Biotechnology in Europe

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The countries of the European Economic Community have recently mounted considerable efforts to commercialize biotechnology. Together, these efforts approach the same number of companies and level of government spending as those in the United States. In Europe there is more government emphasis on support for industry-university collaborations and industrial projects than in the United States, where basic research is emphasized. European efforts are often not easily delineated from those in the United States; many European companies have extensive U.S. operations and many U.S. companies have involvement in Europe. Strategies and efforts in European biotechnology are examined and compared to those in the United States.

RECENT ADVANCES IN MOLECULAR BIOLOGY AND IMMUNOLOGY have opened up the use of biotechnology to many industries, with promises of great commercial reward. To date, few major products of biotechnology have reached the marketplace, and strategies for success are yet to be fully defined. Countries throughout the world have concerted efforts to gain success in the commercialization of biotechnology through individual company efforts and government coordination. The United States and Japan are expected to be the top competitors with the highest potential for success (*1, 2*). However, a number of European countries and European-based companies have substantial involvement in biotechnology and, although no single European country can be considered a major competitor to the United States or Japan, a coordinated effort in Europe could be highly competitive.

The success of European biotechnology will depend on multifaceted strategies. Each country has individual programs for government funding, education, and targeted areas of support. Also, specific programs unite the biotechnological efforts of the European Economic Community (EEC). Companies have individual strategies for their success which, in turn, affect the overall strength of European biotechnology. Programs employed by European countries and companies to gain success in the commercialization of biotechnology are described in this article and strategies compared with those in the United States.

Historical Perspective

The new biotechnologies can be related to advances in genetic research during the past 30 years, mostly in the United States or in the United Kingdom (*3*). Recombinant DNA technologies that evolved from basic discoveries enabled the engineering of cells to produce protein products with great commercial importance. The lure of new products spans many industries; chemical, agricultural, pharmaceutical, and energy, among others. Although many advances in basic research were made in academic or government laboratories, the commercial applications of these processes were clear, and new companies were formed to take advantage of the new opportunities (*4*). Thus, in the 1970's, the biotechnology industry was formed. Between 1979 and 1983, more than 250 such companies were founded in the United States alone, bolstered by an abundance of venture capital (*1, 3, 5*). Although venture capital was not readily available in Europe, new biotechnology companies were appearing there as well (*1*).

The products of biotechnology are expected to generate immense revenues. For example, pharmaceuticals and diagnostics made by recombinant DNA techniques are expected by some estimates to produce more than $12 billion in annual revenues within the next 5 years (*6*). With other recombinant DNA products involved in chemical synthesis, food production, biomass conversion, oil recovery, agriculture, and animal health care, to name just some, a worldwide market of more than $50 billion for recombinant DNA products is expected by the millennium (*7*). Thus, large corporations in many different industries have been prompted to become involved in biotechnology, with specific strategies to do so (*8, 9*). In addition to starting in-house research and development, large corporations have formed valuable relationships with academic laboratories and biotechnology companies in order to more quickly and efficiently get to the marketplace with products of biotechnology (*10–12*). This trend can be noted in both the United States and in Europe.

The biotechnology industry is therefore composed of both small companies and large corporations. The products of recombinant DNA are not easily gained, however, because of high costs, development time, competition, and regulation. Recently, many of the small firms have reduced the sizes of their staffs, and a few have been bought by large corporations amidst predictions that many small biotechnology companies will not survive the next 5 years (*13*). Thus, the biotechnology industry is changing, and strategies of governments and individual companies play an important role in the struggle for commercial success.

European Biotechnology

As in the United States, the 1980's brought the formation of small companies in Europe to pursue the commercialization of biotechnology (*14*). Although the origin of many of these companies was the same—basic research laboratories—their original sources of funding were considerably different. In the absence of significant venture capital, many new European firms were funded with money from traditional industrial corporations and financial institutions, or by direct or indirect government support (*1, 14–16*). In addition, many large European corporations initiated major programs in biotechnology (*14*).

