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The Commercialization of Biology

A Biological Obstacle Course

Scientific Note

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Index Entries: Biotechnology; commercialization; research; public perception.

INTRODUCTION

In a 1985 article entitled "Science and Technology Policy: The Next Four Years," George Keyworth II, former presidential science advisor, defined industrial technology as the endproduct of a multistep process of research, development, and application (Keyworth, 1985). Industrial biotechnology is no different and is presently facing many of the same obstacles as other innovative technologies struggling to develop into identifiable industries. Overcoming technical and commercialization barriers requires the interaction of three principal participants: scientific researchers, government officials, and industrial managers. Figure 1 illustrates this concept.

Ten social/institutional factors have been identified by the Office of Technology Assessment (OTA) as important for ensuring the continued progress toward the commercialization of biotechnology (*1*). These challenges or obstacles are

1. Financial issues and possible tax incentives for firms engaged in innovative biological research.
2. Future direction of government research funding in the life sciences.

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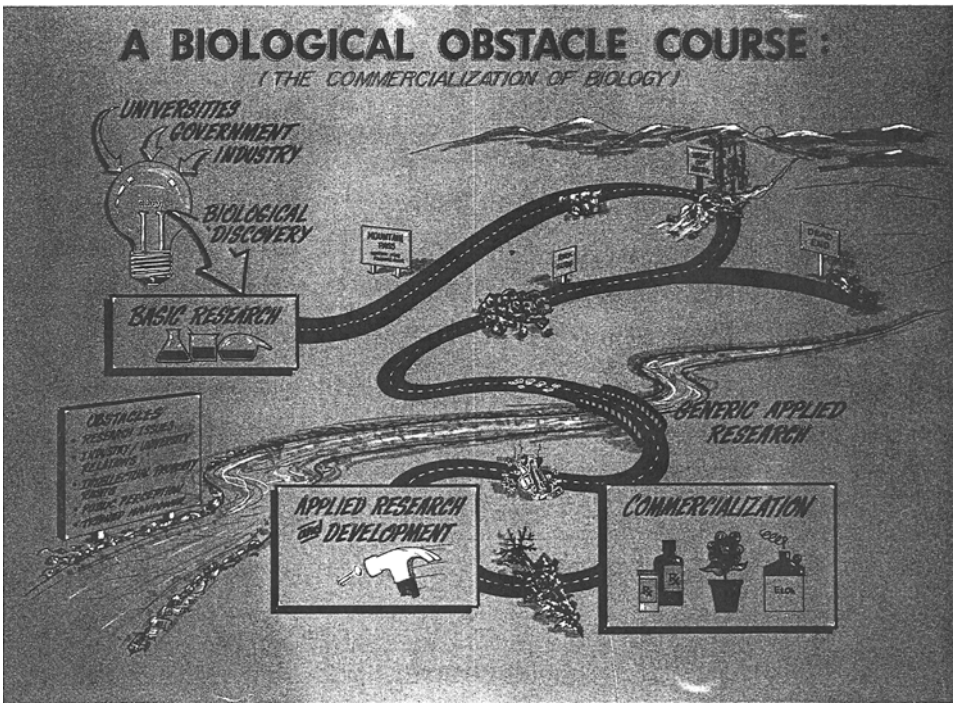

Fig. 1. The path from biological discovery to commercial realization.

3. Availability of trained, talented personnel skilled in the scaleup of biotechnologies from the laboratory phase to commercial operations.
4. Health and safety issues, and potential environmental regulations.
5. Patent and intellectual property laws.
6. Development of university/industry relationships.
7. Antitrust law.
8. International biotechnology transfer, investment, and competition.
9. Federal biotechnology policies.
10. Public perception (1).

Though the list is long, it should be possible to establish a knowledge base with input from industry, academia, and government, that would provide a technical basis from which to make informed decisions concerning commercialization challenges. Three areas from the list, future biological research activities, university/industry relations, and public perception, are discussed in more detail below.

RESEARCH ISSUES

Currently, US science policy is dictated by the paradigm that it is "fundamental knowledge that ultimately drives the process of industrial

innovation." So, with strong congressional support, the current administration has increased government funding for basic research (*2*). Basic research is usually concerned with the science underlying the technology. Results may provide a basis for applied work, however, the focus is on obtaining scientific knowledge. This type of research is necessary to maintain a scientific base upon which the technology will depend.

