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Perspectives on Biotechnology Development in Minnesota

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Minnesota's Strengths

The biotechnology industry in Minnesota can be broadly defined as including biomedical device firms, biological engineering firms, industries that produce research or manufacturing equipment for biotechnology or treatment of process wastes, and industries that provide fermentation substrates. This definition of biotechnology-related industries is significantly different than in other states where the focus of biotechnology-related research and development is primarily in major pharmaceutical and chemical manufacturing firms.

In general, Minnesota has a strong entrepreneurial emphasis for promoting new industries, relatively low unemployment, and an excellent educational system. However, Minnesota has not recognized the potential for positive economic development, specifically for attracting new firms related to biotechnology, as have many other states. Over the last four years, states such as North Carolina, Delaware, New Jersey, Colorado, Michigan, Massachusetts, Maryland, Pennsylvania, Tennessee, Virginia, New York, and California have encouraged biotechnology by marketing their states' educational, business, and high technology resources to investors and entrepreneurs. These states have specifically sought to attract biotechnology firms and to coordinate research in progress in academic institutions, the private sector, and at federal laboratories located within their states. Particularly good examples of effective promotional information are the publication "Techne" by the North Carolina Biotechnology Center and the *Colorado Bio-Industrial Journal* (1), which recently reported on the number of bio-industrial companies founded in Colorado since 1968 (Figure 1).

Minnesota has only recently developed similar comprehensive plans for attracting biotechnology industries. In 1985 the Governor created a task force to decide on the most appropriate direction for educational and business development to attract biotechnology-related industry to Minnesota (2). From this task force report, a state Biotechnology Council was formed, led by industry and higher education, which has recently published an extensive plan for biotechnology development (3). One key component of this plan is a survey of the potential economic impact of biotechnology on the state (4). This recent economic analysis projects that 20,000 to 68,000 new jobs could occur as the result of development of new industries in biotechnology by the year 2000 (Figure 2). These projections may be conservative. The basis for this projection included 100 established firms in Minnesota related to biotechnology, with a current employment of 9,000 individuals (Table 1). The analysis did not include expansion of existing significant biotechnology research groups in related industries.

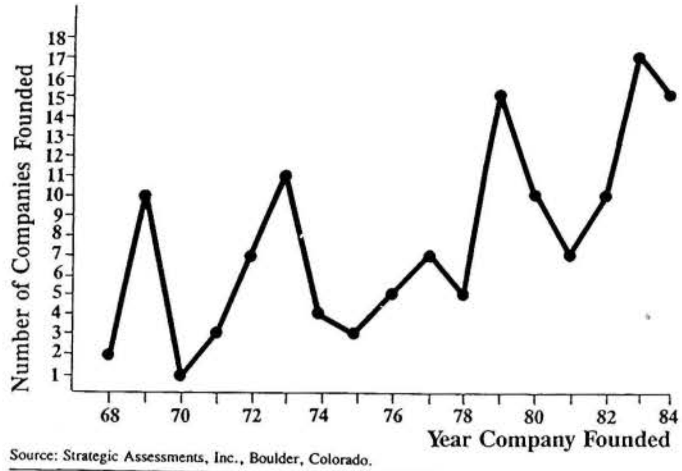
Table 1. Calculation of Minnesota 1985 "base-year" employment in the biotechnology industry (4).

	Biomedical Devices	Biological Engineering
Number of Firms Meeting Definition	83	11
Number for which Employment Was Found	69	8
Identified Employment	8,424	308
Firms for which Employment Figures Missing	14	3
Values Used Per Firm for Missing Employment Figures	15	10
Additional Employment Assumed	210	30
Total Employees (subtotal plus additional)	8,634	338
Figure Used for Projection (rounded)	8,650	350

