International Competitiveness: The Failure to Regulate the Biotechnology Industry

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Biotechnology can be traced back to ancient techniques of fermenting alcoholic beverages and followed through the centuries as practitioners of plant and animal husbandry sought the best seed to germinate offspring. This old biotechnology, however, did not involve the techniques of genetic manipulation which characterize the "new" biotechnology. Today there exists a biotechnology industry composed of over two hundred business firms with various sizes, structures, and strategies engaged in the research, development, and commercialization of genetically-recombined (recombinant DNA) and genetically-altered organisms and microorganisms. In fact, the "industry" is creating a set of techniques and products which will apply to many industrial sectors including pharmaceuticals, animal agriculture, plant agriculture, and specialty chemicals [9, pp. 3, 8, 9].

In this paper, I discuss competitiveness and regulation in the new biotechnology industry by placing it within a broader framework for examining U.S. business-government relations in the late twentieth century. I describe a political and regulatory environment for biotechnology which was strongly influenced by the ideological themes of competitiveness and deregulation (which were, in part, the by-products of a changing macroeconomic and international environment). Within this environment the industry was able to pursue its political strategies in favor of government supports and against government controls.

The framework I adopt has its roots in a pair of papers by William Becker and Joe Pratt, both of whom advocated extending Chandler's strategy and structure approach to examining business and public policy and proposed developing a series of case studies on which to formulate an empirically-based description of post-1945 business-government relations. The case study which I outline in this paper is, I hope, responsive to their call and respectful to the spirit of strategy-structure [1, 3, 10].

One must, of course, recognize the differences among industries when working within such a framework and the U.S. biotechnology industry has a distinctive character. It is the offspring of a somewhat serendipitous wedding

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of a revolutionary technology, entrepreneurially-minded university scientists, corporate managers, and venture capitalists. Its gestation in the mid-1970s followed a decade of regulations which, for the first time, directly interfered with corporate autonomy and control at all levels of management structure, affecting both strategic and operational decision-making, and its birth occurred amidst declining U.S. dominance in world industrial and financial markets.

Extending strategy-structure to the issues of concern in this paper is challenging because Chandler, of course, paid scant attention to the role of government in the rise of the modern business enterprise. The implication of this neglect is to conclude that the relationship was not important. That is, for management, government was simply another potential threat to corporate autonomy and market control and, therefore, the business-government relationship should be seen as the effort to minimize interference and intrusion. Of course, during the rise of modern business enterprise, there was very little government to interfere with private autonomy and control. Nevertheless, the implication or the extended lesson we can learn from Chandler is that when the potential threat of political interference or the equally-important potential opportunity for political support become a reality we should focus on two aspects of this political activity. First, we should examine what level (i.e., top or middle management) of corporate decision-making is being threatened or provided opportunities by political activities and assume that the strategic response will differ accordingly (e.g., as Becker proposes, examining the hypothesis that policies which affect the long-term allocation of corporate resources will elicit a stronger response than policies affecting operational activities [1, p. 27]). Second, we should examine the nature of political activities in terms of how clearly the individual political actors (Congressional committees, agencies, individuals, etc.) have developed well-defined goals and well-organized administrative capabilities to pursue these goals [1, 2].

The outline I propose for examining business-government relations consists of five central elements. First, using the principles of strategy and structure, describe and characterize the firms which make up the industry (i.e., the competitors), their competitive strategies, and the structural arrangements designed to implement these strategies. Second, characterize the nature of competition in the industry, focusing on the different types of competitors which make up the industry, and identify those aspects of competition which are or can be affected by government policies. Third, describe the political actors who identify with issues involving the industry, the evolution of their goals regarding these issues, and the administrative capabilities they have developed to pursue these goals. Fourth, identify and examine the key environmental factors which affect management's strategic decisions. In Chandler's analysis, significant changes in technology and market demand were the forces driving strategic decisions. Yet there are other factors which can be as important as technology and demand. These include the fluctuations of the national macroeconomy and

the international marketplace, the activities of institutions such as universities and financial markets, and, importantly, the distinctive ideological environment of U.S. capitalism. Finally, examine the relationship between the industry and the government as the actors in both the private and public sectors develop strategies and pursue their goals. Aspects of this relationship include the interaction between the two sectors as goals and strategies develop, the efforts by one sector to affect decision-making in the other, and the influence of environmental factors on this relationship.