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The actual number of European companies involved in biotechnology is an elusive figure because there are many types of involvement. A recent compilation of companies with research, development, and production activities in biotechnology contained more than 250 firms located in Europe (Table 1) (*16*). Because of small size or improper categorization some companies may have been omitted (*17*). The greatest involvement in biotechnology in Europe is in the United Kingdom, followed by West Germany and France (*1*). With large pharmaceutical companies based in Switzerland, it also has considerable biotechnology efforts. Because of concerted government involvement, the Netherlands and Italy also have government efforts related to biotechnology (*1, 16, 18*).

European companies in biotechnology have interests ranging from food processing to chemicals to pharmaceuticals (*1, 3, 16*). Some are pursuing products of their own whereas others perform contract research employing hybridoma or recombinant DNA technology. Table 2 contains the number of companies in selected European countries listed by specific areas of concentration. These areas were provided by the companies, and many companies reported involvement in more than one area (*16*). Agriculture, diagnostics, and pharmaceuticals are the strongest areas of concentration. When normalized as a percentage of total companies, the percentage of companies in the United Kingdom and Japan working on fermentation technology is higher than that in the United States, possibly because of the historical involvement of these countries in fermentation (*1, 14*).

In addition to the newly formed companies, many larger established ones have significant involvement in biotechnology (*14*). Of the 20 largest pharmaceutical companies worldwide, eight are European and have major biotechnology programs (11 are in the United States and one is in Japan) (*16, 19*). These companies, Hoechst, Bayer, Ciba-Geigy, Hoffmann–La Roche, Sandoz, Boehringer Ingelheim, Glaxo and Imperial Chemical Industries (from West Germany, Switzerland, and the United Kingdom), represent over $13 billion in 1984 pharmaceutical sales (*19*). The largest pharmaceutical companies in Belgium, Denmark, France, Italy, the Netherlands, Norway, and Sweden also have major efforts in biotechnology (*16, 19, 20*). As with large U.S. pharmaceutical companies, the target markets for the large European-based companies are not just domestic, but worldwide. In turn, many European biotechnology companies are attempting to address world markets; to be known simply as "biotechnology companies," not just as "French" or "British" companies, for example (*17*).

Larger companies, with their multinational presence and immense resources, have access to facilities that transcend national boundaries (*15*). One example is the West German chemical and pharmaceutical giant Hoechst, which has donated a total of $100 million to Harvard University and Massachusetts General Hospital in order to gain access to basic research in molecular biology and to train its scientists (*16, 20*). Hoechst also has subsidiaries in the United States and France. In addition, Hoechst has formed coventures in biotechnology with firms in the United States, the United Kingdom, and Japan (*16*). Being able to work on all these fronts enables Hoechst and other large companies to gain expertise and increase their chance of commercial success. The smaller European biotechnology companies usually compete without the benefits of access to global resources (*15*).

Table 1. European biotechnology. The number of companies with biotechnology research efforts in 1985 are listed. For comparison, there were 312 U.S. companies (*16*).

Country	Number of companies	Representative companies
Austria	4	Biochemie
Belgium	15	Celltarg, Plant Genetic Systems
Denmark	8	Novo Industri
Finland	8	Genesit, Labsystems
France	31	Elf Aquitaine, G3, Genetica, Lafarge-Coppee, Transgene
West Germany	18	Applied Biosystems, Bioferon, Biosyntech
Greece	1	Biohellas
Hungary	7	
Ireland	12	Biocon, Bioquest
Israel	16	Interpharm Laboratories
Italy	16	Erbamont, Sorin Biomedica
Netherlands	12	Gist Brocades
Norway	3	
Spain	5	
Sweden	17	Cardo, KabiVitrum, Pharmacia
Switzerland	16	Ares Applied Research
United Kingdom	79	Celltech, Fermentech, Microbial Resources

Table 2. Involvement in specific areas of biotechnology. Data are selected to indicate the number of companies working in the indicated areas of concentration. U.S. and Japanese data are provided for comparison (*16, 20*).

