

# Technological innovation in a corporatist state: The case of biotechnology in the Federal Republic of Germany \*

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This article examines a decade of federal support for biotechnology in the Federal Republic of Germany in order to determine the impact of liberal corporatist patterns of decision-making on industrial policy. For this purpose, industrial policy is taken to include both public initiatives aimed at promoting the new technology and those designed to control its risks.

Two distinct forms of corporatism are discernible in this case study. In the first, the principal actors are large businesses, the state, and to a lesser extent, the academic research community. These actors have been most influential in defining the scope and specific objectives of the federally funded R&D program in biotechnology. A more traditional form of corporatism, including organized labor, has been engaged in the debate on regulatory policies.

In the case of biotechnology, these patterns of corporatism have created the consensus necessary for the adoption of a comprehensive R&D program, but have perpetuated certain barriers to technological innovation. In particular, the reliance on established peak organizations to formulate policy has discouraged structural changes that could have enhanced Germany's early competitiveness in biotechnology. Incrementalism has produced more favorable results in the context of regulatory policy, by permitting control strategies to develop in step with technological progress.

## 1. Introduction

Departing from the laissez-faire approach of the immediate postwar period, German industrial policy entered a second, more interventionist phase

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in the late 1960s [1]. A powerful new agency, the Federal Ministry for Research and Technology (Bundesministerium für Forschung und Technologie, BMFT) was created in 1972 to promote industrial competitiveness through directed use of R&D funds. BMFT's central mission was to develop effective research programs aimed at the high-technology industries. The field of biotechnology became an early beneficiary of this activist R&D strategy as scientific developments opened the way to new and highly profitable industrial applications of biological processes. Along with such areas as data processing and telecommunications, biotechnology was designated a "key technology", a status that ensured steady federal support for the field throughout the past decade.

With industrial policy standing high on the public agendas of technologically advanced nations, the case of the German biotechnology program deserves closer study. The German example offers, in the first instance, a useful complement to the more frequently examined Japanese and American models, raising somewhat different questions about the relationship between industrial policy and political process. What obstacles has a state with a weak involvement in industrial affairs during the 1950s and 1960s encountered in attempting to further the high-technology revolution of the past decade? More specifically, how have these efforts been constrained or facilitated by Germany's tradition of corporatist decision-making? How successfully has the state coordinated its technology-promoting initiatives with the obligation to regulate the risks inherent in new technological development?

The issues raised by the German biotechnology case assume particular importance in light of the recent revival of interest in corporatism as an alternative to other forms of interest representation in policy-making [2]. Numerous definitions have been suggested for the term, of which perhaps the most comprehensive and best known is the version proposed by Schmitter in a 1974 article:

Corporatism can be defined as a system of interest representation in which the constituent units are organized into a limited number of singular, compulsory non-competitive, hierarchically ordered and functionally differentiated categories, recognized or licensed (if not created) by the state and granted a deliberate representational monopoly within their respective categories in exchange for observing certain controls on their selection of leaders and articulation of demands and supports. [3]

This article does not propose to enter the definitional debate by amplifying or refining Schmitter's formulation. Rather, the object of this inquiry is to identify the varying forms of corporatism that are encountered in one specific sector of German industrial policy and to analyze their impact, a task of considerable potential interest, since industrial policy has not yet figured prominently in studies of different systems of interest mediation.

Before turning to the facts of the biotechnology case, it may be helpful to outline some of the characteristics previously noted in connection with German corporatism. In his essay on liberal corporatism, Lehbruch compares Austrian and West German corporatism in the field of income policies [4]. The German *Konzertierte Aktion* is characterized, in his view, by relatively active governmental leadership exercised over a broadly dispersed set of organized interests. Both business and labor are represented through numerous large federal associations which create a fairly diffuse power structure within each interest group. At bottom, however, the framework for income policies is "tripartite", with the state mediating between powerful labor and industrial interests.

If corporatist patterns carry over into the development of industrial policy, it is not unreasonable to expect some deviation from the traditional tripartite structure of German corporatism. Modern industrial policy, with its heavy emphasis on

technological innovation, involves, besides business, labor and the state, a fourth important set of interests that is often loosely described as the "scientific community". Further, the pressures for including labor in the consensus-building process, imperative in the case of wage policies, may be less acute in the context of promoting R&D. The German biotechnology program thus offers an opportunity to study corporatism under a constellation of pressures that differs significantly from that found in more frequently examined spheres of economic policy-making.

## 2. The new biotechnology

"Biotechnology", broadly defined, encompasses uses of biological processes known to man for thousands of years: the fermentation of beer or leavening of bread with yeast and the selective breeding of plants and animals to improve their desired characteristics. However, modern biotechnology, currently the focus of intense governmental and industrial interest, is an outgrowth of research in genetics, biochemistry and molecular biology dating from the 1940s. Breakthroughs in understanding the double-helix structure of DNA at Cambridge University in the 1950s eventually led to the discovery of processes for manipulating genetic and cellular material. The enormous potential for commercial exploitation of these techniques has begun to be realized only in recent years.

"Genetic engineering" is the basic element in the bundle of innovative biological processes that make up the new biotechnology [5]. Pioneered by Stanley Cohen of Stanford University and Herbert Boyer of the University of California, San Francisco, the process involves the removal of DNA sequences from one organism and their recombination through chemical means with DNA from other organisms. Recombinant DNA techniques are used in conjunction with manipulation at the cellular level, which permits genetically engineered cells to translate or "express" the desired characteristic from appropriately coded DNA molecules. Fermentation and enzyme technologies are employed in the mass production of genetically altered micro-organisms, an essential step in the successful commercial extraction of such products as vaccines, hormones and growth regulators.

The potential range of applications for modern biotechnological processes appears unbounded. Biotechnology promises breakthroughs in health care, food and energy production and pollution control. The pharmaceutical industry has been among the first to realize concrete benefits, with genetic engineering making possible more efficient production of previously available drugs, as well as of new pharmacologically active substances. Human insulin artificially made through gene-splicing techniques was approved for marketing in 1982 in both Britain and the US [6], and clinical trials are underway in several countries on biotechnologically produced interferons [7]. The new biological processes are being experimentally applied in a host of different functions: production of energy from biomass, conversion of inedible wastes into single-cell proteins for animal and human consumption, development of disease-resistant plant strains, extraction of minerals from low-yield ores, treatment of wastewater and oil pollution. Biotechnology also holds numerous possibilities for cutting industrial production costs, for example, by substituting energy-efficient biological processes for high-temperature, high-pressure chemical syntheses.

