BIOTECHNOLOGY: EUROPE RACING TO CATCH UP

By JAMES DAVID SPELLMAN

Biotechnology within the European Community may go the way of Europe's microelectronics industry, meaning that American and Japanese firms will dominate while European enterprises assume subsidiary positions in what is estimated to be a $50- to $100-billion market for biotech goods and services by the year 2000. This is the prophecy of the U.S. Congress' Office of Technology Assessment, some industry analysts, and an EC Commission report, assuming that present patterns of research development and commercialization continue.

Ten years ago, some assessments of Europe's biotech future were optimistic — and with good reason. The United Kingdom, for example, held 30 per cent of the world's biotechnological patents between 1967 and 1971, and the country was considered a pioneer in several areas. The Federal Republic of Germany's Society for Biological Research at Braunschweig, established in the mid-1960s by the Volkswagen Foundation, was envied worldwide. But economic, scientific, political, and, to a lesser extent, social obstacles combined to cause European research to lag behind the dizzying pace set by the United States and Japan.

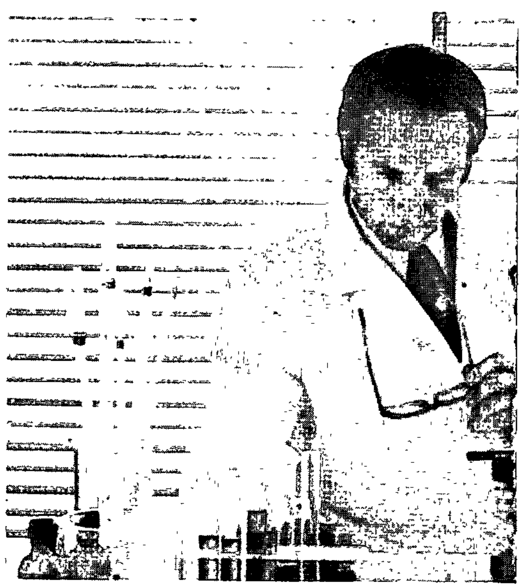
According to the studies mentioned above, research and development expenditures by European organizations — both public and private — were inadequately expanded. The lack of regional or state planning resulted in ad hoc allocations of grants, which meant that research duplication was at times supported and the country's strongest biotech capabilities were not continually funded. Dispersed, isolated centers of research lacked coordination to facilitate the systematic incorporation by the biotech community of the disparate accomplishments. National rivalries prevented cooperation among EC member Governments and private firms in both basic research and patent law development. Further, many European firms failed to move aggressively to commercialize their products and expertise.

EC Member States, however, have not been idle, particularly since 1980. Government-industry commissions have been convened frequently in almost every EC country to analyze how their biotech enterprises ran aground and to plan state incentive programmes and research priorities. The EC and the national Governments have bolstered their financial support. Meanwhile, American and Japanese firms, encouraged partly by the devaluation of European currencies, have been seeking out European firms for research partnerships, licensed production arrangements, and marketing assistance.

But are these efforts in Europe too little too late? Dr. John Walker, who selects the biotechnology investments for Technical Development Capital, a venture capital fund in the United Kingdom, asserted in The Economist that "the field is still open. It is not too late." He believes that 95 per cent of the biotechnology expected to be needed in the 1990s has yet to be invented. But others voice pessimism. A white paper prepared in 1983 for the Office of Science and Technology Policy within the White House concluded: "The United States faces the stiffest challenge from Japan."

The term biotechnology, according to an Organization for Economic Cooperation and Development (OECD) report in 1982, refers to "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services." Often the word "new" is used with biotechnology to differentiate between the traditional research efforts in the natural breeding of animal and plant species and the more recent efforts in both genetic manipulation and the immobilization of enzymes and cells.

The impact the breaking of the genetic code will have on post-industrial economies is expected to be as revolutionary as that of the computer and information processing industries. More than 40 per cent of the manufacturing output in developed



ways, of which the most important is through the development of new technologies. Some $680 million is to be allocated for this purpose, of which the lion's share has been reserved for Information Technology ($600 million) and the balance for biotechnology. Another $350 million is to be spent on improving techniques and products for the conventional industries, which together account for much of the industrial base of Europe.