Area	France	Italy	West Germany	United Kingdom	United States	Japan
Agriculture	5	1	2	15	73	12
Antibiotics	1	2	4	1	4	8
Chemicals	1	—	1	4	37	31
Diagnostics	3	5	6	10	141	15
Fermentation	3	—	—	6	21	13
Food	2	—	1	12	18	17
Hybridomas	2	4	4	4	50	13
Pharmaceuticals	2	5	4	5	28	28
Total	31	16	18	79	319	161

Government Coordination and Support of Biotechnology

With the lure of high revenues, governments in some European countries have sponsored multifaceted programs to achieve success in biotechnology. Government strategies include support for academic programs in relevant sciences, support for new companies entering the industry, support for large corporation-based projects in biotechnology, and support for industry-industry or industry-academic interactions (*21*). In contrast, U.S. government support is primarily for basic research with little for the private sector, although the presence of venture capital may obviate this need (*1, 2, 5, 16*). Further, European government programs are aimed at large targeted projects or commercial goals, whereas U.S. government programs have less direct focus on commercial success (*1, 5, 14*). However, recent U.S. funding of a large Center on Biotechnology Process Engineering at the Massachusetts Institute of Technology and other smaller programs may indicate a broadening of U.S. government focus in support of biotechnology (*2, 5*).

The combined government support in all European countries approaches the same level as U.S. government support, but the focus of support of the largest government programs is quite different (Table 3) (*15*). Some individual government programs are described below.

United Kingdom. Support for biotechnology in the United Kingdom was minimal before 1980, when the Advisory Council for Applied Research and Development published their report on biotechnology (*22*), outlining shortcomings in the ability to develop biotechnology in the United Kingdom and recommending specific strategies to counteract them. Particularly encouraged were the transfer of technology from the public sector to industry and the enlargement of programs for basic research and innovation (*22*). The British government responded with a broad program of support (*23*).

Public funding in the United Kingdom comes from a number of sources. The Department of Trade and Industry (DTI) funds training programs, innovative industrial projects, and is establishing centralized database and cell depository centers (*16, 23*). The Science and Engineering Research Council (SERC) is developing a program to advance nine priority sectors (*15, 23*). The Medical Research Council (MRC) funds extramural programs as well as in-house research at its various units, including the Laboratory of Molecular Biology in Cambridge that has been the home of many Nobel laureates including Francis Crick, Frederick Sanger, James Watson, Cesar Milstein, and George Koehler (*3*).

The British Technology Group (BTG), a public corporation, was funded by DTI to assist in the transfer of biotechnology from the basic research laboratory through commercialization. As such, BTG is a public source of venture capital. For example, Celltech was formed in 1980, funded by BTG and four corporations, and given the first right of refusal for patents related to genetic engineering and hybridoma technologies that came out of in-house MRC research (*1, 24*). Thus far, Celltech has had considerable success, especially with monoclonal antibody technology and the scale-up production of custom-made antibodies. In 1984, Celltech's exclusive access to MRC patents was renegotiated and suspended, leading to their transition from government control to becoming a public company (*24*). This is an excellent example of a government-coordinated effort to foster the development of technology and, with its success, allowing private enterprise to take over. Another example is the transfer of the Centre for Applied Microbiology and Research (CAMR) to the Porton International Group, a private investment group with industrial and banking shareholders (*16*). CAMR was started as part of the Public Health Laboratory Service with eight laboratories related to microbiology and biotechnology.

A major focus of the British government's strategy is to scale up biotechnological processes. By making an effort to concentrate on production, the United Kingdom is hoping to attract foreign companies to locate manufacturing facilities within the British Isles or to gain revenues and employment by contract production. This strategy is apparently working; at least four foreign pharmaceutical manufacturers have gone to the United Kingdom for production (*20*). However, it is possible that the United Kingdom and other European nations cannot be competitive in scale-up production because of high costs of fermentation nutrients due to EEC pricing policies (*25*).

West Germany. The Federal Ministry for Research and Technology (BMFT) funds biotechnology research in West Germany with specific goals, such as basic technology development and technology transfer from academia and government to industry (*1, 26*). Especially supported are projects that address West Germany's traditional strength in fermentation processes (*14*). The BMFT also funds grants to institutes (such as the Max Planck Institute), universities, and government laboratories. The most notable government research center is the Society for Biotechnological Research (GBF), which has a research staff to perform basic studies and provide services to the public and private German community. A major focus of the GBF is to foster technology transfer to industry (*1, 14, 16, 26*). The goals of the GBF include bioprocess and scale-up technologies, joint projects with industry, and interdisciplinary training. The GBF is now considered one of the best biotechnology research facilities in Europe (*1*).