The Case of Biotechnology: An Outline

1. Competitors, competitive strategies, and structures

There are two distinct types of biotechnology firms in the United States: the recently-established or new biotechnology firms, the "NBFs" (e.g., the initial three -- Cetus, Genentech, and Genex), which were created as partnerships between venture capital companies and university-based scientists; and established, multinational corporations (e.g., Monsanto, Dow Chemical, Eli Lilly, Standard Oil) whose primary commercial interests are in pharmaceuticals, agriculture, or chemicals. Outside the United States the biotechnology industry consists, for the most part, of established corporations in the chemical and pharmaceutical industries. The most visible international competition for the U.S. industry is that of Japan which has targeted the commercialization of biotechnology as the "last major technological revolution of this century" [9, p. 11] and major established multinationals in Germany, France, Switzerland, and the United Kingdom.

The new biotechnology firms were started in the late 1970s to commercially exploit the new genetic technologies. They initially focused on research and development activities where they perceived (and were perceived by venture capitalists and established firms to have) a distinct competitive advantage. The goal for many of these firms is to compete with the established corporations and other NBFs in future product markets. These NBFs have chosen different strategies to pursue their goals including the following: a long-term focus on a narrow product niche; a long-term, risk-reducing product differentiation focus; a short-term focus on products with short lead-times from research lab to market; and an intermediate product market focus on supplying other biotechnology firms with contracted items such as "specialized genes" [4, p. 17; 12, p. 333; 9, pp. 95-96].

To carry out these strategies the NBFs are dependent on acquiring the necessary personnel and significant amounts of capital. To achieve the former, most NBFs were created by university-based scientists with continuing ties to their departments and have built on these connections even when they have left

the universities. (This differs from other industrial experience where scientists generally have severed their university ties.)

The fundamental survival factor for NBFs, however, is money. In their brief existence the NBFs have moved through three stages in their search for financing. The initial source was venture capital in the form of agreements predominantly with venture capital firms (which sought short-term, high-risk, high-profit ventures), but also from equity investments made by venture capital funds in established corporations. The NBFs were not able to look to the stock market at the early stage of their development because the reporting requirements of the Securities and Exchange Commission contrasted with the NBFs' perceived secrecy needs. The second source of financing involved NBFs going public when prospects for genetic products, such as insulin, appeared to be forthcoming and the profits to original investors were potentially staggering. And, most recently, as marketable products seemed even more certain, yet profits long-term rather than short-term, and with corporate biotechnology strategies changing, the NBFs have used research and development limited partnerships as a key source of funds [12, pp. 345-353].

The established corporations are pursuing a different set of objectives based on protecting their current market positions against potentially new competition and attempting to ensure a significant position in prospective future markets [12, pp. 332-33; 6, p. 211]. The pursuit of these strategies in the initial years took the following forms: making equity investments in NBFs, which minimized the risks of entering the industry as corporations spread their investments to many NBFs and allowed them a "window" onto the developments in this field; securing research and development contracts with NBFs, which gave the corporations both access to knowledge and rights to future product development and marketing; and agreeing to long-term contracts with universities for directed research and securing licenses to commercialize university discoveries, which gave them future product rights and access to university labs where the "cutting edge" research was being performed. When genetically-engineered products became a reality in 1982 corporations began to shift their involvement and to bring it inside the company by creating in-house research and development capabilities (whereas only a few corporations had been doing this in the early years). One method of developing this in-house capability has been corporate acquisition of NBFs [12, pp. 345-353].

2. The Nature of the Competition

There are four levels of competition in the biotechnology industry with each level having a distinct set of competitive objectives and, in most instances, each objective having the potential for government support or control (and thus providing a basis for the firms to develop and pursue political strategies). As the different political objectives are described below, it will be apparent that these

are not generally zero-sum decisions, i.e., the award of benefits to one type of firm does not necessarily mean the others have lost.

The first level of competition is among NBFs for capital resources and qualified personnel. In the quest for money, the federal government provides the opportunity for NBFs to entice investors by pursuing adjustments in the tax laws. The areas of intense interest to NBFs have been in reducing capital gains taxes and in the tax treatment of R&D limited partnerships. In the area of personnel, which some NBFs see as a more critical area than money, the stress is on federal funding for university-based science and engineering in the federal budget process.

The second level of competition is among established corporations over protecting existing markets, creating new products and processes in existing markets, equity investments in NBFs, licensing and contract agreements with NBFs, and research contract and licensing arrangements with universities. Established corporations are generally interested in the same tax objectives as the NBFs, although given their respective investment strategies, corporations are more concerned about R&D tax credits. But in public statements they have indicated even more concern about maintaining a good overall macroeconomic business climate because these firms are not dependent on outside sources of capital for their biotechnology investments. These established firms are also interested in government policies regarding the licensing of products developed from university-based, federally-funded research.

The third level of competition is at the intra-national level among both NBFs and the established corporations. The objectives here are profits to be derived from patentable discoveries and innovations, acquiring scientific talent and skilled technicians from a limited pool of such talent, gaining advantages in both established and new product and process markets, and gaining governmental support to pursue company strategies.