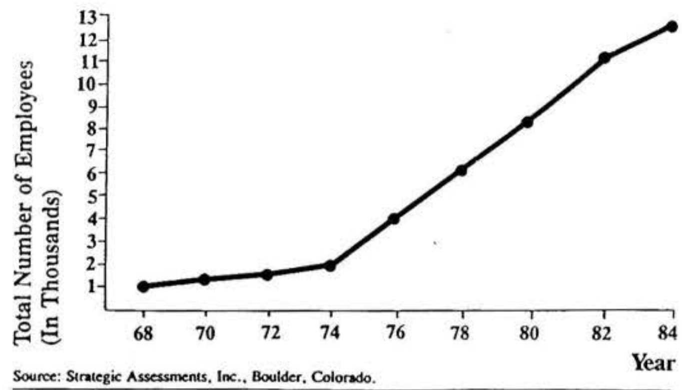
The major components of Minnesota's strength in biotechnology development are the breadth and quality of the University of Minnesota biological, engineering, biomedical, agricultural, and dairy research programs, which rank among the highest in the nation in terms of funded research (5). These programs have been augmented by a baccalaureate biotechnology interdisciplinary degree program in the State University system, which includes a program for introducing high school science teachers to basic methods in biotechnology (3).

Major Constraints

Even though a statewide plan developed by industry, state government, and the academic institutions exists (3), two



Source: Strategic Assessments, Inc., Boulder, Colorado.



Source: Strategic Assessments, Inc., Boulder, Colorado.

Figure 1. Biotechnology company foundings and employment in Colorado since 1968 (1).

constraints must be overcome if development of a more active biotechnology-related state industry is to occur. These constraints are 1) ineffective two-way communication between faculty associated with basic research and scientists in firms interested in applications of these results; and 2) the present minimal coordination among faculty and among academic institutions resulting in duplication of research and educational programs.

A variety of techniques exist for the transfer of genes into appropriate vectors and host organisms for expression and subsequent scale-up to manufacture of large quantities of diagnostic or therapeutic proteins, drugs, enzymes, and biopolymers for industry. Much of this technology is poorly protected by traditional process patent or new-composition-of-matter patent law. Consequently, for competing firms to maintain a competitive technology, research and development must remain trade secrets. This results in major communication restraints between industries and between industry and academic laboratories unless specific proprietary agreements are negotiated with each faculty laboratory to limit the dissemination of research results prior to publication or patent disclosure.

Communication

Communication problems in three areas exist that have in the past constrained development of new industries created from basic research in academic institutions: university-university communication, university-industry communication, and the developing industries' ability to effectively communicate with state government. If biotechnology specifically is to be fostered, then these communication constraints need to be considered carefully before major decisions or programs are created.

Widely promoted is the concept of technology transfer between the university community and industry. However, before questioning whether this can be fostered, it is important to consider communication among faculty at the same academic institution and between academic institutions.

Past experience indicates that communication among faculty at the same institution is often less than optimal. The organization and coordination of faculty within a discipline is often difficult—much less between disciplinary areas. Communication between academic institutions is hindered and actually discouraged due to the traditional mechanisms of competitive grant support from federal or industrial sources.

With respect to biotechnology as a specific new industry and the proprietary constraints dictated by current patent law, additional professional and ethical guidelines often need to be developed to insure separation of academic and business interests for faculty that teach and supervise students while consulting or actively participating in the creation of new start-up industries. This question of limited communication between industry researchers and academic scientists has often been debated with regard to the potential negative effects it may have through limiting academic freedom. Recent evidence suggests that funding of academic research by industry over the past two decades has not resulted in significant compromises of the freedom of the researchers to train students and publish their results (6).

Academic faculty in related fields can interact with industry by a variety of mechanisms: on a one-to-one basis or as groups of faculty in a cooperative or consortium agreement (Table 2).

Table 2. University-Industry Interactions.

Communication	Advantages	Disadvantages
• One-on-one		
-consultant	-specific	-limited scope
-seminars	-timely	-not generic
-conferences	-maintain proprietary interest	-limited participants
• Cooperative		
-sponsored research	-cost benefits	-singular solutions
-licensing	-risk minimized	-not long lasting
-sharing personnel, facilities	-timely	-cannot maintain proprietary position
-internships		
-consortium		

The one-to-one relationship between faculty and industry will always exist. This is a rapid way for industry to address specific questions. It can be done efficiently by faculty giving seminars or conferences, and faculty acting as individual consultants. Proprietary interests can be maintained because the relationship is limited in scope. This type of interaction, however, involves a limited number of participants, is not generic, and usually does not lead to development of major new industries.