France. Despite a late entry into biotechnological research, the French government has stated a goal of capturing a 10% share of the world market for biotechnology by 1995 (*14, 16*). Government funding is provided by the Ministry of Research and Industry and specific government institutes. In an effort to support future commercialization, the major focus of government support is technology transfer to industry. Research centers, such as the Centre National de la Recherche Scientifique (CNRS) and the Institut de la Santé et de la Recherche Médicale (INSERM) have research programs in molecular biology (*27*). Despite these efforts, technology transfer from academia to industry in France has been reported to be far less than optimal (*1*).

In contrast, a number of institutions with a large percentage of government support have gained significant strength in biotechnology. The Institut Pasteur receives almost half its funding from

Table 3. Government funding of biotechnology (*1, 16, 20*).

Country	Government branch or institute	Goals and favored technologies	Annual funding ($\times 10^6$)*
France	Institut de la Recherche et l'Industrie; other biomedical agencies	Academic-industry collaboration Commercial processes Bioprocess scale-up	\$100
West Germany	Ministry for Research and Technology; Society for Biotechnological Research	Academic-industry collaboration Technology transfer Basic biotechnology Scale-up Pharmaceuticals New compounds	\$120
Netherlands	Ministry of Science Policy	Five-year plan to foster collaborations Scale-up	\$30
Switzerland	Federal Institute of Technology	University-industry collaboration Bioreactor designs	
United Kingdom	Department of Trade and Industry; Medical Research Council; Science and Engineering Research Council; British Technology Group	Fund industrial projects Technology transfer to industry Scale-up Fermentation Downstream processing	\$80
United States	National Institutes of Health; National Science Foundation; departments of Agriculture, Energy, Defense	Basic research (95%) Applied generic research (<5%)	\$750

*Data are approximate for years 1983–1985 (*1, 5, 14–16*).

Table 4. European presence in the United States. European pharmaceutical companies with major U.S. operations and their world rank in 1984 pharmaceutical sales (*1, 19, 20*).

Company	Rank
Amersham (United Kingdom)	
Bayer (West Germany)	4
Ciba-Geigy (Switzerland)	5
Glaxo (United Kingdom)	18
Hoechst (West Germany)	3
Hoffmann–La Roche (Switzerland)	11
Imperial Chemical Industries (United Kingdom)	20
Rhone-Poulenc (France)	26
Sandoz (Switzerland)	12
Wellcome Foundation (United Kingdom)	23

Table 5. European companies with U.S. subsidiaries involved in biotechnology (*16, 19, 20*).

Company	Subsidiary
Bayer	Cutter Labs
	Miles Labs
	Molecular Diagnostics
Biocon (United Kingdom)	Biocon (United States)
Boehringer-Mannheim	Boehringer-Mannheim Biochemicals
Elf Aquitaine	Ceva Labs
Fisons PLC (United Kingdom)	United Diagnostics
Gist Brocades (Netherlands)	Gist Brocades (United States)
Hoechst	American Hoechst
	Hoechst-Roussel Pharmaceuticals
Imperial Chemical Industries	Stuart Pharmaceuticals

government grants. Institut Pasteur Production, a private company jointly owned by the Institut Pasteur and Sanofi (part of Elf Aquitaine, a nationalized pharmaceutical and chemical corporation) receives first right of refusal for discoveries in many areas of research conducted at the Institut Pasteur (*16*). Two other large pharmaceutical and chemical companies with substantial biotechnology programs are owned by the French government: Roussel Uclaf (a subsidiary of Hoechst, 40% owned by the French government) and Rhone-Poulenc (100% government owned) (*1, 16*). With the nationalization of these corporations, the French government is directly involved in the business of biotechnology and thus plays a large role in the commercial success of biotechnology in France.

Other countries. A few other European countries, such as the Netherlands, Switzerland, Belgium, and Italy, have government programs to develop biotechnology. These programs are more modest than those in the United Kingdom, West Germany, and France, but the goals are similar—technology transfer to industry and commercialization. Of course, there are individual approaches. The Netherlands, for example, has launched a program of support for biotechnology that includes tax and funding incentives to recruit biotechnology companies to locate facilities within its borders (*16, 21*).