The emphasis is on multisectoral technologies — e.g. the development of new techniques for shaping and working materials, using lasers in particular. Such techniques could be adapted to the clothing industry as well as shipbuilding. At the same time there is to be adaptation of convergent technologies (such as computer aided manufacturing, new materials and new joining techniques) to specific industrial sectors. Priority will be given to those currently most vulnerable or of economic or strategic importance.

COMMON ENERGY POLICY

The Community has been facing up to the energy challenge since 1974, with R & D activities aimed at reaching the following major objectives: independence, long-term security of supply, competitiveness and safety. These objectives are reflected in the framework programme, whose goal is improving the management of energy resources and reducing energy dependence.

To this end the specific scientific and technical objectives include (1) the development of nuclear fission energy (with the emphasis on reactor safety); (2) controlled thermonuclear fusion (essentially a long and costly endeavour, unlikely to pay off before 50 years); (3) the development of renewable sources of energy and (4) the rational use of energy.

In developing renewable energy sources the EC is seeking not only to promote energy independence but also industrial competitiveness and agricultural productivity. Priority is to be given to direct solar energy, biomass and geothermal energy, followed by wind and hydroelectric power.

The framework programme also provides for improvement in the management of raw materials, notably minerals and wood. In the exploration of mineral deposits, the emphasis will be on the prospecting of deposits at great depths and the development of offshore methods. The extraction and treatment of ores will involve research into exploiting lean and complex ores, making marginal deposits workable, etc.

The EC imports over half its requirements of wood and wood products, resulting in a trade deficit almost as large as the oil deficit. The two-fold objective therefore is to reduce dependence on outside sources and improve the economic viability of the EC's wood industries. Finally, research will focus on two ways of making optimum use of scarce materials, one of which is to recycle them, the other to develop substitutes.

It is obvious that many of the R & D activities to be undertaken over the next 4 years will interest the developing countries, and some $150 million have been allocated in fact to stepping up aid to them. Six areas have been selected, largely because they are compatible with Community policy on development aid. They are agriculture (with the emphasis on promoting food self-sufficiency); the environment; health (nutrition; tropical diseases); soil resources; energy (especially renewable sources suitable to subsistence economies) and population (demographic studies).

In the last analysis the goal of scientific research should be the betterment of human welfare. The framework programme, not surprisingly, provides for research into improving living and working conditions. The two broad objectives are (1) improving safety and protecting health and (2) protecting the environment and preventing pollution. The areas of research therefore include not only health technology (diagnosis and treatment) but also the interaction between man and his environment (the effects of urban encroachment, tourism and intensive agriculture, for example).

The success of the framework programme, as indeed of any R & D programme, will depend to a large extent on the effectiveness of the Community's scientific and technical potential. In fact the EC Council of Ministers adopted last June a 2-year experimental programme aimed at seeing how best to stimulate European scientific and technical cooperation and exchange. The Commission is already working on a more detailed 4-year plan, which it hopes can be implemented from next January.

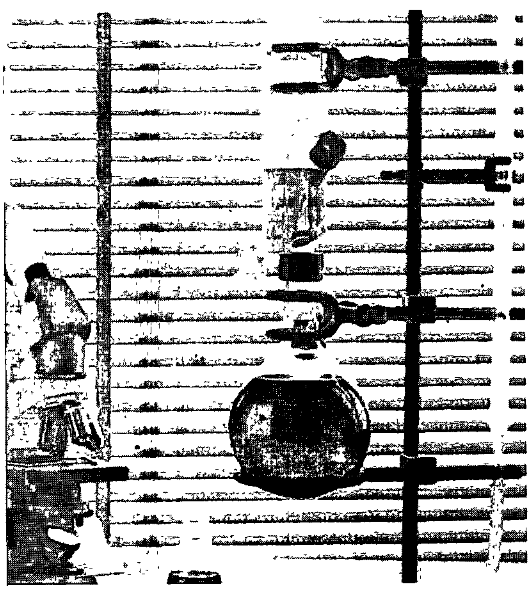
The plan would seek to increase the mobility of researchers within the EC; develop cooperation between European R & D teams and encourage the training and launching into a career of young researchers. To this end there are to be grants to encourage exchanges (particularly between universities and industry); financial support for laboratory "twinning" and grants for bringing people together from different disciplines and countries.

