Chapter 3

Introduction: Commercial Activity

"Ifentrepreneurs and arbitrageurs were our heroes of the '80s, we hope scientists and engineers will be the stars of the '90s."

Mary Ann Liebert
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BIOTECHNOLOGY AND COMPETITIVENESS

Biotechnology is a new set of techniques that can be used in basic research, product development, and manufacturing in several different industries. Although it was primarily developed in the United States, funded mainly through government support for basic biomedical research, there are growing concerns that, like some other native technologies, biotechnology will be rapidly adopted and commercially applied elsewhere, leading to a loss of U.S. preeminence in this area.

Biotechnology was first applied commercially in producing diagnostics and therapeutics. These applications were the most obvious because most of the developers of the new techniques were conducting basic biomedical research. Most recently, genetically engineered biopesticides have won regulatory approval in the United States. Further agricultural applications are expected within the next 10 years.

In the United States, the earliest firms to exploit these new techniques were the dedicated biotechnology companies (DBCs). Financed with venture capital, they were founded in the late 1970s and early 1980s to apply the new techniques to the development of diagnostics, pharmaceuticals, pesticides, plants, and other products. Although these firms are often referred to collectively as the "biotech industry," the dedicated biotechnology firms are, in fact, developing products and competing with firms in existing industries. DBCs, regardless of the products they make, share some characteristics and certainly compete with each other for capital. But industries are defined primarily by the products they produce and the markets in which they compete. As DBCs develop and become engaged in commercializing products, the problems they face are characteristic of the existing industries to which they belong. Thus, their problems become more understandable if DBCs are regarded not as "biotech companies' but as young firms in, for example, the pharmaceutical, agricultural, or waste treatment industries.

Although DBCs have actively applied biotechnology to existing industries, more and more, established multinational firms in these industries are investing in biotechnology, either through investment in in-house research programs or through linkages with small firms. Over the last 10 years, as it has become clearer which applications are potentially useful and which are not, the research and development (R&D) conducted by small firms has become more narrowly focused, and investments of larger firms have become more aligned with their long-term strategies.

Increasingly, biotechnology is becoming part of the mainstream of R&D in several industries. In assessing its ultimate impact on industry and productivity, it is less useful to ask, "Is the United States competitive in biotechnology?" and more useful to ask, "HOW can biotechnology contribute to the competitiveness of the industrial sectors in which it can be used?" and, "What factors influence the adoption of biotechnology in these industries?" To understand the adoption of biotechnology by these industries requires some understanding of the organization of the industries and the role of innovation and R&D.

Like other new technologies that have the potential for major effects on a number of industries, the ultimate impact of biotechnology is impossible to predict. But, as with other new technologies, its incorporation into research, product development, and manufacturing is likely to be gradual (1,2). A number of factors influence investment in biotechnology and its diffusion into new industries, including:

. Technical feasibility. The earliest research projects in every industry have been chosen mainly for ease of accomplishment because new companies or new research teams need to demonstrate their competence and achieve commercial success in a relatively short time. Beyond initial projects, technical limits constrain the projects that may be done. Work in agriculture, for example, has been limited because of difficulties in transferring deoxyribonucleic acid (DNA) into the cells of major cereal crops and the relative lack of basic knowledge of plant genetics and biochemistry

compared to knowledge of common microorganisms and mammals.

- Ability to recoup investment in R&D and capture profits. In some industries, biotechnology can provide an alternative production process for a marketable product (e.g., insulin or growth hormone), the development of improved versions of current products (e.g., tomatoes or cotton), or the development of novel products (e.g., tissue plasminogen activator (tPA) or biopesticides). But in some cases the new production processes are not competitive with current technology. For other products that are technically feasible, the potential size of the market is too small to justify the investment in R&D needed to bring the product to market. The cost of research can be offset by marketing products more widely, especially through exports. The ability to protect technology investments by patenting also influences a firm's ability to capture markets and therefore profits.
- Availability of a research base and labor pool. In the United States, federally funded basic research in biomedical sciences has provided a wealth of information that can be exploited by industrial research teams. Much less basic research has been conducted in plant biology and microbial ecology. Federal funding of research has also resulted in the training of scientists with skills useful to some industries. The European research base is not as extensive as that in the United States, and in Japan and other Asian countries there is relatively little public funding of basic research in biology. Scientists in these countries must often go abroad to obtain training.
- Availability of capital. The development of biotechnology in the United States coincided with the availability of a high level of funding for new firms from venture capitalists and public equity markets. In Europe and Japan, venture capital and public equity have played a much smaller role. Outside the United States, industrial biotechnology is largely confined to the research laboratories of major corporations.
- Fit with industry or company strategy. The chemical industry inmost industrial nations has undergone a restructuring in the last 10 to 20 years. Many major corporations have been reducing their operations in commodity chemicals while investing in specialty chemicals and life sciences, including pharmaceuticals. Investment has followed this corporate strategy. Investment in biotechnology by pharmaceutical firms is also made to complement existing product lines and research needs. Seed firms use biotechnology to complement their efforts in plant breeding.
- Public acceptance. In the United States, farmer resistance to the use of bovine somatotropin (bST), a protein hormone that increases milk production, has delayed its introduction and may deter investment in the development of similar products. In some parts of Europe, particularly Germany, public concerns about the use of biotechnology has slowed commercial development. On the other hand, consumers have favored the development of new drugs, diagnostic products, and environmentally benign biopesticides.
- Regulations. Regulations can delay the introduction of new products and thus delay returns on investment. For example, the lengthy process for obtaining drug approval in the United States has been widely criticized. The time it is taking the Environmental Protection Agency (EPA) to develop regulations for field-testing genetically modified micro-organisms is thought to have had a negative impact on investment in this area. The development of biotechnology regulations in Europe and Japan has also been slow and, especially in Denmark and Germany, has been thought to inhibit investment.
- Effects of other government programs. Agricultural programs that affect acreage planted or that protect farmers can influence investment in agricultural biotechnology. Laws on environmental protection affect the use of bioremediation. The Orphan Drug Act and the Plant Variety Protection Act (PVPA) are intended to encourage investment in new drug and new plant development, respectively. Other examples of government policies that influence investment in biotechnology include tax policies and laws on intellectual property protection.

The ensuing five chapters are not intended to be exhaustive descriptions of the industries or the applications of biotechnology. The intention is to give a fuller explanation of forces that affect

adoption of biotechnology. In each sector, market forces beyond the scope of government authority largely determine the use of biotechnology.Governments can influence the climate for technology development and adoption as they influence the climate for all business activity. Congress can influence technology adoption through its activities concerning basic scientific research and training, regulations, patents, and in legislation that specifically affects the industries in which biotechnology will be used.

CHAPTER 3 REFERENCES

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