Although government intervention in the commercialization of biotechnology has been predicted to play an important role in national success, the strength of individual companies also lends to that success. One company considered a leader in biotechnology in Europe is Novo Industri, which is based in Denmark, a country with no major national policy for supporting biotechnology (*16*). Novo, in collaboration with Squibb, has begun marketing its human insulin produced from genetically altered porcine insulin, a potential challenge to Lilly's recombinant DNA insulin market (*16*). Nevertheless, the greatest benefit of European government programs is likely to come from the transfer of people and ideas between the university and corporate sectors. This transfer generally does not occur easily without intervention (*15*).

Scientific Manpower

Two distinct categories of manpower requirements are necessary in biotechnology. For basic research, access to laboratory scientists engaged in molecular biology, genetics, and immunology is necessary. For commercialization and scale-up there must be sufficient manpower in bioprocess engineering. To achieve success in biotechnology, a country must have training programs and trained personnel in both areas. A few years ago, there was a projected shortage of researchers in the United States trained in molecular biology (*28*). Although this situation has abated, there is increasing concern that only few programs of instruction in bioprocess engineering are located in the United States (*1, 2, 29*). Japan reportedly has an ample supply of bioprocess engineers, which may contribute to their predicted commercial success (*2*).

In Europe the availability of trained personnel varies by country. The United Kingdom has sufficient training of basic research personnel (*1*). However, personnel trained in scale-up may be in short supply, in part due to a low salary scale and leading to a "brain drain" to other countries (*1, 14*). The outlook is brighter for West Germany, which has been training personnel in bioprocess engineering and in the new basic technologies for many years (*1, 14*). In France, the picture is much less optimistic, with predicted serious shortages in both categories of manpower (*1*). How this situation affects a country's success in biotechnology should become apparent within the next few years, as more products reach the marketplace.

European–U.S. Interactions

Many of the companies involved in biotechnology in Europe are large corporations with a considerable presence in the United States. Table 4 lists ten European corporations, including some of the world's largest multinational chemical and pharmaceutical companies, that have major U.S. operations (such as research or manufacturing facilities). For example, Ciba-Geigy has located its agricultural biotechnology research group in the United States (*16*). In Table 5 are eight European corporations involved in biotechnology that own U.S. subsidiaries. The Japanese presence in the United States is less obvious (*2*). With major research and development operations in the United States, European companies gain immediate access to trained manpower and proximity to the hundreds of U.S. biotechnology companies.

Just as the large U.S. and Japanese corporations work with U.S. biotechnology companies to gain access to basic research and development, so, too, do European corporations (*2, 8*). Joint efforts between European companies and U.S. biotechnology firms involving pharmaceuticals are shown in Table 6. The list of products involved is virtually identical to products being developed in conjunction with Japanese and U.S. corporations (*2, 20, 29*). Most of the European corporations listed in Table 4 already have substantial U.S. marketing operations and are well poised to capture a substantial U.S. market share for their products.

Many U.S. corporations have significant European subsidiaries or facilities. Also, many U.S. and Japanese companies have joint ventures with European biotechnology companies. For example, Celltech has joint agreements with Interferon Sciences and Serono Laboratories of the U.S., as well as with Sankyo and Sumimoto of Japan (*16*). However, there are no clear examples of U.S. firms with the majority of their biotechnology research facilities in Europe.

Current drug export laws in the United States do not generally allow the export, for purposes other than clinical testing, of drugs that have not received full Food and Drug Administration (FDA) approval. However, regulatory agencies in some European countries may approve the release of a compound before approval is completed in the United States. To gain access to European markets before FDA approval is granted, many U.S. pharmaceutical companies have built manufacturing facilities in Europe and other parts of the world (*30*). One U.S. biotechnology firm, Centocor, recently built a manufacturing facility in the Netherlands, at least in part for the same reason (*31*). If the U.S. drug exportation laws are not modified, this trend will likely continue (*18*). In addition, with European labor costs at 40 to 75% of those in the United States, and with European government programs to attract industry, U.S. firms have further incentive to locate facilities abroad (*22, 32*).

Consolidating European Efforts

Individual European countries have resources and industrial efforts in biotechnology that are overshadowed by those in the United States. However, as an aggregate, European biotechnology is almost as large in number of companies, training, and government funding. Historically, the unification of European countries has been difficult, but specific programs are directed at consolidating biotechnology efforts in Europe.