Although there are some common objectives, differences emerge between NBFs and established corporations at this level. There has been little disagreement among firms over federal regulation of industrial research; although the industry wanted few restrictions, they wanted the "legitimacy" of government sanctions for their activities. Thus, at different times the industry supported voluntary guidelines, supported regulations which incorporated the "spirit" of the guidelines (after the threat of numerous and conflicting state and local regulations), opposed regulations in favor of voluntary guidelines, and finally supported the phase-out of federal oversight of the voluntary guidelines altogether.

In the area of product testing, scale-up, and distribution the corporations (as well as NBFs with research and development agreements with corporations) took the lead in advocating limited controls when actual product development seemed imminent. Differences arose over the options available to corporations which the NBFs did not have, i.e., if restrictions at any level of activity were too

onerous, the corporations had the ability to shift the activity to an overseas location, which would put the NBFs at a competitive disadvantage. Other differences include the NBFs concern about the close relationship between corporations and universities because of the possibility of being "frozen out" of the bidding for personnel and about patent and licensing restrictions which would limit the NBFs' ability to move into product markets.

The final level of competition is at the international level among the aggregate of firms comprising the national industries. The objectives here are to capture significant positions in both process and product markets (nationally and internationally) so the respective national economies can reap the benefits of economic growth, productivity, and technological diffusion and convince their respective governments to minimize interference with the industry's business activities and maximize their support for these activities. At this level, all of the government supports and controls introduced above are brought together. Contrasting these biotechnology "industrial policies" and examining the "complementarity" or competitive "fit" among the national firms are the basis for analysis at the level of international competition [9, p. 11].

3. Political actors and actions

The loci of federal political activities during the early years, 1977-1982, was in the Recombinant DNA Advisory Committee in the National Institutes of Health ("RAC") and a number of Congressional committees. Since 1982, the activities have shifted to the White House Office of Science and Technology Policy, the Environmental Protection Agency, the Food and Drug Administration, and additional Congressional committees. There continues to be activity regarding patent and licensing issues in the federal courts and the U.S. Patent and Trademark Office which have each made important decisions affecting the industry.

In 1977 and 1978 most observers believed that Congress would pass legislation to regulate the industry. Five different committees or subcommittees held hearings and numerous bills were introduced. The focus of the debates was on safety, but after university researchers were able to satisfy Congressional leaders on the important scientific issues, the movement toward legislation waned. This left the RAC, which had the mandate only to provide mandatory guidelines for federally-funded research, as the sole governmental body overseeing genetic engineering.

In 1979 the RAC, under the urging of the Secretary of Health, Education, and Welfare (and the industry), created a set of voluntary guidelines. As the technology advanced from the lab to scale-up and production, the RAC was under pressure to function as the government body overseeing industry activities in these areas (although still on a voluntary basis for industry). As the RAC accepted the results of research which they believed had demonstrated the limited

risks in recombinant DNA activities, the guidelines were periodically revised so that by 1982 most of what was left (save for a few prohibited experiments) was directed to local authorities for oversight.

When the possibility of marketable products became a distinct probability, the political interests turned to issues (in Congress and at the executive agencies) of environmental testing and consumer protection. In 1983 the Environmental Protection Agency claimed jurisdiction over the issue of deliberate release of genetically-altered organisms under the Toxic Substances Control Act.[1] But in the spring of 1984 the White House Office of Management and Budget, under a general administration order to reduce government regulation and with an eye on international competitiveness, strongly advised the EPA to rethink its position.

Because the initial products of biotechnology have been pharmaceuticals, the Food and Drug Administration has also had a prominent early role. Other government agencies (claiming a mandate from their respective governing legislation) have also been interested in biotechnology. In an effort to manage these potential administrative disputes and not hinder industrial progress, the White House Office of Science and Technology Policy began in 1984 to develop (and has yet to finally conclude) a "coordinated framework" for federal oversight of biotechnology.

The emphasis in Congress has been in two areas: continued concern about the absence of specific regulations dealing with the biotechnology industry (under legislation passed in the early 1970s and not directly addressing biotechnology) and the proposed White House oversight of agency activities; and budget and finance committees which have been interested in U.S. competitiveness with Japan and Western Europe in biotechnology areas.