The aim of a common R & D strategy, in the European Commission's view, is not the "Europeization" of scientific and technical activities; rather, it is to create and sustain the most favourable conditions for joint growth. Where Member States have cooperated together they have been able to keep up with the competition through innovation (nuclear fission, thermonuclear fusion, space). In the absence of such cooperation the EC has begun to fall behind the United States and Japan (computer science and biotechnology but also automobiles, chemicals and materials). But the Council of Ministers' decision of February 28 launching ESPRIT shows that the lesson is being learnt in time.

countries is biological in nature or origin. In the U.S. market, biotech-developed products will, by 1995, constitute 26.6 per cent of the $70-billion health care products market and 21.5 per cent of the $470-billion agricultural products market. This projection is according to Predicasts, a U.S. market research firm.

In medicine, only insulin and interferon are now commercially available and the marketing of a human growth hormone to treat dwarfism is anticipated shortly. By 1985, commercial production of the human serum albumin (a protein to replace blood plasma), amino acids (the building blocks of proteins which in turn are the basic structural and functional materials of cells), antibiotics, vitamins, and both therapeutic and diagnostic monoclonal antibodies is expected.

The trends in biotech research, as indicated by the patents granted in the United States between 1963 and 1982 show the greatest activity in enzymes (proteins which promote chemical change without being consumed in the reaction) and their production processes. Japan gained most of its patents in amino acids and the lowest amount in tissue cultures, the exact reverse of the American position. Ownership of U.S. patents by EC-based firms is more extensive in mutation/genetic engineering and enzymes than in tissue cultures, starch hydrolysates (processes, for example, to cause the enzymatic hydrolysis of starch to glucose), and amino acids. The patents that are held by the United Kingdom, the Federal Republic of Germany, and France constitute on average three-fourths of the total number of U.S. patents granted to EC-based firms. U.S. firms own half of the 3,381 biotech-related patents issued. This amount, however, may be exaggerated because the nationality of those patents which are filed by U.S. affiliates of foreign-owned corporations is classified as American.



The EC Commission was presented in January 1980 with a five-year — 1981 to 1985 — proposal for R&D in biomolecular engineering. Adopted by the EC Council of Ministers in December 1981, the $7-million programme's goal over five years was initially to encourage innovations in agri-food products. Funds for research were made available through cost-sharing contracts with private and public organizations. The Commission subsequently approved in June 1983 a $6-million budget to pursue the programme's second phase, that of expanding research and training to all industrial fields.

The Commission has been progressive in its thinking about what policies could be implemented to foster the commercial maturation of biotechnologies. Its report urges:

- a Community-wide programme to plan R&D;
- patent laws to better protect European inventors, terming the existing system "embarrassing and far from satisfactory;"
- harmonizing members' regulations covering pharmaceuticals and chemicals; and
- ameliorating the negative effects of EC policies, such as the Common Agricultural Policy (CAP) which hampers market access by EC-based biotech firms selling agri-food products.

Prospects for the achievement of these goals seems dim now, given that EC member Governments at the Stuttgart European Council summit in June 1983, as a report in European Trends, a publication of The Economist Intelligence Unit, observed, "were especially suspicious of the Commission's attempts to move from research to development of a more positive industrial programme." European states have been increasing their direct subsidies to biotech research, but total public R&D expenditure — estimated by the Commission to be in the range of $156 million to $300 million per year — is behind that of the United States at between $200 million and $500 million per year. The EC outspends the Japanese government at $50 million a year.

More essential to progress, however, than the comparative levels of public support will be the degree to which research and commercial applications are coordinated both within and among states. "One of the central challenges of biotechnology," the magazine Biotechnology wrote in August 1983, "is organizational: It is a boundary-crossing, multidisciplinary, statistician's nightmare." Within states, governments have been encouraging cooperation between universities and industries to commercially exploit research findings and map directions for research. But among states, despite the Commission's efforts, cooperation has been minimal. Whether the emergence of research and production collaboration now occurring among European firms will facilitate political coordination, the argument of the functional integrationists, it is too early to tell.

Several political and economic differences are apparent in a comparison between those European, American, and Japanese factors which have contributed to the emergence of biotechnology in each state. The market for venture capital is larger and more sophisticated in the United

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