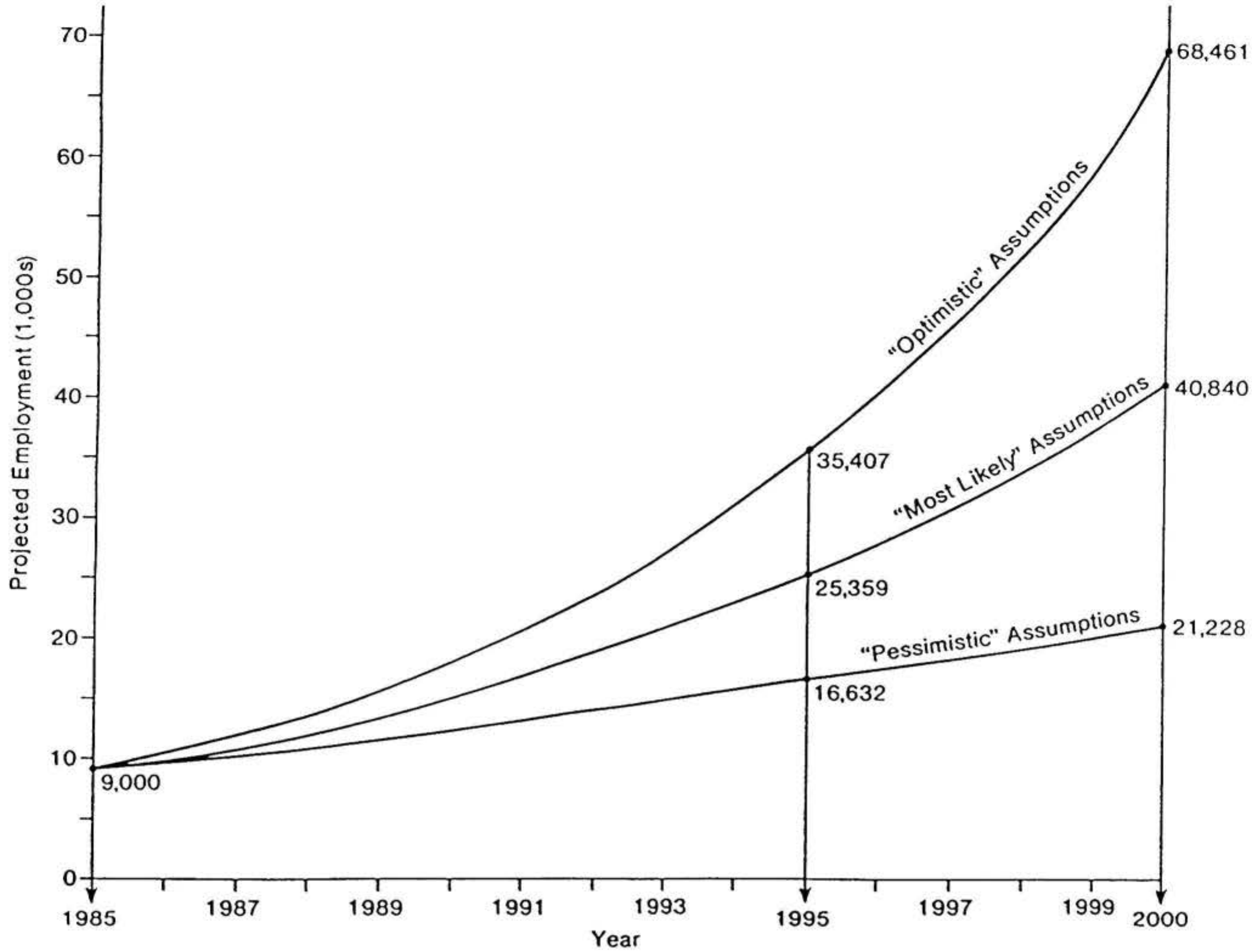


Figure 2. Projected Minnesota employment in the biotechnology industry. (4).

Coordination

Cooperative agreements among faculty and with more than one industry are being actively fostered by federal research programs such as the Industry/University Cooperative Research Centers program of the National Science Foundation (NSF) (Table 3) (6). This program has created national centers for consortia of companies and large numbers of participating faculty. These types of interactions differ from the one-on-one faculty-industry interactions in that a large number of faculty are involved and more than one industry is participating. Firms in this program may sponsor research that crosses disciplinary lines and involves faculty from a variety of traditional academic departments. The participating firms may have the opportunity to negotiate with the university for reduction in indirect costs, licensing, acquisition of particular technologies and patenting of research results in order to create incentives for sponsoring research in an academic environment as opposed to within their own firms. There may also be sharing of personnel and facilities between the university and participating industries in these centers or consortia. The students participating in these activities may obtain beneficial exposure to the significant problems in the participating industries or even work in industrial research laboratories as part of their educational experience.