The corresponding trend in US science policy is to leave the development of new technologies to the private sector (*2*). The objective of applied research and development is to gain necessary knowledge that will allow the research to proceed to a product or process level. As the path from laboratory to marketplace can be long, there is often a tendency by corporate management to focus on research with a near-term potential return on investment.

In order to develop a strong technological base for new biological developments, government or industry must also support the longer-term research that bridges the gap between basic research done mainly by the universities and the often proprietary applied research conducted by industry. This type of research is termed generic applied research by the Office of Technology Assessment (*1*). Others expressions, such as, "directed basic research," "basic applied research," and "exploratory research," are sometimes used to describe this type of research activity. Regardless of which phrase is used, bridging research is aimed at solving general problems associated with the use of a technology.

Though the United States has made large financial commitments to basic biological research in the past, funding for research activities in generic applied research is relatively small. The low level of US funding for generic applied research in biotechnology could lead to a bottleneck in our national biotechnology commercialization efforts (*1*).

The performance of this bridging research is especially important since international competitors, such as Japan, also have strong commercial interests in biotechnology. In the past, the Japanese have been able to capitalize on the basic research performed in the United States and other countries, and have concentrated on performing applied research that can be quickly commercialized (*1*). This ability, combined with their experience in the traditional bioprocessing technology of fermentation, provides them with significant advantages in future commercial ventures involving the "new" biology (*3*).

One government program in this country, the DOE Energy Conversion and Utilization Technologies Program (ECUT), has focused on addressing the longer-term technical problems encountered in the attempt to apply recent biotechnologies to large-scale processes. The approach is multidisciplinary, with inputs from industry, academia, and government. Research funded by the ECUT Biocatalysis Project has been investigating the potential of biocatalysts for the production of bulk chemicals. The goal is to develop and improve the knowledge base so that industry will be able to displace the significant level of nonrenewable resources using biologically based production processes. Research

underway is addressing issues in process kinetics, bioreactor productivity, and separation energetics.

UNIVERSITY AND INDUSTRY RELATIONSHIPS

The concepts of invention and innovation are very different and should be understood when considering questions surrounding university/industry relationships and intellectual property law. Often, inventions occur that are never developed into innovations affecting commercial applications. Innovation in an emerging technology area can be defined as the outcome of a process of combining production factors in novel ways to produce old products more efficiently or to create entirely new products (*4*). An example of this is tissue culturing, which has been available as a scientific tool for over 20 years. Only recently could it be considered an innovation, because industrial applications have been developed to utilize this technique (*4*). The questions of who owns the intellectual property, the inventor or the innovator, and who absorbs either the profits or losses associated with its development may result in considerable controversy.

Another issue is how well universities can meet their own needs and still meet the needs of emerging industries. While research is a vital part of the academic setting it cannot be allowed to overshadow a primary purpose of an educational institution—education. In order to ensure that there will be adequately trained individuals, industry and academia will have to work together and strike a balance between the near-term needs of industry and long-term requirements of basic research in the university setting.

PUBLIC PERCEPTIONS

Industry should seek help in tackling the public's perception of the safety hazards associated with the "new" biology. As both the nuclear and the chemical processing industries have learned, the public is no longer willing to rely on "expert" assurances that a technology is safe. If enough publicity is generated that emphasizes the negative attributes of a technology, public sentiment can turn against the technology.

It is important that groups engaged in the research, development, and promotion of these new technologies explain the beneficial attributes. At the same time, honesty is required concerning possible negative aspects.

Benefits such as new medications and energy-efficient chemical processes can be easily understood by the general public if described in a manner not burdened with sometimes difficult to understand technical jargon. By presenting biotechnology to the public in a positive, easily un-

derstood manner, it should be possible to develop the public's perception in a way that will aid, not hinder, the commercialization of biology.

CONCLUSION

This country has many resources to draw upon as it attempts to commercialize recent developments in the "new" biology. However, there are also many obstacles to overcome that will require cooperation among different interest groups in order to develop a strong and vital industry.

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