Public and private sector eagerness to exploit this protean technology is reflected in the diversification of firm types within the new biotechnology industry. A predictable segment consists of established firms, including giant multinationals, that have turned to biotechnology for new product development or the replacement of existing chemical processes. Particularly in the US, however, early commercialization of biotechnology has been accompanied by a mushrooming of small venture capital companies, whose chief function has been to speed the transition from basic research to industrial production. Additionally, in several other countries, notably Japan, France and Britain, public investment in biotechnological R&D has led to the formation of "public-private" enterprises designed to exploit the results of publicly funded research.

Most US analysts concede that the venture capital firms have played a highly significant, though necessarily bounded, role in bringing the fruits of biotechnology to the marketplace. Because of size and capital constraints, few of these firms are in a position to scale up independently to the production stage. For many, the possibilities of

eventual extinction or merger with larger companies loom large, especially in the event of a prolonged economic downturn [8]. Others may lose their competitive edge in basic research through a financially induced need to reorient their activities towards quickly marketable products. Nevertheless, their organizational flexibility, and the special financial and intellectual incentives they offer, have enabled the small firms to attract talented researchers who might not have left the freedom of an academic laboratory for the more bureaucratic ethos of a large corporation. One enthusiastic supporter of the biotechnology start-up firms has summed up their achievements as follows:

[They] have...succeeded in establishing their own special enclaves in which loyalty and creativity are fostered. In ordinary circumstances at universities, in government, or in industry, a scientist typically manifests only a small fraction of his or her potential. This is due to distractions, multiple responsibilities, interruptions, personality clashes, conflicts with management, and less than complete motivation. An organization that can foster a culture that brings out the best in its people can outdistance its rivals. A number of the new companies are succeeding in doing so. [9]

Financial stability, an elusive goal for most venture capital firms, is the primary source of strength for state corporations or other public-private enterprises associated with the development of biotechnology. Backed by the financing power of the state, such companies need not show immediate profits in order to justify their existence. Their position may be further strengthened by a variety of hidden state subsidies. Reinforcing these advantages, public-private enterprises also offer a promising organizational format for internalizing political conflict and for harnessing an adaptive new technology to meet the public interest.

The impact of modern biotechnology on the conduct of basic research has been, if anything, more pronounced than its impact on private industry. The mid-1970s witnessed an unprecedented inquiry into the risks associated with the new genetic technologies, spearheaded by scientists engaged in recombinant DNA (rDNA) research. A visible result of this activity was the

adoption of government guidelines governing rDNA experiments in most advanced industrial nations [10]. More recently, the prospect of large-scale industrial applications, as well as the growing potential for genetic manipulation of higher order animal and plant species, have sparked renewed interest in regulating the adverse impacts of biotechnology. While the rDNA guidelines focused on physical risk, future regulatory debate is more likely to confront the ethical and moral dilemmas aroused by recent advances in the biological sciences.

Though less visible than direct government controls, the increasing contacts between university researchers and the private sector in areas related to biotechnology are likely to influence the future of scientific research even more profoundly. Industry now recognizes that competitiveness in biotechnology hinges on the speed with which breakthroughs in basic research are linked into production. Corporate attempts to enlist the cooperation of promising scientists has ushered in a troubled era of university–industry relations, in which the private sector's demands for secrecy or exclusive use of discoveries threaten to undercut the universities' traditional commitment to freedom of information and detached scientific inquiry. This development has generated particular concern among scientists and university administrators in the US, where, since the rise of government funding in the 1940s and 50s, the legitimacy of academic research has been closely identified with the researcher's independence from specific sources of private capital [11].

Ramifications such as these merely hint at the diversity of the social readjustments necessitated by the integration of any complex new technology into the economy. They also underscore the need to define industrial policy in broad terms, so as to include not only those public initiatives that are narrowly designed to generate investment capital or to enhance innovation, but also measures that seek to attenuate or accommodate the disruptive social impacts of technological progress. A fair evaluation of the state's role demands that both types of action be taken into account, since both are crucial to a society's smooth transition to higher stages of technological development. With such considerations in mind, this article examines both the German government's R&D promoting strategies in biotechnology and the regulatory

measures it has adopted to control the negative impacts of the new technology. A detailed analysis of the federal biotechnology program is preceded by a brief description of the organization of German research in this field.

### 3. The research structure in biotechnology

Private sector research in biotechnology has been dominated in Germany by the large chemical and pharmaceutical companies that built up their postwar strength in organic chemical compounds, such as dyestuffs and sulfa drugs. The chemical industry is highly concentrated, with three giant multinationals – Bayer, Hoechst, BASF – accounting for 80 percent of German chemical sales in 1980. All three firms have pursued a strategy of innovation based on heavy investment in R&D, consistently devoting 4–5 percent of sales to research [12]. The pharmaceutical sector is significantly less concentrated, with the five leading concerns holding roughly 26 percent of the market in 1977. Two of the “Big Three” chemical companies, Hoechst and Bayer, also hold the lead in pharmaceutical sales. According to industry estimates, only about 50 of the German drug companies are in a position to conduct research programs, and a much smaller handful, some half-dozen firms in all, have the capacity to undertake expensive R&D in a new technological area, such as the modern biological processes.

Start-up firms of the kind that dot the biotechnology landscape in the US are unknown in Germany. Part of the reason for this is the conscious decision of the leading chemical and pharmaceutical firms to develop fully integrated in-house research capacities in this field. Bayer, for example, installed a “Biotechnikum” (biological research division) in 1972 and Hoechst and BASF followed suit later in the 1970s [13]. The leading pharmaceutical firms also have separate divisions devoted to biological R&D, such as Boehringer Mannheim's research facility in Tutzing. In contrast to firms like Eli Lilly in the US or Hoffmann-LaRoche in Switzerland, the German multinationals have not sought to establish joint ventures with successful biotechnology start-up firms.

