Biotechnology Institute International (MBI) and its commercial subsidiary Grand River Technologies (GRT) to achieve the following objectives.

1. Examine the role that university related firms play in agricultural biotechnology markets.
2. Identify the incentives and transactions costs related to vertical linkages in the biotechnology product development/marketing channel.
3. Analyze the identification, valuation, and commercialization chain of biotechologies relative to the traditional chain of events for an innovation to see where differences exist and whether small, university-related firms can strategize to effectively reflect these differences.
4. Analyze the role of information about the technology and resulting output market in the commercialization strategy.

These traits and the SMURFs are then brought together to:

5. Understand how biotechnologies are identified, valued, and marketed by small and university-related firms.

These objectives are all realized in the MBI context. The result is a deeper understanding of the sources and values that agricultural biotechnology has in today's economy.

MBI International

MBI is a private, non-profit entrepreneurial center focused on biotechnology. MBI also has a for-profit technology commercialization firm as a wholely-owned subsidiary, Grand River Technologies (GRT). MBI has responsibility to validate, develop and demonstrate technologies which are then commercialized by GRT through new companies, joint ventures, or out-licenses. MBI states its mission is "to be the premier commercially focused non-profit technology and business development corporation for the commercialization of biobased industrial products and processes using the tools of biotechnology." (MBI, Strategic Five-year Plan).

Started in 1981 as the Molecular Biotechnology Institute, the name was changed to Michigan Biotechnological Institute International when the scope was expanded to the international arena and the core technology areas identified as: environmental technologies, specialty chemicals, biomaterials, applied biocatalysts, and industrial technologies (MBI, January 2000).

Initially, MBI generated revenues through large general-purpose grants and contracts from the State of Michigan, Kellogg Foundation, Dow Foundation, USDA, and Cargill. These grants provided for development and infrastructure. MBI has evolved from a basic/applied research focus to fully developing technology packages for commercialization (MBI, January 200). To date MBI has started 11 companies, licensed several technologies and assisted in commercializing approximately a half-dozen technologies.

MBI fills a gap between the discovery process that takes place in Universities and Federal laboratories and the commercialization in private firms and industry. Organizations like MBI are important because U.S. and State governments invest hundreds of millions of dollars in research each year. Many of the resulting technologies are not commercialized because the researchers do not sufficiently understand the markets in which those products compete.

Marketing/Commercialization Channels and Vertical Linkages

The discovery, development, and marketing—or commercialization—of products is a well-developed system for most products in most markets. The standard innovation is either induced innovation to fill a specific need or an easily interpreted improvement on an existing product. In both of these cases the market is easy to identify and quantify.

Biotechnological products do not fit this market identification and quantification mold because they are often entirely new products and because quantifying the market has the added complication of a potential consumer backlash. Neither of these market traits are necessarily unique to biotech products. However, we argue that biotech products are subject to an unusually large amount of uncertainty in the market plan because of these market traits.

The standard product market plan is:

1. Discovery and development of marketable products.
2. Introduction and market education.
3. Establishment of markets.
4. Exploitation of markets.
5. Diversification or consolidation.
6. Product and market decline leading to discontinuation. (McCalley).

This standard plan pushes the technical aspects of the research and development (R&D) process and the evaluation of product and market traits into a single, first step. The remaining five steps are all focused around economic considerations of the product market supply and demand.

Biotechnological products market plans might better be characterized as having a "pre-commercial" and a "commercial" phase (Kalatzandonakes and Bjornson). Using this dichotomy, MBI fits squarely into the pre-commercial phase and passes on the commercial phase to GRT. Consider the technology development plan of MBI.

While large life science firms have the resources and infrastructure to effectively evaluate the market and value of a new technology, small firms and universities are often not equipped to perform these evaluations. This can lead to both, a lack of proper remuneration for new technologies and lack of resources to fund productive avenues of research. Thus, creating a need for a vertical linkage between the researchers/innovators and the commercialization agents.

The current MBI technology development plan has the following steps:

1. *Identify and evaluate new technology opportunities.*

Technology identification is the duty of all technical staff. Methods of identification include technical meetings, personal contacts, and technology offices at universities and federal laboratories. Evaluation is completed by a team of administrators which meet monthly to discuss the technical soundness and market opportunity of the technologies.