Realizing that European biotechnology might lag seriously behind programs in the United States and Japan, the Commission of the European Communities created programs to assist long-term research and development priorities in Europe (*33*). The Biomolecular Engineering Program, first proposed in 1976, was initiated in 1982 to support specific research projects (*15*). This program, due to end this year, has spent about $15 million on 100 contracts, yielding highly successful research, especially in the area of plant molecular biology. Another 5-year program, FAST (Forecasting and Assessment in Science and Technology), was initiated in 1978 to determine futures in science and technology (*15, 33*). Weaknesses in European biotechnology were noted, including lack of cohesiveness, emigration of scientists and isolation of individual efforts, thus preventing the attainment of "critical mass" (*33, 34*). Steps had to be taken to allow the European Community to create a concerted effort in biotechnology (*34*). The Biotechnology Action Program was established, along with the Concertation Unit for Biotechnology in Europe (CUBE), to help monitor and coordinate the program (*33, 35*). This six-point program was proposed in late 1983 and included support of research and training, concertation of government policies involving biotechnology processes, uniform regulatory policies and patent laws, and other special projects (*34*). Although not approved until March 1985 and funded at about $50 million (two-thirds of the requested budget), many research projects have already received support, especially transnational projects (*15, 34*). It is, however, too early to tell whether these programs will enable European biotechnology to coordinate efforts and allow Europe to catch up with the United States or Japan.

One program with funding from the European Commission is the European Biotechnology Information Project (EBIP), housed in the Science Reference Library in London. According to its director, John Leigh, the main purpose of EBIP is to "act as a focus for biotechnology information within the European Community" (*36*). Toward this end, EBIP conducts seminars in biotechnology information since "there is a need for a more cohesive approach to biotechnology information within the European Community . . . a federation of countries with different customs and languages, the EEC lacks the fluid exchange of information which Japan and the United States do have," according to Leigh (*36*).

Another group working on coordinating biotechnology in Europe is the European Federation of Biotechnology. Founded in 1978, this group now has 52 member societies from 17 European countries. Their goal is to promote the interdisciplinary nature of biotechnology and its development in Europe through working parties, conferences, and documentation (*37*). In addition, they organize a European Congress of Biotechnology every 3 years, next scheduled for May 1987 in The Hague (*37*).

Also serving biotechnology in Europe is the European Molecular Biology Organization (EMBO), based in West Germany. The primary functions of EMBO are to promote transfer of information about molecular biology and to promote basic research (*38*). The

Table 6. Joint agreements between U.S. biotechnology companies and European companies. Joint efforts involving pharmaceutical products between 1982 and 1985. Abbreviations: IFN, interferon; mAb, monoclonal antibody; KPA, kidney plasminogen activator; IL-2, interleukin-2; hGH, human growth hormone; HSA, human serum albumin; and CSF, colony-stimulating factor (*1, 16, 20*).

U.S. company	European company	Product
Biogen	Bioferon (West Germany)	IFN
Biogen	Burroughs-Wellcome (United Kingdom)	Vaccine
Biogen	KabiVitrum (Sweden)	Factor VIII
Centocor	Hoffmann–La Roche (Switzerland)	mAb's
Cetus	Roussel Uclaf (France)	Vitamin B_{12}
Collaborative Research	Sandoz (Switzerland)	KPA
Damon Biotech	Hoffmann–La Roche	mAb's
Flow Labs	Bioferon	IFN
Genentech	Gruenenthal GMBH (West Germany)	Urokinase
Genentech	Hoffmann–La Roche	IL-2
Genentech	KabiVitrum	hGH
Genentech	Speywood Labs (United Kingdom)	Factor VIII
Genetics Institute	Sandoz	IL-2
Genetic Systems	Cutter Labs (Bayer)	mAb diagnostics
Genetic Systems	Institut Pasteur (France)	Diagnostics
Genetic Systems	Miles Labs (Bayer)	mAb's
Genex	KabiVitrum	HSA
Genex	Schering AG (West Germany)	Blood protein
Hana Biologics	Recordati S.p.A. (Italy)	mAb diagnostics
Hybritech	Boehringer-Mannheim	mAb's
Immunex	Behringwerke (Hoechst)	CSF
Unigene Labs	Sigma-Tau S.p.A. (Italy)	Diagnostics