A further obstacle to the creation of research-oriented start-up firms in Germany is the extreme

tightness of the capital structure. The three large institutions that dominate commercial banking – Deutsche Bank, Dresdner Bank, Commerzbank – have neither the inclination nor the expertise to finance high-risk enterprises seeking to market technological innovations [14]. Recognizing this defect in the traditional banking structure, 29 banks entered a cooperative agreement in 1975 to form the Deutsche Wagnisfinanzierungsgesellschaft (WFG), an institution specifically charged with helping small and middle-sized firms to commercialize new technological processes. Perhaps predictably, WFG operated in the red during its early years, but this disappointing performance pointed the way to some needed institutional reforms. In the future, WFG is expected to build up its technical expertise so that it can better evaluate the commercial potential of a diverse array of innovative proposals. WFG may also experiment with new kinds of collaborative arrangements that give the institution a greater say in the management decisions of the ventures it elects to support [15]. For the present, however, WFG has not identified biotechnology as a focus of interest for its activities.

The character of German public sector research institutions creates additional social and psychological barriers against the establishment of high-risk business enterprises based on new technologies. Three institutional settings have figured prominently in the sponsoring of basic research related to biotechnology: the large federally operated research institutes (Grossforschungseinrichtungen), the universities, which are funded and controlled by the Länder, and the Max Planck Institutes. Though each type of institution offers unique opportunities for wide-ranging scientific inquiry, each also erects characteristic impediments between the generation of new ideas and their successful application in industry.

Most vulnerable to changing political and financial constraints, the universities occupy a troubled corner in Germany's triangle of public sector research institutions. Starting in the 1960s, the universities were subjected to a series of reforms that left the system of higher education in turmoil [16]. Litigation about the rights and duties of students often took precedence over the traditional academic goals of research and teaching. Money troubles have now been added to the administrative and legal conflicts created by the uni-

versity reforms. As a new discipline, biotechnology is particularly susceptible to budgetary cutbacks, since it must compete with better established science departments for limited government funds.

The fact that the universities are public institutions and that professors are civil servants (Beamten) also hinders easy technology transfer from academia to industry. State officials generally take a negative view of market-oriented research by the teaching faculty and have done little to facilitate contacts between academic inventors and industry [17]. Patenting, for example, is not encouraged as a matter of university policy, and although individual faculty members are free to patent their own inventions, in most cases they must personally bear the substantial costs of patenting. The absence of any positive incentives for entrepreneurship by university scientists is reinforced by an elaborate network of welfare legislation that encourages employees to work within established organizations. Job security, combined with relatively generous pay and fringe benefits, makes the position of German university professors more comfortable than that of academics in many other countries, encouraging complacency rather than a desire to take risks.

However, these sociological deterrents do not fully explain the apparent reluctance of most German scientists to realize the commercial potential of their research. It is worth noting, for example, that two highly-regarded German microbiologists serve on the scientific board of Biogen, a biotechnology start-up firm based in Switzerland that was initially financed by venture capital from the US. The availability of outside funding in this case made possible a transition from the university laboratory to the marketplace that Germany's own more restrictive financial structure did not readily sanction.

Unlike their counterparts in the universities, researchers in the elite Max Planck Institutes need not worry about the pressures of teaching or the vagaries of academic politics. Institutionally, moreover, the Max Planck Society has taken a more positive attitude towards marketing scientific research results than have the administrators of the university system. The Society has created its own company, Garching Instrumente GmbH, for patenting and licensing its employees' inventions. The quality of research at the institutes remains high in a number of areas, including the biological

sciences. The Max Planck Institute for Plant Research in Cologne, for example, is an acknowledged leader in fundamental research on plant genetics. From the standpoint of technology transfer, however, the Society's elite character rather inhibits than facilitates productive collaborations with industry. One complaint frequently heard in recent years is that the Max Planck Institutes have developed into self-contained ivory towers, unconcerned with the need for intellectual exchange between basic research centers and commercial enterprises [18]. The federally-owned biotechnology institutes that form the third element in the non-industrial research structure fall directly under BMFT's funding program. Their particular problems and achievements are discussed in the following section.

#### 4. The federal biotechnology program

##### 4.1. *Defining the goals*

In 1966, the Organization for Economic Cooperation and Development (OECD) issued an influential report on the need for new forms of public and private sector cooperation in promoting new technologies. OECD's recommendations provided the impetus for Germany's "new technologies" program, introduced in 1968 by the Federal Ministry for Scientific Research (Bundesministerium für wissenschaftliche Forschung) [13, p. 73]. The program's objective was to establish new industrial infrastructures and to improve German industry's international competitiveness through planned support for R&D in innovative technologies. Under its umbrella program for biological and medical research, the science ministry began funding biotechnology projects as early as 1971. However, a comprehensive biotechnology program was put in place only after BMFT was created through a reorganization initiated by the SPD government in the following year.

As a new agency, BMFT possessed neither the experience nor the technical expertise required to formulate priorities and project support criteria in the field of biotechnology. Accordingly, the ministry commissioned a background report from a private professional association with a growing interest in the area, the German Society for Chemical Engineering (Deutsche Gesellschaft für chem-

isches Apparatewesen e.V., DECHEMA). The DECHEMA study, completed in 1974, effectively laid the groundwork for a coherent federal funding policy. It identified the principal sub-branches of biotechnology, described the state of the art in each, and suggested projects that were worthy of public support. Federal funds in the early years of the biotechnology program were dispensed largely in accordance with the DECHEMA blueprint.

The manner in which DECHEMA arrived at its recommendations had important repercussions for federal policy. Consistent with its past practices, the association appointed an expert group, consisting of industry, government and academic scientists, to consider a research agenda for biotechnology [13, pp. 78–79]. The group reflected not only the multidisciplinary character of the field but the established patterns of leadership within it. For example, DECHEMA selected industry representatives only from the leading chemical and pharmaceutical concerns with a capacity for intensive research and development. Smaller companies were excluded from the discussion on the ground that they did not have the R&D capability to make effective use of federal research funds. The selection of academic scientists was motivated by dual considerations of the participant's interest in the project and potential for making a significant contribution to the field. The working group also included three members from state-supported research institutes in recognition of the fact that such centers would play an important part in the future of German biotechnology. Notably absent from these early discussions were scientists involved in basic biochemical research.