2. *In-license commercially-promising technologies.*

Promising technologies are acquired through technology license from the inventing institution. Alternatively, an option or material transfer may be used. MBI generally negotiates a no or low license fee in preference for additional royalty payment based on “market parameters” and mutually agreeable commercialization milestones.

3. *Validate new initiative technologies.*

An in-firm committee proofs the concept and commercial interest. MBI Contract Services validates the science and methods of new technologies.

4. *Develop and demonstrate new project technologies.*

Once a technology is elevated to project status, a "technical driver" and "business driver" are chosen to lead the development process. MBI management establishes annual goals to push the technology to commercialization status. Pilot or field demonstrations are scheduled once the technology has been adequately developed.

5. Transfer commercially viable technologies to for-profit subsidiary.

Success to this point results in the technology being transferred to the for-profit subsidiary for commercialization. The timing of this occurrence considers the current status of the MBI development "pipeline" (Figure 1).

The result of this plan is that the intellectual property provided by Universities and Federal laboratories is combined with venture capital and technologies that might otherwise fall by the way-side are commercialized.

The MBI strategy is remarkably simple and reflects the current funding level and marketing plan sophistication. As reflected in Figure 2, MBI sifts through hundreds, or even thousands, of technologies each year to arrive at an initial 10 promising technologies. The internal staff at MBI then investigates the novelty and potential market of these technologies. From these, 4 are moved forward with only 2 ultimately being commercialized (MBI, 1997).

Only once MBI is focused on 4 primary technologies are outside consultants brought in to conduct a market analysis which is used to narrow the choice to 2 technologies which are commercialized. Until this point, MBI relies on scientists to estimate the benefits of the technology and the potential market value and size.

However, in order to effectively achieve the goals of the organization, the economic analysis that is performed at the commercialization step should be done earlier in the product development. The economic decision model MBI follows should focus on product characteristics, market characteristics, and related markets to assess the promise of new biotechnologies. Some important factors include:

1. *Potential for application or use in many commodities and/or regions* (i.e. economies of scale or scope).

MBI has made a conscious effort to avoid commercializing in commodity markets. Instead they have looked for specialty markets. The ability to sell commodity type innovations to larger firms may mean that these innovations can still be profitably pursued by MBI. However, even in the specialty type markets, MBI should consider the size and scope of the innovation in its early product development decisions.

2. *Consumer preferences and attitudes.*

The recent European backlash against any product that might be considered "genetically modified" illustrates the importance of consumer reaction in product development.

3. *Infrastructure or distributional needs and capabilities*.

Since MBI is well acquainted with the capabilities of its commercialization, it should identify the infrastructure needs to facilitate early sale or licensing of products with larger needs than GRT can support.

4. *Demand and supply elasticities which encompass complements and substitute goods*.

Related to the size and scope considerations above, MBI should consider product differentiation aspect that will allow an inelastic demand for the product.

5. *Financial, or capital constraints, and goals other than profit maximization*.

The financial considerations are accurately reflected by necessity and financial success will allow MBI to later expand the size and scope of their operations. The innovations under consideration by MBI are also examined for public welfare improving aspects such as environmental quality.

The success of MBI pre-commercial product identification and development strategy might be reflected in the number of successful technologies commercialized.

Information and Commercialization Strategies

Grand River Technologies (GRT) was formed as a for-profit subsidiary of MBI whose sole purpose is to commercialize the technologies that MBI passes on to them. The product identification and pre-commercialization strategy of MBI outlined above results in the sale of many technologies to larger corporations. The sale of many technologies to other corporations is not inherently wrong and, indeed, it may improve social welfare by moving more products rapidly to commercialization. However, it does beg the question: does this strategy maximize profits? or are the large life science companies merely allowing SMURFs to take the risk of selecting and proving technologies and then moving in to purchase the promising technologies for pennies on the dollar.

At any given stage of the commercialization process, GRT has three basic options. They can continue to commercialize the product themselves, they can sell the product or pursue some other similar option with a larger corporation, or they can trash the technology as not commercially viable. Assuming that MBI can effectively evaluate the technical viability, let’s consider a representative technology which can either be commercialized in-house or sold to a large corporation.

