

PART IV

**Analysis of U.S. Competitiveness
in Biotechnology**

Chapter 11

Framework for Analysis

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Framework for Analysis

With the increasing importance of high-technology industries in the United States and the decreasing competitiveness of U.S. goods in world markets, U.S. policy makers need to be able to assess the country's future with respect to the

commercialization of emerging technologies. If the country's potential competitive position can be defined, policy analysis can suggest possible governmental steps to improve that position.

Factors influencing competitiveness in biotechnology

To analyze the future competitive position of the United States in biotechnology, OTA identified 10 factors believed to have potential influence on the international competitiveness of products resulting from an emerging technology. * Many of these factors relate to the legal system and various governmental policies, although societal and private sector factors were also identified. The 10 factors are:

- financing and tax incentives for firms;
- government funding for basic and applied research;
- personnel availability and training;
- health, safety, and environmental regulation;
- intellectual property law;
- university/industry relationships;
- antitrust law;
- international technology transfer, investment, and trade;
- targeting policies in biotechnology; and
- public perception.

These 10 factors are described in the chapters that follow. The chapters are presented, more or less, in the order of the factors' importance to competitiveness in biotechnology. Each of these factors was analyzed for the United States and five countries identified as the major potential competitors of the United States in biotechnology: Japan, the Federal Republic of Germany, the United Kingdom, Switzerland, and France.

The three factors that OTA believes to be most important to a country's success in commercializing an emerging technology such as biotechnology are financing and tax incentives for firms, government funding of basic and applied research, and the availability of trained personnel,

The first of these factors encompasses the availability of capital both for starting new firms and for financing the growth of existing firms. It also includes tax policies that affect the formation and availability of capital as well as the strategic decisionmaking in firms.

Funding of basic, generic applied, * and applied research is necessary both to maintain a science base and to ensure the availability of the technical means to apply scientific knowledge industrially. The distinction between basic, generic applied, and applied science research is an important one, because, in establishing a competitive position, a comparative advantage in applied science may be more important than an advantage in basic research. optimally, an analysis of funding for basic, generic applied, and applied research would include funding from both government and industry. Industry figures are usually proprietary, however, so the analysis in this report necessarily concentrates on government funding,

The third factor, availability of personnel trained in essential disciplines in a new tech-

*OTA's model for determining the future competitive position of different countries with respect to the commercialization of biotechnology could very well be useful in determining international competitiveness with respect to the commercialization of other emerging technologies. For emerging technologies other than biotechnology, however, the relative importance of specific factors would not necessarily be the same.

*Generic applied research is research whose objective is to gain the understanding necessary to solve a problem common to a particular industry. Such research falls between basic research, the objective of which is to gain understanding of the basic aspects of phenomena without goals toward the development of specific processes or products; and applied research, the objective of which is to gain understanding necessary to meet a recognized and specific need, process, or product.

nology, is important to firms considering the commercialization of that technology. Furthermore, the quality of science and engineering education is a major factor in determining the future availability of personnel.

Three factors were identified as having moderate importance in the commercialization of biotechnology: health, safety, and environmental regulation, intellectual property law, and university/industry relationships.

To determine the importance of health, safety, and environmental regulation, several issues had to be weighed. On the one hand, the more stringent the regulations protecting against potential risks of the technology, the more positive the public's reaction to the development of the technology is likely to be. On the other hand, stringent regulations may discourage commercialization. Most companies will seek to enter domestic markets first, and for these companies, the domestic regulations will be of primary importance. Companies interested in developing international markets, however, must also consider the regulations of other countries. Some countries' regulations are effective nontariff trade barriers that discourage entry by foreign firms into domestic markets.

The intellectual property laws of a country partially affect whether a company will pursue a line of inquiry. If one is unlikely to reap the benefits of the discovery of an invention, then one is less likely to work on such an invention. Furthermore, if a country's patent laws are not sufficiently protective, then a company may choose to keep its inventions as trade secrets. Protection through trade secrets usually discourages technology transfer.

Active interaction between industry and academia is a factor that could promote the competitiveness of a country in an emerging technology. Usually when a technology is in the early experimental phase, most of the important research is carried out in universities. Ongoing dynamic university/industry relationships are an effective means of domestic technology transfer. Generally therefore, such interactions promote a country's competitiveness.

Three factors were determined not to be very important to the development of biotechnology

now, although these factors could increase in importance as biotechnology becomes a more mature technology. They are antitrust law; international technology transfer, investment, and trade policies; and government targeting policies in biotechnology.

U.S. and foreign antitrust laws were originally intended to stimulate competitiveness among domestic industries by prohibiting restraints of trade and monopolization. As countries have sought international markets, however, questions have been raised about whether antitrust restrictions accomplish their intended purpose. Governments of some countries have taken a relaxed attitude toward the interpretation of these laws with respect to research joint ventures and technology licensing, while the governments of some countries continue to have strict interpretations. It is possible that the strict interpretation of antitrust law with respect to joint ventures and technology licensing could decrease a country's international competitive position.