Interestingly, the process leading to the formulation of a federal biotechnology program followed many of the norms of corporatist decision-making, though it was carried out under the auspices of a private organization. Dominant groups with a direct interest in dispensing and expending research funds were well represented. Interests viewed as marginal to the central enterprise – including, at this stage, basic science, labor and environmental groups – were excluded. Guided by common objectives, the DECHEMA expert group was able to produce a consensus program within two years. In turn, with a plurality of major interests already lined up in support of the program, BMFT could begin immediately to implement it, without having to engage in further political mediation.

The federal biotechnology program of the 1970s was remarkable for its breadth of coverage. Responding to a parliamentary question in 1979, BMFT listed 11 priority areas within the program, covering a much larger array of specialized research topics [19]. It is tempting to attribute this relatively uncritical delineation of priorities to the negotiating process that generated the biotechnology program. As a consensus document, the DECHEMA study, which formed the basis for the federal program, predictably erred on the side of over-inclusiveness. Constructing a more selective set of priorities from the DECHEMA report would have required a mixture of technical expertise and aggressive leadership which BMFT, at least in the early 1970s, was in no position to provide.

To the extent that BMFT had ascertainable goals of its own in this period, they were consistent with the taxonomically complete approach recommended by DECHEMA. The ministry was concerned, in the first instance, with establishing the infrastructure for a new technology in an industrial milieu that did not seem particularly hospitable to the novel biological processes. The traditional fermentation industries, brewery and food processing, remained uninterested in biotechnology, and the chemical and pharmaceutical concerns appeared still firmly committed to chemical synthesis [13, p. 70]. In this environment, attempts to implant biotechnology through a broad-based funding program may have seemed strategically more promising than any effort to develop more precisely tailored goals. As an actor on the political arena, BMFT was also committed to serving a very broad definition of the public interest, encompassing health, nutrition and environmental quality. This public posture, expressed in many of

BMFT's statements about biotechnology [20], likewise favored a multifaceted funding strategy. At the same time, with its interests squarely fixed on technological development within industry, BMFT could afford to remain relatively unconcerned about the basic research end of the biotechnology revolution.

#### 4.2. Implementation – the first decade

In the first ten years of the biotechnology program, BMFT, acting with the advice of a specialized expert committee, provided two kinds of research support: funding for individual projects and funding for the state-owned biotechnology institutes. Table 1 provides a breakdown of federal expenditures (in millions of DM) between 1969 and 1977 [21]. As a rule, BMFT has committed about two-thirds of total federal research funds to projects and the remaining one-third to institutional support. This proportion remained constant from 1979 to 1982, with about 66 million DM of a total biotechnology budget of 177 million DM earmarked for institutional use [22]. During the earlier part of this period, German funding for biotechnology far outstripped British or French public expenditures in this field, at one time by a factor of ten to one [23].

BMFT's overall strategy was to use public funds to fill gaps in the nation's R&D budget that would not otherwise be filled for institutional or economic reasons. Thus, BMFT provided up to 50 percent support for projects that private corporations were likely to reject as unprofitable, too risky or promising overly distant returns. However, BMFT made no attempt to use its financial leverage to bring about institutional change. Funds

Table 1  
Federal funds for technological research and development and biotechnology

	1965	1970	1971	1972	1973	1974	1975	1976	1977
Technology research and development <sup>a</sup>				251	401	674	769	812	915
New technologies	16	33	87	100	(400)	(530)			
Biological, medical and ecological R&D					25	40	116	232	235
Biotechnology		2	4	9	17	20	39	39	42
GMBF/GBF (VW)			6.8	4.8	4.8	5.4			
(BMFT)				4.2	7.2	10.7	14.2	12.3	14

<sup>a</sup> This program area expands upon and replaces "New technologies" from 1972 onwards.

were channeled to existing firms and public institutes. There was no effort to link BMFT's R&D policy to a more active strategy of promoting technology transfer from academic research institutions to industry. BMFT seemed to accept the view that German competitiveness in biotechnology could be achieved without creating new forms of corporate enterprise, such as the American start-up firms, or more systematic university-industry linkages. The two prongs of the federal funding program are examined in greater detail below.

*(1) Support for private sector projects.* One of the first biotechnology projects funded by the federal government, commencing even before the formal adoption of a biotechnology program, was the collaboration between Hoechst, the chemical-pharmaceutical giant, and two smaller companies to develop a process for producing single cell protein (SCP). In level of support, the SCP Project remains one of the largest public-private undertakings in German biotechnology. Ten million DM were committed to the project in the first two years alone [13, p. 70]. Yet, the private sector's inability to fund such a project on its own could not have been the primary reason for the government's decision to back SCP development. As one of Germany's "Big Three" chemical manufacturers, Hoechst has an annual worldwide R&D budget of more than a billion DM. Accommodating the SCP project in this budget would hardly have caused a major financial dislocation.

Foreign examples, reinforced by ideological considerations, probably supplied the chief impetus for the SCP project. A number of leading foreign companies, prominently including Britain's Imperial Chemical Industries (ICI), were known to be experimenting with SCP processes. Moreover, a project aimed at producing low-cost proteins from inedible substrates must have been viewed at BMFT as an ideally non-controversial candidate for public funding. The SCP project has in fact served a politically useful purpose through incorporation into Germany's technology-transfer policies towards developing countries. BMFT has already sponsored the building and operation of a pilot plant for protein production in Egypt and there are plans to construct similar facilities in other countries.

The SCP project, however, was a more ques-

tionable choice from the standpoint of a strategy for placing Germany in the forefront of biotechnological competition. The project was "successful" in a narrow sense. The partnership of Hoechst and its daughter firm Uhde developed an SCP process rivaling that of ICI in Britain. In contrast to ICI's product, which may be suitable only for animal feed, Hoechst's SCP product is claimed to be of food-grade quality, thus providing Hoechst with potentially more lucrative markets than are available to ICI [24]. But the high capital and operating costs of SCP production, particularly in the case of food-grade products, may render this advantage largely illusory. According to one recent assessment, large-scale commercial production of SCP may be profitable only in areas where low-cost energy sources and waste substrates are available and conventional feedstuff proteins, such as soybean or fish meal, are in short supply [25].

