Chapter 2

Introduction

Contents

Chapter 2

Introduction

This report assesses the international competitive position of the United States with respect to the development and commercialization of industrial applications of new biotechnology. New biotechnology is defined as the use of novel technologies–recombinant DNA (rDNA) technology, monoclinal antibody (MAb) technology, and new techniques used in bioprocess engineering—to develop commercial products and processes that use living systems.

Despite its rather narrow focus on new biotechnology, this report can be viewed as an introduction to the entire subject of biotechnology, a field that will become increasingly important in industrial production during the next few decades. Developments associated with new biotechnology could spur a renaissance in traditional biotechnology. The lure of profitability in new biotechnology, for instance, will very likely attract students to bioprocess engineering, and an increase in the number of engineers will probably improve bioprocess technologies applicable to the traditional uses of biotechnology. Another reason biotechnology may increase in importance is the movement, albeit not very rapid, toward the use of renewable resources. Diverse micro-organisms able to convert biomass into useful chemicals, some of which are a source of energy, are known, and these micro-organisms have yet to be exploited to the fullest extent. Furthermore, the industries that use traditional biotechnology are showing interest in the novel techniques mentioned above, and many of these industries will probably be using these techniques, because of their broad applicability, in some aspect of their operations in the future.

Impact of biotechnology on the research community

A point to be mentioned that does not relate directly to this report is the impact of the novel technologies, especially rDNA technology, on the biological research community. Recombinant DNA technology has already allowed a greatly increased understanding of the basis of life, and thus, of the genetic basis of disease. Research over the next 10 years may yield an increased understanding of the mechanism of carcinogenesis, genetic susceptibility to disease, the functioning of the immune system, the basis of debilitating diseases such as diabetes and arthritis, and some knowledge of brain function. Additionally, gene transplantation technology may reach a stage where some genetic diseases could be cured. It may be that the main benefit of the new biological technologies will be the advances in fundamental knowledge that accrue. Thus, even if no commercial products were to result from them, these technologies would still have a substantial impact on the quality of life.

The multidisciplinary nature of biotechnology

Biotechnology is unusual among most technologies in that it spans an array of scientific disciplines. Individuals seeking to be well versed in applications of biotechnology must have interdisciplinary training. Bioprocess engineers, for example, need some knowledge of biochemistry and microbiology as well as knowledge of engineering design so that the most efficient combination of micro-organism and bioreactor can be determined. Similarly, plant molecular biologists

25-561 0 - 84 - 3

need to know both plant physiology and molecular genetics. People working in microbial enhanced oil recovery need training in microbiology as applied to a specific geological environment.

The multidisciplinary nature of biotechnology has extensive implications for educational and industrial structures. To excel in biotechnology, universities will need to draw on the resources of several departments. Diversified companies may have an inherent advantage over other companies, because technologies perfected for the production of one product (e.g., a pharmaceutical product) can be modified and used for the production of another (e.g., a food additive).

Biotechnology in developing countries

One area where biotechnology could certainly have an impact, though not considered extensively in this report, is in developing countries. Plants that have been genetically manipulated for growth in tropical and desert climates could improve agricultural production. Vaccines that do not need refrigeration could have widespread influence on the health of the people and their livestock. Small local factories that convert biomass to ethanol could help solve the problem of costly petroleum imports for energy.

The applications of biotechnology to developing countries was discussed in a workshop held by the National Academy of Sciences and the U.S. Agency for International Development (l). The proceedings of this workshop include suggested priorities for research and time frames for development of various biotechnology products important to developing countries, Additionally, the United Nations Industrial Development organization has proposed the construction of an international center for biotechnology (2). The proposed center would have 50 staff scientists, 26 postdoctoral fellows, and 100 visiting scientists; the annual budget would be $8.6 million; and the research would concentrate on problems specific to developing countries.

This report does not cover developing countries for two reasons. First, developing countries are not likely to compete with the United States for market shares in biotechnology in the near future. Second, all countries in a competitive position generally have equal access to markets in developing countries, allowing them equal access to international market shares. Some developing countries give preferential treatment to the first company to market a product in that country, but all countries have equal access for first introductions.

Local efforts to promote the development of biotechnology in the United States

Many State governments are actively promoting ***the*** establishment of local high-technology centers to stimulate the local economy, and many of these include centers for biotechnology. The oldest and best known of these is the North Carolina Biotechnology Center. This report does not analyze the development of these centers because they are analyzed in another OTA report, ***Technology, Innovation, and Regionnal Economic Development,*** due to be published in 1984. It is important to note, though, that it will take several years to recoup the costs of initiating one of these centers. Local biotechnology centers cannot be viewed as a short-term solution to economic problems.

Organization of the report

This report is organized into four parts. Part I introduces the scientific background of the new technologies and forms a basis for discussion of the commercialization of new biotechnology. The three chapters consider the construction of rDNA, the formation of MAbs, and the relevant engineering principles for the large-scale growth of microorganisms and the use of immobilized enzymes to perform specific catalytic functions. Each emphasizes the industrial use of the technologies and identifies the problems yet to be solved.

Part II is an overview of the companies using biotechnology in the United States and its five major competitors in biotechnology: Japan, the Federal Republic of Germany, the United Kingdom, Switzerland, and France. The discussion considers the relative importance of and level of collaboration between established companies and new biotechnology firms in determining a competitive advantage. This part also includes a discussion of the firms producing the necessary reagents and equipment for the commercial use of biotechnology. Joint ventures among firms, both foreign and domestic, are analyzed.

How specific industrial sectors are applying biotechnology is the subject of the several chapters in Part III. The sectors discussed are pharmaceuticals, agriculture, specialty chemicals and food additives, environmental applications, commodity chemicals and energy, and bioelectronics. The order of the chapters corresponds to the approximate time frames for the development of products and processes in the various sectors– beginning with the sectors in which developments are likely to occur first. Priorities for future research to promote the development of biotechnology in each of the specific industrial sectors are outlined at the end of each chapter.

Part IV is an analysis of specific factors believed to influence a country's competitiveness in biotechnology. It considers only those factors that government policies could potentially affect. The first chapter of Part IV describes the framework used for the analysis. Subsequent chapters analyze specific factors, more or less in order of their importance: private sector financing and tax incentives, government funding of basic and applied research, personnel availability and training, health, safety, and environmental regulation, intellectual property law, university/industry relationships, antitrust law, international technology transfer and trade policy, targeting policies in biotechnology, and public perception. The analysis of the relative importance of each factor in determining a country's competitive position in biotechnology and where the United States stands is presented in ***Chapter 1. Executive Summary.*** Throughout Part IV, issues of congressional interest and a range of policy options are examined with respect to improving the U.S. competitive position in biotechnology.

This report is a follow-on study to OTA'S April **1981** report entitled ***Impacts of Applied Genetics: Micro~rganisms, Plants, and Animals (3).*** Much useful information is contained in that report and is not repeated here. The reader is advised to read the earlier report for more information on the biological technologies and market forecasts.

Chapter 2 references

1. Board on Science and Technology for International Development, Office of International Affairs, National Research Council, ***Priorities in Biotechnology Research for International Development: Proceedings of a Workshop*** (Washington, D. C.: National Academy Press, 1982).
2. Newmark, P., "International Biotechnology: U.N. Center To Be Based in India," *Nature 302:100, 1983.*
3. US. Congress, Office of Technology Assessment, ***Impaets of Applied Genetics: Microorganisms, Plants, and Animals, OTA-HR-132,*** Washington, D. C., April 1981.