first function is accomplished by sponsoring workshops, courses, and other educational programs. The second important function is the basic research taking place in their centralized facilities, the European Molecular Biology Laboratory (EMBL) in Heidelberg. A third function is the funding of short-term and long-term fellowships for study in molecular biology totaling about 400 each in 1985 (*38*). According to its Executive Secretary, John Tooze, "EMBO does not see itself responsible for promoting biotechnology in Europe as such, but rather for promoting basic molecular biology in Europe. Of course, the biotechnology programmes and biotechnology companies recruit from the academic molecular biologists who benefit from EMBO's activities" (*38*).

Lastly, with a worldwide concern about the safety of molecular biological processes, the Organization for Economic Cooperation and Development (OECD) is in the process of creating a uniform set of guidelines to govern the use of these technologies. Along with many EEC countries, the United States has participated in this process. By providing a uniform set of regulations, the OECD guidelines should facilitate the transfer of biotechnology between countries and assist the commercialization process. On the other hand, the OECD guidelines will be in the form of advice rather than law. Also, it is not certain whether forthcoming U.S. government guidelines will encompass OECD guidelines and thus place U.S. firms in a favorable competitive position in Europe (*39*).

Conclusions

The term "European biotechnology," like "U.S. (or Japanese) biotechnology," is highly misleading. Clearly, European biotechnology is the summation of many efforts in biotechnology; it encompasses the activities of hundreds of companies and many governments. However, with billions of dollars and thousands of jobs at stake, if any one of these "entities" can achieve a competitive edge in biotechnology, considerable reward should follow. What distinguishes European biotechnology is that many different nations make up the aggregate effort, with their distinct programs, levels of support, targeted research areas, and so on. There are also strong individual company efforts in Europe, such as those by Novo Industri, Celltech, Elf Aquitaine, Hoechst, Bayer, Transgene, and others. Government programs in the United Kingdom, West Germany, and France appear strong, but, as with most ventures in biotechnology, the full extent of their success remains to be determined.

Three key features of European biotechnology bear repeating as they may lead to the success of the aggregate program. First, European programs that transcend national boundaries should enhance the aggregate program. Most notable in this category are the programs of the EEC Commission, which will provide common resources and foster collaboration, as well as the EMBO programs, which provide a unified source of training. Second, is the common focus on technology transfer seen in individual government programs as well as the EEC programs. By supporting academic-industry joint projects and the transfer of research from government laboratories to industry, these programs should facilitate the commercialization process. Although a passive transfer of biotechnology to industry in all countries normally exists, there has been little effort on the part of the U.S. government to assist in this process, possibly decreasing the future competitive strength of U.S. biotechnology. Third, the distinction between U.S. and European biotechnology is not as fine as that between U.S. and Japanese biotechnology. Many large European-based companies, such as Bayer, Hoechst, Ciba-Geigy, Hoffmann–La Roche, Wellcome, and Sandoz, have previously penetrated U.S. markets and have U.S. facilities for research and development. These companies thus have ready access to U.S.-trained personnel, as well as access to scale up in their home countries.

The race for success in the commercialization of biotechnology will have no clear winners for many years. Recent reports have predicted a close race between the United States and Japan. European biotechnology, although a dark horse, should not yet be eliminated from the running. Already, individual efforts from European companies are showing the first signs of success. If cohesiveness and critical mass can be achieved in the aggregate program, European biotechnology has the potential to become a strong competitor in the long run.