Taking a more optimistic view, there is little reason to doubt assertions by Hoechst spokesmen that the SCP project gave the company a valuable opportunity to experiment with the design and control of fermentation processes. The project also allowed Hoechst to acquire some expensive equipment that can be turned to a variety of other uses. But these arguments hardly suffice to justify a large expenditure of public funds out of a program specifically designed to foster innovation. At best, the SCP project permitted Hoechst to do some technological catching up which the company could equally well have done without public support. Hoechst's subsequent decision to invest heavily in American genetic technology, discussed in detail below, is also troublesome, because it suggests that BMFT's own investment in the company did not bring adequate returns in terms of support for research in Germany.

As in the case of SCP, BMFT's decision to fund research on interferons, one of the most rapidly developing sub-fields within the new biotechnology, was motivated by considerations going beyond the concern for German competitiveness. Finding that most research in other countries had focused on human leukocyte interferon, BMFT decided to direct its own funds towards the study of fibroblast interferon from tissue cells. The desire to avoid wasteful duplication of international research efforts was cited as the primary reason for this decision [26].

Funds dispensed by BMFT have been used not

only for product but also process development. A number of firms have displayed interest in using micro-organisms to extract minerals from beds that are inaccessible or uneconomical to process by other means. In the field of environmental protection, BMFT has sponsored research on microbial methods of wastewater purification. In the energy sector, BMFT has supported the construction of several plants for the production of biogas from vegetable and animal wastes. Some 45 biogas plants are already in operation in Germany and more than 30 others are under construction [27]. In the long run, such projects may have a limited beneficial impact on the national economy by reducing the costs of pollution control and promoting more efficient energy supply.

(2) *Institutional support.* The two principal beneficiaries of BMFT's institutional support for biotechnology are the Society for Biotechnological Research (Gesellschaft für biotechnologische Forschung, GBF) in Braunschweig and the much smaller biotechnology program located in the nuclear research installation at Jülich. The Jülich center acts as the administrative agency for the federal biotechnology program and hosts the periodic "status seminars" held by BMFT to bring researchers and the public up to date on the results of federally funded projects. GBF, however, is the home for most of Germany's public sector research in biotechnology.

GBF is the successor to an institute for molecular biology funded by the Volkswagen Foundation in the 1960s. Negotiations for public takeover of this institute initially ran into opposition from the federal government, which was reluctant to add another center for basic research to its existing network of state-owned research institutes. The difficulty was surmounted by transforming the Braunschweig center into a more practically oriented biotechnology institute supported 90 percent by federal and 10 percent by state funds. In 1982, GBF's operating expenses were projected at 31.6 million DM, of which 0.7 million DM were supplied from the institute's earnings [28]. With a staff of more than 350 persons, GBF is probably the most ambitious publicly operated biotechnology research institution in the world. But although state ownership confers the advantage of financial stability enjoyed by public-private enterprises, it also hampers creativity in predictable ways.

GBF's size is at once a source of strength and weakness. Although the smallest of the large federal research facilities, GBF is big compared with most analogous institutions in other countries. It is thus in a position to provide in-house coverage of the most important aspects of biotechnology. Its ten scientific departments permit interdisciplinary cooperation and cross-fertilization on a range of subjects from molecular biology to chemical engineering. Generous federal funding has made GBF one of the best equipped biotechnology institutes in Europe. Its fermentation laboratory permits active experimentation with equipment and process technology, as well as scale-up of biological processes to the pilot-plant stage. In the early 1980s GBF was subjected to a 7.5 percent cutback in personnel, along with all other federal research centers, but this was a minor concern in comparison with the survival worries that plague biotechnology start-up firms in the US.

But GBF also suffers the common malaise of the large public bureaucracy. The budget is rigid, providing little room for transfers from one project to another, and strict administrative procedures have to be followed in order to account satisfactorily for the use of public funds. The institute's program must be approved annually by two supervisory councils – administrative and scientific – so that researchers are subjected to considerable amounts of report writing. Some scientists affiliated with GBF see a more subtle problem in the concept of public ownership. Most members of GBF are public employees and enjoy effective tenure under civil service rules. As a result, the ratio of permanent to temporary staff is skewed more heavily in favor of the former than in a typical university laboratory or private firm. Without the freedom to hire younger, more creative scientists, GBF runs a risk of intellectual stagnation that may be difficult to overcome. Heavy administrative obligations may also impede the development of loyalty and high motivation, which some see as the greatest assets of researchers in the small US biotechnology firms.

#### *4.3. Regulating the new technology*

One of the more interesting features of German policy towards biotechnology is the integrated control exercised by BMFT over both regulatory and promotional strategies focusing on the new

technology. BMFT supervised the development of guidelines for recombinant DNA (rDNA) research. Ordinarily, the Health Ministry (Bundesministerium für Jugend, Familie und Gesundheit, BMJFG) has complete jurisdiction over federal health and safety regulation. This anomalous distribution of authority, with BMFT encroaching on BMJFG's traditional role, could well continue as long as federal health and safety policies threaten to have a major impact on the commercial future of biotechnology. At the same time, private industry has displayed an active interest in identifying and assessing the risks associated with the scale-up of biotechnological processes for commercial production. Whether organized under public or private auspices, the discussion of control strategies takes place in multipartite expert groups or other tightly organized pluralistic forums. These corporatist institutional mechanisms produce an incremental pattern of regulation that is not likely to interfere seriously with the pace of biotechnological innovation.

(1) *The recombinant DNA guidelines.* The assumption of public control over rDNA experimentation in Germany initially occurred with very little fanfare. An ad hoc group of experts appointed by BMFT recommended guidelines closely patterned on those developed by the National Institutes of Health in the US [29]. These were almost immediately adopted by the Max Planck Institutes for in-house research and were used by other major foundations in evaluating funding requests for genetic research projects. Guidelines based on the advisory committee report were officially approved by the federal cabinet in February, 1978. They were binding only for projects carried out with federal funds, hence not for privately supported research in or outside industry or for university research funded by Länder governments.