Table 3. The role of university/industry consortia in biotechnology development.

- Forum for exchange
- Collaborative projects
- Provides industry-industry exchange
- Two-way internships
  - -personnel
  - -lectures, seminars, courses
  - -facility sharing
- Industrial advisory roles
- Leveraged R&D expenditures
- Right of first refusal
- Recruitment
- Faculty insights to industry
- "Beta" site at university

In biotechnology-related disciplines, however, these research consortia are difficult to foster because of the proprietary nature of the research. Consortia by definition have to pool resources to address common or generic questions to the benefit to all sponsoring organizations. This significantly leverages each participating firm's investment as well as minimizes the risks. Because of the mechanism of pooling of resources, however, it is less likely that this type of research will be related to a specific product for a specific firm.

It is unfortunate that among the 39 NSF centers specifically designed to foster industry/university cooperative research, only two directly related to biotechnology have been supported by industry. These are the Monoclonal Antibody Lymphocyte Engineering Research Center in North Carolina and the Center for Biocatalytic Processing in Minnesota.

In addition to the Industry/University Cooperative Research Programs, the NSF has also created Engineering Research Centers (ERCs) as an additional mechanism to develop university-industry collaborative consortia (6). One ERC directly related to biotechnology is the Massachusetts Institute of Technology's Engineering Research Center in Biochemical Process Engineering, which has a five-year, $20 million grant from NSF with active financial participation from biotechnology-related industries. In this case, a major commitment was required by the academic institution in terms of space, administrative staff, industrial liaison staff, and patent office staff to coordinate the center. The annual operating overhead expenditure for the administration of this large corsortia is $200,000-$300,000. This cost does not include the space required by visiting industrial scientists and new equipment specifically for the center use. Nor does this figure reflect the amount of time required by the faculty involved, not only for the research but to effectively interact with the large number of participating firms by presenting research reports at annual center meetings, entertaining visiting scientists from industry, and acting as individual consultants to the member firms.

The commitment of faculty time is, in many cases, the greatest restraint. These collaborative and consortia activities compete with faculty teaching time and the time required for faculty to effectively recruit and train graduate students. Faculty members continue, as they always have in the past, to be primarily interested in scholarly publication and teaching, which lead to their ability to attain tenure and be promoted. Unless academic-industrial interactions are recognized and fostered by the promotion and tenure process, as they are at a small number of technological institutions in this country and more extensively in foreign countries, there will continue to be little incentive for many faculty to participate in view of their other time commitments.

Some institutions have created centers or industries known as organized research units (ORUs) to address these interdisciplinary administrative, space, and time commitment problems (7). In some instances, collaboration has been fostered by releasing faculty from teaching and university service responsibilities. If not monitored closely by the institution, this may contribute to inequities among faculty and further discourage faculty participation.

Creation of Incentives

Many firms in advanced technologies have traditionally sought to leverage their abilities by locating themselves near academic institutions. The objective is to foster translation of developing technologies from an academic, basic research environment into the developing new industry.

Implicit in this assumption is that there are few communication constraints between the academic and private sector institutions. How realistic is this assumption for biotechnology and should Minnesota emphasize this similar approach for development of new biotechnology industries?

State Promotion

Many states are seeking to promote biotechnology-related industries in spite of the proprietary nature of this technology by promoting evidence of existing collaborations between academic and private researchers. The state of Texas, for example, has structured an approach where the major fraction of biotechnology-related new research funds could come from the private sector through the Dallas Biotechnology Development Corp. (8). Other states have created similar mechanisms, primarily using private or state funds derived from a major existing state industry to attempt to stimulate translation of biotechnology research into industrial results.

Some states have chosen to foster communication by creation of industrial parks specifically tailored in their design and facilities for biotechnology industry. One example of this is the Massachusetts Biotechnology Research Park (9), which is located adjacent to 10 educational institutions with specific business incubator facilities for biotechnology-related industry. Table 4 summarizes the time lag from creation of the Worcester Biotechnology Development Corp. (WBDC) to the actual beginning of construction of facilities (9). This example emphasizes the legislative milestones, enabling legislation, tax incentives, and zoning, which had to be created prior to actually building and attracting tenants.