REFERENCES AND NOTES

1. Office of Technology Assessment, *Commercial Biotechnology: An International Assessment* (Government Printing Office, Washington, DC, 1984).
2. M. D. Dibner, *Science* **229**, 1230 (1985).
3. J. Elkington, *The Gene Factory* (Carroll & Graf, New York, 1985).
4. W. Gilbert and A. Taunton-Rigby, *Res. Dev. Ind.* (June 1984), p. 176.
5. S. Olson, *Biotechnology: An Industry Comes of Age* (National Academy Press, Washington, DC, 1986).
6. S. Harford, *Can. Pharm. J.* **118**, 467 (1985).
7. Projected economic data are highly varied, those presented are mid-range; W. P. Patterson, *Ind. Week* (7 September 1981), p. 64.; *Chem. Mark. Rep.* (19 October 1984), p. 23.
8. M. D. Dibner, *Pharm. Exec.* **5**, 81 (1985).
9. D. Webber, *Chem. Eng. News* **63** (No. 46), 25 (1985).
10. D. Blumenthal, M. Gluck, K. S. Louis, D. Wise, *Science* **231**, 242 (1986).
11. M. D. Dibner, *Trends Pharm. Sci.* **6**, 343 (1985).
12. W. F. Hamilton, *Technol. Soc.* **7**, 197 (1985).
13. D. Webber, *Chem. Eng. News* **62** (No. 25), 10 (1984).
14. M. Sharp, *The New Biotechnology: European Governments in Search of a Strategy* (Sussex European Paper 15, Sussex, United Kingdom, 1985).
15. M. F. Cantley, personal communication; M. F. Cantley, *Swiss Biotech* **2** (No. 4), 7 (1984); Commission of the European Communities, *Communication 328* (1983).
16. A. G. Walton and S. K. Hammer, *Genetic Engineering and Biotechnology Yearbook, 1985* (Elsevier, Amsterdam, 1985).
17. The BioCommerce Data, Ltd., database lists over 9000 organizations worldwide that have had some association with biotechnology. Many are only incidental or minor associations with biotechnological research and development (A. Crafts-Lighty, personal communication).
18. A. Goldhammer, personal communication; A. Klausner, *Biotechnology* **3**, 1062 (1985).
19. *SCRIP Pharmaceutical Company League Tables, 1984–1985* (PJB Publications, Surrey, England, 1985).
20. A database created by M.D.D. contains records of company actions involving biotechnology in pharmaceuticals taken by U.S., Japanese, and European firms between 1981 and 1985 and were used to derive industry trends and make assessments of individual company efforts (*2, 8, 11*).
21. L. R. Meagher, personal communication; R. Walgate, *Nature (London)* **309**, 500 (1984).
22. A. Spinks, *Biotechnology: Report of a Joint Working Party* (Her Majesty's Stationery Office, London, 1980).
23. D. Dickson, *Science* **224**, 136 (1984); R. Colman, *New Sci.* (9 February 1984), p. 26.
24. Celltech, *Annual Report, 1985*; *Eur. Chem. News* (25 July 1983), p. 13.; *SCRIP World Pharmacol. News* (20 January 1986), p. 6.
25. P. Dunnill and M. Rudd, *Biotechnology and British Industry* (Report to the Biotechnology Directorate of SERC, London, 1984).
26. D. Dickson, *Science* **218**, 1287 (1982); *Chem. Ind.* **37**, 561 (1985).
27. *Chemscope* (May 1984), p. 23; *IMS Pharmaceut. Marketlett.* (26 July 1982), p. 3; D. Dickson, *Science* **217**, 516 (1982).
28. N. Howard, *Duns Bus. Month* (January 1982), p. 92.
29. C. Norman, *Science* **228**, 305 (1985).
30. S. C. Stinson, *Chem. Eng. News* **63** (No. 37), 25 (1985).
31. *Biotech Newswatch* (17 January 1985), p. 3. Centocor also received considerable up-front financial support from the Dutch government and access to an academic base at the University of Leiden.
32. A. L. Malabre, Jr., *Wall St. J.* (17 July 1985), p. 6; G. Putka, *ibid.* (8 April 1985), p. 1.
33. M. F. Cantley, paper presented at Future Developments in Technology: The Year 2000, London, 5 April 1984.
34. Commission of the European Communities, in (*15*); *ibid.* **672** (1983); *ibid.* **230** (1984); *Off. J. Eur. Commun. L83/1*, Council Decision (12 March 1985).
35. K. Freeman, *Genet. Eng. News* **5** (No. 3), 3 (1985).
36. J. Leigh, personal communication; general descriptive literature provided by the European Biotechnology Information Project.
37. Descriptive literature provided by the European Federation of Biotechnology.
38. J. Tooze, *EMBO J.* **1**, 1 (1981); descriptive literature provided by the European Molecular Biology Organization (EMBO); J. Tooze, personal communication.
39. B. F. Mackler, *Genet. Eng. News* **6** (No. 2), 4 (1986).

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