Trade policies and laws that guide the transfer of products and technology internationally could influence a country's competitive position if the laws and policies are not reciprocal among countries. Technology transfer laws are generally concerned with national security issues and transnational joint ventures. Investment control and exchange laws when applied to technology licensing or technical assistance agreements or foreign investment, can restrict the importation of foreign technology or capital into particular countries and thereby restrict foreign access to that local market. Trade policies important to biotechnology include tariffs and nontariff barriers, such as packaging requirements and nonacceptance of foreign clinical data.

Some governments target selected emerging technologies to promote rapid commercialization. In consultation with experts from academia and industry, they formulate the direction, backed by funds, that technologies should take to ensure rapid commercialization. Countries with targeting policies may have a competitive advantage in commercializing an emerging technology.

The last factor analyzed is how the public perceives the benefits and risks of the technology.

In democratic countries in particular, public perception can promote or undermine the commercialization of an emerging technology. Depending on the nature and intensity of the public's response to an emerging technology, which cannot be readily predicted, public perception could

be an overriding factor in the commercialization of a new technology. In the case of biotechnology, the public's perception of an accident or perceived risk could significantly influence the development of the technology.

Firms commercializing biotechnology

In addition to analyzing the factors just discussed, it is also necessary for this competitive assessment to analyze the aggregate level of industrial activity. OTA's industrial analysis, presented in *Chapter 4: Firms Commercializing Biotechnology*, was approached from the following perspectives:

- the number and kinds of companies commercializing biotechnology,
- the commercial areas toward which industrial biotechnology R&D is being directed,
- the interrelationship among the companies applying biotechnology, and
- the overall organization of the commercial effort.

The analysis focused on the United States and then made comparisons with other countries.

U.S. efforts to commercialize biotechnology are currently the strongest in the world. The U.S. strength is in part derived from the unique complementarity that exists between small entrepreneurial firms founded specifically to develop new biotechnology and established companies in a variety of industrial sectors. While the entrepreneurial new biotechnology firms (NBFs) specializing in research-oriented phases of development have been the major force behind the commercialization of biotechnology in the United States to date, the role of established companies is expanding. Established companies have assumed a major share of the responsibility for production and marketing of, and, when necessary, obtaining regulatory approval for, some of the earliest products developed by NBFs. Through equity investments and licensing and contract agreements, these companies have also provided many of the NBFs with the necessary

financial and marketing resources to remain solvent. Furthermore, many established companies are now beginning to make substantial contributions to the commercialization of biotechnology in the United States through their increasing investments in their own research and production facilities.

In European countries such as the Federal Republic of Germany, Switzerland, France, and the United Kingdom, biotechnology is being commercialized almost exclusively by large pharmaceutical and chemical companies, many of which already have significant strength in biologically produced product markets. Large established companies are critical to the development of biotechnology in Europe, and they also establish the rate at which biotechnological development takes place. Although such companies have been slow to invest in biotechnology R&D, their inherent financial, production, and marketing strengths will be important factors as the technology continues to emerge internationally.

In Japan, dozens of strong "old biotechnology" companies from several industrial sectors have extensive experience in bioprocess technology, and these large companies are using new biotechnology as a lever to enter profitable and expanding pharmaceutical markets. Japanese companies dominate biologically produced amino acid markets and are also major competitors in new antibiotic markets. They could dominate new specialty chemical markets as well.

Pharmaceutical markets will be the first proving ground for U.S. competitive strength in biotechnology. International competition will be intense. American pharmaceutical and chemical companies will be competing not only against Japanese

companies, but also against the pharmaceutical and chemical companies of Western Europe, all of whom expect to recover their biotechnology

investments through extensive international market penetration.

Results of the analysis

The results of the analysis of the relative importance of the factors affecting the competitive position of the United States and other countries in biotechnology both now and in the future is presented in *Chapter 1: Summary*. Also discussed is the current U.S. competitive position with respect to the other countries analyzed.

Congressional issues and options for improving the competitive position of the United States in biotechnology are discussed at the end of the following chapters. To improve the competitive position of the United States, legislation could be directed toward any of the factors discussed, although coordinated legislation directed toward all the factors might be more effective in promoting U.S. biotechnology.

The chapters that follow discuss only those congressional options that are specific to the development of biotechnology or were pointed out to OTA by U.S. firms commercializing biotechnology. Policy options in some areas are not specific

to biotechnology, but to high technology or industry in general. These options are:

- to improve U.S. science and engineering education and the retraining of industrial personnel,
- to ease U.S. antitrust law to promote more research joint ventures among domestic firms,
- to regulate U.S. imports to protect domestic industries,
- to regulate the transfer of technology from the United States to other countries, and
- to target specific industries or technologies for Federal assistance.

There are many arguments for and against these options that are beyond the scope of this report. Because of their broad applicability to industry in general, these options are not discussed in the chapters that follow. It is important to note, however, that legislation in any one of these areas could affect the development of biotechnology.