Though BMFT's expert committee included neither labor nor industry representatives, the guidelines, as adopted, made provision for participation by these interests in the implementation phase. To review applications concerning rDNA research, the guidelines established a Central Commission for Biological Safety (Zentrale Kommission für die Biologische Sicherheit, ZKBS) [30]. Ostensibly modeled on the concept of "community review" developed in Cambridge, Massachu-

setts and elsewhere, the ZKBS represents a plurality of social interests, as well as different areas of technical expertise. But the notion of "community" reflected in the commission's composition conforms more closely to German corporatist norms than to the broad view of participation endorsed by the Cambridge Experimentation Review Board in the US. The rDNA guidelines prescribe that four of the twelve ZKBS members must be experts in genetic engineering, four must have experience in biosafety issues, and four must be drawn from affected interest groups, such as labor, industry, occupational health professionals or research-supporting institutions. The unorganized lay public has no role in ZKBS's review process.

Patterns of corporatist decision-making not only influence institutional structure, as in the case of the ZKBS, but also govern the organization of political debate on key issues. In particular, BMFT successfully drew upon the corporatist tradition in deflecting pressure from the labor unions for more stringent regulation of rDNA research. Bowing to demands from its powerful labor constituency, BMFT in 1979 drew up a bill authorizing the federal government to regulate genetic research in all sectors, both public and private. Proponents of the legislation argued that a statute was needed not only to place the government's regulatory efforts on an adequate legal footing, but also to ensure that workers would be protected against the risks of rDNA research regardless of their place of employment.

In September, 1979, BMFT convened a hearing of German and foreign experts to discuss the proposed legislation, as well as more speculative questions about scientific autonomy and the probable impacts of full-scale commercial utilization of genetic technology. Foreign participants ran the gamut from scientists representing major universities and research centers to prominent individuals with a political or even journalistic involvement in the rDNA controversy. The latter were selected not only because of their institutional affiliations but because of a known record of activism in the rDNA debate. The German contingent, by contrast, consisted of representatives from large organizations with an institutional interest in rDNA research policy, but with no individualized commitment to particular policy outcomes. In this respect, the German group constituted a typical negotiating forum for corporatist decision-making,

providing opportunities for major interest groups to bargain with each other, but excluding marginal or extreme viewpoints.

The meeting elicited a great deal of negative comment on the BMFT proposal, with a number of participants questioning the bill's wisdom, its technical sophistication, and even the federal government's constitutional authority to pass such legislation [31]. Having generated a substantial record against the planned legislation, BMFT was able to drop the bill, to the satisfaction of both the press and the pharmaceutical industry. Yet this action could have aroused significantly more opposition, especially from labor, if two major sectors of the research community – private industry and the universities – had not agreed voluntarily to abide by the government guidelines. The trade associations for the pharmaceutical industry (Bundesverband der Pharmazeutischen Industrie, BPI) took the lead in mustering industry support for the guidelines, using the threat of legislation to persuade its members that voluntary compliance with the more flexible guidelines would be the course of greatest wisdom [32]. At the same time, the Länder governments agreed to extend the federal guidelines to the state-controlled university system so as to prevent arbitrary variations in the standard of care expected of academic researchers employing rDNA techniques.

(2) *The "safe biotechnology" study.* More recently, the German biotechnology industry has widened its self-regulatory efforts by studying risks not specifically related to rDNA research. Assuming a lead role as before, DECHEMA's Committee on Biotechnology established a working group to examine the hazards associated with the handling of micro-organisms in biotechnology. The group's second objective was to review the existing laws and regulations under which such hazards might be controlled and to make any necessary recommendations for legislative revision. The working group reflected the representative principles favored by DECHEMA: it included scientists from the large chemical and pharmaceutical firms, as well as experts from relevant trade associations and universities. Its findings were made public in 1982 as a report entitled "Safe Biotechnology" [33].

Given the institutional affiliations of its members, it is not surprising that the DECHEMA

working group took a pragmatic and technology-facilitating approach to the evaluation of risks. The group focused narrowly on risks to health and the environment presented by the use and disposal of cellular materials, particularly live micro-organisms. It did not consider secondary hazards arising from substances produced through biological processes in industry, such as poisonous or explosive organic compounds. The study concluded that existing laws and regulations give the federal government sufficient legal authority to control the risks that can be identified in connection with industrial-scale applications of biotechnology. These conclusions are not likely to be seriously disputed by federal authorities, since they were developed by precisely the kind of expert group that BMFT would itself have assembled to investigate the issue of safety.

Channeling the discussion of technological risks through such structured expert groups has one obvious advantage for industry. It tends to focus the policy debate on the kinds of risk that experts can easily identify and that readily lend themselves to technical control. Wider social impacts that have begun to concern some US scientists and policy-makers – effects on employment, population distribution, agricultural production, or academic freedom, for example – are not examined in such forums. Thus, by seizing the initiative at a very early stage in the policy process, organizations like DECHEMA can place practical limits on the government's regulatory agenda, at the same time guarding industry against charges of heedlessly exploiting a new technology. The latter factor could prove extremely significant in a political milieu where the environmental party has finally secured seats in the Bundestag and where a strong lobby of animal lovers and antivivisectionists has demonstrated its ability to influence legislative policy.

(3) *Product regulation.* In Germany as in the US many of the products that commercial biotechnology promises to make available in the next few years, such as human and animal drugs, hormones, medical diagnostic kits or biological pesticides, require governmental approval prior to marketing. Stringent testing and quality control standards adopted by the government could present significant barriers to innovation and international competition by delaying the entry of such products

into the market. The structure of the German regulatory process, however, is likely to minimize such impediments. Product safety standards have traditionally been developed through a process of negotiation among affected interests under the umbrella of a broad enabling statute [12]. While legislation precisely dictates what forms of intervention are available to government, it leaves officials considerable freedom to choose among alternative control instruments and degrees of control. In practice, standards are most often established in accordance with the recommendations of multipartite advisory committees, composed of government, industry, consumer or labor representatives, as consistent with the aims of the regulatory program. This framework permits considerations of cost and competitiveness, as well as safety, to be routinely factored into decision-making, though not necessarily in explicit detail. Controls on new products are generally responsive to the needs of the manufacturing industry, since patterns of consultation and compromise are already established within the expert groups that exercise *de facto* control over regulation.