Table 4. Milestones in the development of the Massachusetts Biotechnology Research Park. (MBRP)

• WBDC First to Propose a Biotechnology Complex on 75 acres on Plantation Street in Worcester	1981
• Land Declared Surplus by the Board of Trustees of the University of Massachusetts	May 1982
• Deadline for Developers' Proposals for Use of Plantation Street Land	November 1982
• WBDC Awarded Development of Park by Governor Michael S. Dukakis	April 1983
• Enabling Legislation Passed	July 1983
• Scientific Director Appointed	July 1983
• Cooperation Between the WBDC and the University of Massachusetts Medical Center Established	August 1983
• Sasaki Associates Selected as the Design Firm	October 1983
• Environmental Impact Report Process Initiated	February 1984
• Massachusetts Biotechnology Research Institute Incorporated	April 1984
• Title to Land Conveyed by State	June 1984
• City Zoning Ordinance Approved	July 1984
• City Biomedical Research Ordinance Approved	August 1984
• Title Insurance Obtained	September 1984
• Project Director Appointed	January 1985
• Bill Creating Center of Excellence in Biotech Park Signed by Governor	January 1985
• Final Environmental Impact Report Certified by Massachusetts Secretary of Environmental Affairs	March 1985
• Hines Industrial named developer for MBRP	April 1985

Recently, the city of Minneapolis and the University of Minnesota have rekindled development of a similar high technology park to be located next to the University as a potential lure to attract new high technology industry (10). Current tenants in this development include the University's Supercomputer Institute and firms that will benefit from access to this facility. In the future, however, this development could also be tailored to attract biotechnology-related industries. A similar 110-acre Minnesota Medical Enterprise Park devoted exclusively to medical technology is being developed in Coon Rapids (11).

Industry-University Communication

Physical proximity of these developing industries to academic institutions alone, however, does not insure effective communication between academic and industrial researchers.

Effective avenues of communication in Minnesota need to be opened so that industry-university communication is not a one-way street. Developing industries seeking collaborations with academic scientists require mechanisms not only to find faculty involved in related basic research but also to protect disclosure of their needs and plans. This is the primary problem in development of a biotechnology industry—complete disclosure is seldom possible due to the proprietary nature of the developing technology.

The fostering of industry-university communication could also be stimulated by distribution to industry of information concerning faculty research interests and expertise. Where does a new company go when it wants to find this basic information? Simply listing faculty research interests will not indicate to firms which faculty have any interest in or perception of the significant technological hurdles for development of new industries.

Overcoming Constraints in Minnesota

Table 5 summarizes the active participation required by industry, state government, and academic institutions in order to overcome communication and coordination constraints and enhance university-industry interactions in Minnesota in biotechnology. Primary considerations must be to coordinate efforts among academic institutions, avoid duplication, and at the same time promote communication between industrial and academic scientists (Table 6).

Table 5. Commitments needed by state industry and government to foster biotechnology development.

- Industry must demand active participation and financial support from state government for:
    1. Training programs for workforce
    2. Long term high quality research and facilities for research
    3. Mechanisms to reward participation by faculty in both basic and applied research
- Industry must work with State government to revise the business climate for both biotechnology start-ups and expansions.
- Government and industry must promote Minnesota as a coordinated biotechnology climate with existing educational programs.

Effective and equitable mechanisms must be explored to reward faculty for participation in research and industrial collaborations to foster state industry. This reward mechanism must be factored into the regular promotion and tenure process in such a way to sustain only the highest standard of teaching and research. The experience of other states has shown that in order to foster new industry, academic institutions must contribute the highest quality and most innovative research and teaching programs, which can be coordinated with a business environment that promotes rapid development and translation of the results of basic research into new ventures.

Table 6. Methods to enhance university-industry interactions in Minnesota.

- Develop university, private colleges, AVTI consortia
    - Sharing of personnel, facilities, students
- Method of faculty reward for participation
    - Contribution to tenure, promotion decisions
    - High standard of quality in both research and teaching
- Clear definition to state industry of educational resources
    - What talent exists and where
    - Specific interests of individual universities
    - Geographic distribution within the state

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