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Commercial Biotechnology

The United States now enjoys a lead in biotechnology, but other countries are attempting to overtake us. In this race, what are our strengths and weaknesses as compared with those of other nations? The Office of Technology Assessment, using many advisers and consultants, has made an in-depth study of this matter. A report issued by OTA* contains detailed descriptions of activities and participants in the U.S. effort.

Japan, West Germany, France, the United Kingdom, and Switzerland are named as our principal competitors, and Japan is expected to be the major one. Japanese companies have extensive experience in bioprocess technology; in addition, they have more established bioprocessing plants and more bioprocess engineers than the United States. The Japanese government has targeted biotechnology as a key technology of the future.

The level of efforts in the United States is impressive. Some 219 companies are pursuing applications of biotechnology. All the major pharmaceutical firms are active. In addition, most major chemical companies are engaged as are many oil companies. The most dynamic outfits are the new biotechnology firms, which now number about 110. The OTA report identifies all the known participants and lists their areas of effort—for example, pharmaceuticals, plant agriculture, animal agriculture, and others. Insofar as available, the number of Ph.D.'s on the staffs of the new firms are listed. This shows that a total of 35 companies employ 10 or more Ph.D.'s.

The path from ideas to research and to a remunerative commercial product is a long and costly one. As of the middle of 1983, none of the new firms had achieved an operating profit. Nevertheless, they had obtained assets totaling more than $1 billion. Between March and July of 1983, 23 new biotechnology firms raised about $450 million. As of July 1983, the total market value of 19 new biotechnology firms was about $2.4 billion.

Of more scientific interest are the many projects under way to exploit the opportunities created by recombinant DNA and hybridomas. By far the largest effort is being devoted to pharmaceuticals. A favorite target has been the interferons. These have been prepared by recombinant DNA techniques and are now undergoing clinical trials to test their effectiveness in the treatment of many disorders, including viral diseases and various forms of cancer. However, results to date appear to be equivocal, and approval of interferons for clinical use by the Food and Drug Administration is some distance away. In contrast, by 14 June 1983, the United States had already approved 41 in vitro monoclonal diagnostic products. Development and approval of vaccines is not as far along, but the potential is great: "The combined technologies of biotechnology find perhaps no greater promise for medicine than in the preparation of vaccine and other pharmaceuticals to combat infectious diseases" (page 136).

In the pharmaceutical game, the new biotechnology firms will be up against fierce competition in marketing. They also must endure the long delays and costs entailed in clinical trials and the time spent in awaiting FDA approval. Animal agriculture, on the other hand, provides many opportunities suitable for the new companies. Although the markets are comparatively small—for example, $5 to $25 million—they are of a size not so attractive to big companies. Federal approval of medicines for animals is a less difficult hurdle than approval of those for humans.

These samples of the content of the OTA report represent only a minor fraction of the total. In its entirety, the document presents factors that in the future will condition the competitive position of the United States. The presentation of foreign activities is less detailed. At this juncture, other countries are still trying to catch up, and they tend to be less willing to reveal their status and plans. In any event, it is apparent that competition in biotechnology will be intense and that many valuable products will be marketed in the next decade.—PHILIP H. ABELSON

**Commercial Biotechnology: An International Analysis* (OTA-BA-218, Office of Technology Assessment, Washington, D.C., January 1984).