## 5. A period of reappraisal

Although BMFT has not undertaken a public review of the biotechnology program, it is clear that a process of reappraisal began in the early 1980s. Much of this development can be credited to one extraordinary external stimulus: the highly publicized decision by Hoechst to fund basic research in molecular biology at Massachusetts General Hospital (MGH) in Boston. The agreement between these two organizations and its impact on the German biotechnology program are considered below.

### 5.1. *The Hoechst-MGH Agreement*

In May, 1981, Hoechst entered into a contract with MGH to establish a new Department of Molecular Biology headed by Howard M. Goodman, formerly of the University of California at San Francisco and a leading American figure in this field [34]. The contract marked the endpoint of an eight-month negotiation initiated by Goodman, whose successful work in cloning insulin genes had already won him a consulting relation-

ship with the giant chemical company. The contract, seen by many in the US as an important model for future university-industry relations in biotechnology, confers substantial benefits on both parties. Hoechst has agreed to provide the hospital about \$70 million over a ten-year period, an extraordinarily generous level of support for a single department. In return, the company is entitled to send up to four of its own scientists to be trained in Goodman's laboratory at any time. Hoechst will receive pre-publication drafts of manuscripts that may contain patentable material, as well as exclusive licenses to patents arising from research financed by the company.

It is difficult to predict what effect the Hoechst-MGH agreement will have on the German firm's long-term competitiveness in biotechnology. Skeptics point out that Hoechst's investment in MGH does not purchase product-oriented research. Moreover, even a large university department under the guidance of a highly talented scientist may not be able to match the diversity and potential for generating commercially interesting results of successful start-up firms like Genentech, Cetus or Biogen. By contrast, Hoechst supporters note that the company wanted and obtained a "window on science" at a time of substantial expansion in its own biotechnological activities. In the long run, training Hoechst scientists in Boston and reintroducing them into its in-house research establishment could give a large boost to the company's innovative capacity.

For purposes of the present discussion, however, the wisdom of Hoechst's American investment is less interesting than the repercussions this decision had within Germany. The announcement of the Hoechst-MGH contract seemed to have hit both bureaucrats and scientists as a minor bombshell. German scientists were distressed not only at the prospect of "German millions for U.S. research", [35] but also at Hoechst's more or less explicit admission that genetic research in Germany was not worth a major investment by the private sector. For officials at BMFT, Hoechst's massive commitment of research funds abroad signaled a missed opportunity on the part of the federal government to secure a proper return for its own extensive support of the firm's entry into biotechnological research. The MGH deal also underscored the importance attached by Hoechst to basic research in molecular biology, an area that

had not previously figured prominently in BMFT's funding strategy. The firm's actions thus raised serious questions about the assumptions underlying the biotechnology program constructed by the federal government on the basis of DECHEMA's 1974 recommendations.

### *5.2. New directions for federal support*

A look at some of BMFT's most recent initiatives with respect to biotechnology strongly suggests that the Hoechst-MGH agreement set in train a critical review of the existing program and a search for new directions. A programmatic statement made some three months after the effective date of Hoechst's American contract gave an early indication of changes in the ministry's outlook. BMFT's answer to a parliamentary question in August, 1981 [36] discussed the aims of the biotechnology program in a considerably more focused way than before and sounded themes that were conspicuously absent in earlier government pronouncements. The response stressed the importance of basic research and the need for greater interdisciplinary cooperation between biologists, chemists, medical experts and engineers. Active policy objectives included the encouragement of closer contact between industry and state-owned research centers such as GBF. The ministry also reaffirmed its willingness to support high-risk projects for which there is insufficient support within industry.

BMFT has taken a number of steps since 1981 towards realizing these objectives. Public involvement in some of the early biotechnology projects, most notably the SCP process, has been completely phased out. The fostering of closer relations between public research centers and industry, particularly in the area of genetic engineering, was flagged as an issue of major concern by mid-1982. BMFT's objective has been to promote systematic cooperative agreements between leading biological research institutions and private firms, supplementing the looser individual consulting relationships that were previously the norm for contacts between public and private sector research organizations.

Among the first fruits of BMFT's efforts to establish such linkages are the arrangements entered into by BASF and Bayer with institutions in Heidelberg and Cologne, respectively. BASF's

agreement with the University of Heidelberg will bring the university \$450,000 per year for biological research over a five-year period [37]. Reflecting its continuing interest in the agricultural applications of biotechnology, Bayer Works in Leverkusen has made an unrestricted grant of 3 million DM to the Max Planck Institute for Plant Research in Cologne [38]. The announcement by Schering that it will establish an institute for genetic engineering in West Berlin, with the cooperation of the city government, reflects an overall improvement in the climate for public-private collaboration in biotechnology, though this particular agreement was apparently not facilitated by direct intervention from BMFT [39]. Some German analysts see in such agreements the beginning of a period of rapid change, in which state support for biotechnology will be channeled through Länder and municipal governments, as well as BMFT.

As far as support for fundamental research is concerned, the Deutsche Forschungsgemeinschaft remains the federal government's principal policy-making and funding agency. But although BMFT does not plan to intrude on DFG's territory, the former's increased interest in genetic engineering opens up numerous opportunities for cooperative efforts by the two agencies. For example, in 1982 DFG funded a "special collaborative project" (Sonderforschungsbereich) designed by two universities in Munich to explore the biological, chemical and technological aspects of bioconversion. The purpose of such long-term grants is to permit strong university departments to develop competence across a broader scientific area than is ordinarily encompassed by individual research projects. The bioconversion grant was entirely consistent with BMFT's interest in promoting basic research in biotechnology and the ministry actively collaborated with DFG by reviewing the proposal prior to funding.

In the aftermath of the 1982 national election, it has fallen to a new CDU/CSU/FDP coalition to decide whether and to what extent it should follow through on policies recently initiated by the SPD. According to early indications, the new government's objectives in science and technology policy are consistent with the new directions discernible in the federal biotechnology program within the last two years of SPD rule. In particular, the CDU Minister for Science and Technology announced soon after his appointment that BMFT would

press for more market oriented research at the large government-owned centers, including GBF, as well as for greater cooperation between industry and the public research structure [40]. Continuing a policy of the previous administration, BMFT will phase down its direct support for individual projects in favor of less direct subsidies through taxes, loans and related mechanisms. BMFT will also try to compensate for the absence of small venture capital firms in the high-technology field by providing up to 50 percent support for projects jointly undertaken by two or more small firms [39, p. 1288].