In the context of the negotiations between MBI and the large corporation, consider the role of information in the commercialization strategy. Since MBI has done the pre-commercial development, usually in conjunction with the inventing scientist, they have complete technical knowledge of the innovation. They also have some amount of market research. However, a large corporation has an entire department related to the market research of the innovation they are interested in acquiring.

Information asymmetries exist on both sides of the negotiations, MBI has the technical knowledge advantage while the large corporation has the market knowledge. Signaling occurs by both sides. MBI signals the technical capabilities of the technology to the corporation by the simple fact that they have moved the product to GRT from the pre-commercial phase. Similarly, the large corporation signals at least some commercial viability from its market analysis by interest in acquiring the technology.

The potential stale-mate in information exchange is likely broken by the requirement of complete technical disclosure by MBI/GRT. That is, in order to make the sale MBI/GRT would necessarily need to reveal the technical viability of the innovation. The result of this revelation would be a shift of market information power to the corporation and the logically conclusion of the negotiations is more profit for the corporation. MBI/GRT is likely to sell products to large corporations at less than market value.

Selling innovations at less than market value does not necessarily mean that MBI/GRT is losing money. They are just not making as much as they could. This exercise does, however, underscore the value of market information and the importance of early market analysis.

Conclusions

The advent of agricultural biotechnologies and the case of MBI offers many lessons for small firms and universities. Michigan Biotechnology Institute offers a chance to apply these lessons to a small, university-related firm. The Bayh-Dole Act allows federally funded research to be commercialized and creates a viable market position for small university related firms such as the MBI. MBI fills a gap between the discovery process that takes place in Universities and Federal laboratories and the commercialization in private firms and industry. While large life science firms have the resources and infrastructure to effectively evaluate the market and value of a new technology, small firms and universities are often not equipped to perform these evaluations. This can lead to both, a lack of proper remuneration for new technologies and lack of resources to fund productive avenues of research. Thus, creating a need for a vertical linkage between the researchers/innovators and the commercialization agents.

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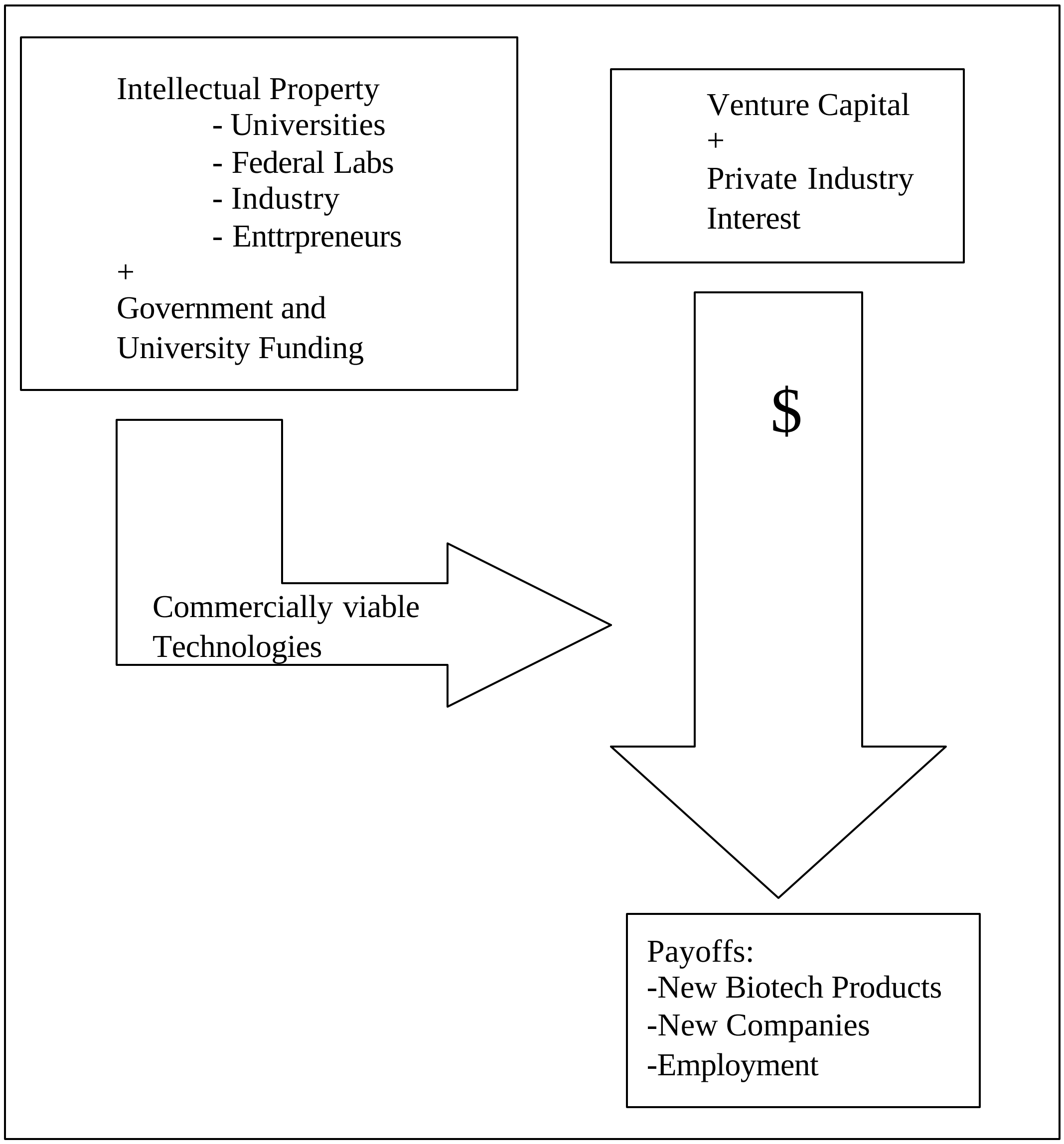