The decision to use R&D funds to remedy certain structural deficiencies in the technology transfer system may mark a third phase in the development of post-war German industrial policy. It is worth noting that a rising concern with such structural problems was visible even before the 1982 election, when the SPD-controlled BMFT used its influence to promote collaborations between the large chemical and pharmaceutical companies and the academic centers of excellence in genetic research.

## 6. Conclusion

Despite the limits of the case study approach, and the rapidly changing character of policy in this field, the story of the German biotechnology program suggests some interesting conclusions about the impact of corporatism on industrial policy-making. The first ten years of the federal program not only illustrate the continued vitality of corporatist patterns in German decision-making, but also the constraints they can place on the government's ability to formulate innovative policies. The program's early successes and failures appear to follow naturally from the character of the decision-making process. On the one hand, the practice of negotiating with large corporations and trade associations permitted BMFT to launch, with little controversy, a broad-based R&D program comprising most major applications of biotechnology: chemical, pharmaceutical and food production, agriculture, energy, waste processing and mining. The corporatist approach also facilitated incremental regulation of the new technology, defusing demands for potentially constraining legislation in the case of rDNA research. On the other hand, the first phase of the biotechnology program

did not generate particularly efficient or creative solutions to the problems of commercializing new technologies: the dearth of venture capital, the barriers to technology transfer from basic research organizations to industry, and the attendant need for new corporate forms, including public-private partnerships. The recent steps taken by BMFT to remedy some of these structural deficiencies remain tentative and must, in any event, be seen as reactive policies triggered largely by incidents outside the ministry's control.

Reviewed in light of the biotechnology program's early record, corporatist interest mediation seems in certain respects antithetical to the notion of an activist industrial policy, especially one geared to the promotion of new technologies. Liberal corporatism depends on the creation of large organizations through which major interest groups can engage the state in a continuing dialogue on policy. The essence of corporatism is cooperative rather than competitive, favoring continuity over quick change. A new technology policy, by contrast, demands flexibility and the rapid adaptation of existing institutional forms to meet competitive challenges. Individual German organizations, such as Hoechst and the Max Planck Society, have demonstrated their ability to respond in this way to developments in biotechnology. Some Länder and university towns, as well, have developed novel institutional relationships to capitalize on growth in biotechnology. By comparison, BMFT's initial policies were more conventional, and it is tempting to attribute the relatively sluggish federal response to the constricting influence of large private sector organizations such as DECHEMA, the trade associations and the labor unions.

The German biotechnology case also illustrates the power of particularly committed interests in a corporatist framework to seize the initiative in policy formulation. Indeed, it appears that once the decision-making structure is in place, it can be mobilized and manipulated by private groups to their own advantage. The model of corporatism sketched by Schmitter and Lehbruch, with the state in the controlling role, thus gives place to a model in which private organizations take the lead in setting the agenda and selecting their negotiating partners. In at least two instances DECHEMA used this variant of corporatist mediation to define policy objectives ahead of any ini-

tiatives by BMFT or other federal agencies. Through its exploratory study on biotechnology from 1972 to 1974, DECHEMA not only defined the boundaries of the federal funding program, but helped establish certain key assumptions: that large firms should have a dominant voice in policy development in this area, that the accent should be on applied rather than basic research, and that the federal program should be founded on a very broad definition of biotechnology. Similarly, the more recent study of technological safety sponsored by DECHEMA has focused attention on risks to health and the environment that lend themselves to relatively easy control through existing legislative approaches.

The multipartite discussion forums organized by DECHEMA deviate from the traditional state-dominated corporatist norm in excluding organized labor but including the scientific community. This accords with the view that the definition of R&D strategies and the identification of risks are tasks for experts and hence beyond the competence of labor unions. DECHEMA committees are comprised of technically qualified individuals from university faculties, federal research institutes and industry. Policy formulation in such forums is treated as an apolitical exercise, through it gains credibility from the joint participation of experts from both the public and the private sector. Understandably, these expert groups have little interest in exploring the larger socio-political questions associated with the future of biotechnology, such as the possible impact of the new technology on employment. In spite of these limitations, their initiatives may preempt the discussion of such issues in the more openly political, state-organized forums that include organized labor and environmentalists.

During the first decade of the biotechnology program, BMFT was apparently motivated by a concept of the "public interest" that was distinctly wider than the mere promotion of German industrial competitiveness in the world market. Concern for nutrition, energy supply, environmental quality, international cooperation and technology transfer all played a role in the selection of research projects. Yet as the case of the SCP project suggests, there is a continuing tension between some of these broader concerns and the demand for highly profitable industrial products in an export-oriented economy. For example, BMFT's de-

cision to foster closer contacts between industry and the universities within Germany, though consistent with the ministry's overall aim of preventing the drainage of research funds out of the country, may not serve the large chemical and pharmaceutical firms nearly so well in the short run as an aggressive policy of buying into the more advanced field of genetic engineering in the US. This is a strategy that Japanese firms have pursued with notable success. While corporatist negotiations may create a semblance of unified support for BMFT's policies, it cannot paper over real disjunctions between the aims of government and industry. Unless these are quite closely aligned, as they appear to be in Japan, one can expect industry to take recurrent action violating the apparent consensus, such as Hoechst's decision to establish a major research department in a US institution.

Finally, although it is far too early for a final verdict on German biotechnology policy, the case presented here sheds some light on the power of the state in relation to other large interests organized according to corporatist principles. BMFT's control appears to have been weakest in the early stages of policy formulation, and the Hoechst-MGH agreement is widely interpreted as a sign that the ministry failed to extract a return from the company commensurate with the public investment in the SCP project. In contrast, the history of the rDNA guidelines shows an effective use of corporatist negotiations to resolve conflict. Industry's voluntary acquiescence with the guidelines may be viewed as a successful assertion of policy control by the state. The record, then, is mixed. The organization of large private interests as equal bargaining partners clearly necessitates a loss of autonomy for the state, but the corporatist framework imposes constraints on the private groups as well. Indeed, what may be feared most in the context of industrial policy is that the corporatist approach induces a degree of institutional paralysis and ideological conformity among all major actors that undermines the prospects for innovation.

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