Figure 1. MBI Technology Pipeline

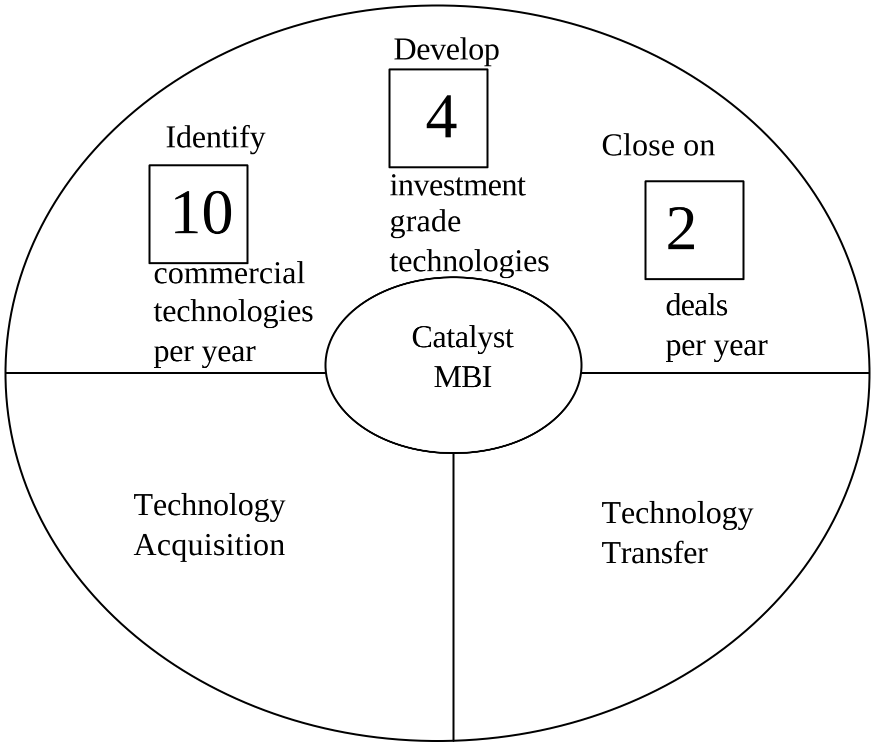

Figure 2. MBI Commercialization Strategy