4. Environmental factors

The following factors have had a strong influence on the development and implementation of strategies in both the private and public sectors. (i) technological change: In an unexpectedly few years researchers have proceeded from the basic understanding of how genes work, to developing the ability to isolate and remove DNA, to being able to recombine and alter genetic material, to producing genetically-altered and recombined organisms and microorganisms for the marketplace [11]. (ii) market demand: When genetically-altered and recombined products became a market reality, the various industries which saw potential applications of the new techniques and products reexamined their market strategies. (iii) macroeconomic issues: The early years of the industry, the late 1970s, coincided with declining U.S. dominance of industrial and financial markets in the wake of OPEC policies and an inflationary economy; this decline led to a still-continuing debate over the ability of U.S. businesses to

[1] Ironically, the early scientific and political debates were dominated by concerns of accidental release.

compete against international corporations [5]. (iv) university research: Contrary to most previous industrial experience, biotechnological researchers maintained their connection to their universities and, in turn, university research labs were the source of "cutting edge" knowledge in the field and the recipients of both federal and industrial money to support this research. (v) venture capital markets: The availability of this type of financing (and the existence of the institution itself) is distinctive to the United States, and many observers who recognize the importance of the NBFs in creating this industry characterize venture capital as the element which created and maintains the U.S. competitive edge [9]. (vi) entrepreneurial spirit: The importance of small business is another distinguishing factor of the U.S. economy and in biotechnology this spirit extended to the university-based scientists who led the movement from the research lab to the marketplace. (vii) ideological factors: The early years of the industry coincided with a still-continuing debate over the effects of regulation and deregulation on business productivity and innovation versus the needs of environmental, consumer, and workplace protection; the debate over the ability of U.S. businesses to compete in the world economy had its genesis in the macroeconomic declines of the 1970s and the notion of "competitiveness" has become a distinct value to be invoked in all business-related political discussions.

5. Business-government relationship[2]

The business-government relationship in biotechnology has been a product of two key ideological and macroeconomic factors: the recent and continuing debate over regulation and deregulation and the effort to enhance the competitiveness of U.S. industries in the international marketplace. These factors underlie the strategies which industrial and political actors pursue and influence the policy outcomes.

From the beginning of their involvement with this technology the industry repeatedly and publicly insisted in its desire to follow any regulations which the government thought necessary to protect environmental health and safety. This position was based on the feelings that the industry must have "legitimacy" to conduct research activities which might, because of their nature and because of the regulatory climate, invite strict limitations on future production activities if they were to proceed without any governmental oversight.

This search for legitimacy took industrial representatives to the Secretary of Health, Education and Welfare, who had jurisdiction over the National Institutes of Health, and the Congress in pursuit of some type of regulatory

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[2] This outline of business-government relations is based on a set of documents which the National Institutes of Health has created and which contains verbatim transcripts of RAC meetings, Federal Register announcements of proposed regulations, and letters to the HEW and NIH [8] and a series of Congressional hearings in a variety of House and Senate committees from 1977 to the present.

structure. When Congress failed to enact any biotechnology regulations in 1977 and 1978 the industry successfully convinced HEW to enact voluntary guidelines under the oversight of the RAC. The RAC members debated this new responsibility for nearly two years even as the voluntary guidelines were promulgated. Although the industry wanted the oversight legitimacy they also wanted this oversight to be voluntary and this, in fact, remained the case.

Once under the aegis of the RAC, the industry made continuous suggestions to modify the guidelines to adjust to their future production needs. In particular, they were able to convince the RAC to put into place severe restrictions on disclosure of proprietary information (a concept alien to most academic researchers) and to ease the limitations on the volumes of laboratory scale-up in anticipation of production. As the technology progressed from research to scale-up and production, the industry participated in the debate which convinced the RAC to reduce most restrictions and to shift oversight from the federal level to the local biosafety committees (which were mandatory for federally-funded labs and which each company had voluntarily created). Finally, in 1984, industry representatives were given voting membership on the RAC.

Although the industry originally wanted legislation to oversee research, it is clear that they favored the voluntary NIH guidelines. Yet, because they feared the promulgation of numerous regulations at the state and local levels, they emerged to support a uniform federal system of regulation. When Congress failed to regulate research in 1977 and 1978 it did so at the urging of the academic community which fought legislation under the banner of scientific freedom. The industry did not even have to enter the debate. But once Congress and the executive agencies began to consider the regulation of activities beyond research -- testing, scale-up, production, and distribution -- the industry actively participated in Congressional hearings, wrote responses to proposed regulations, met with governmental representatives, and, eventually, organized two industrial trade associations.

During these political activities, the industry continually invoked the need for U.S. competitiveness as the focal point of their dual political strategy against regulation of their production and distribution activities and in favor of government supports (particularly changes in tax law and export restrictions). They were aided in this effort by sympathetic members of Congress and the administration as well as by a series of key reports issued by the Congressional Office of Technology Assessment, the Department of Commerce, the General Accounting Office, and the National Academy of Sciences. These reports recognized the lead of the U.S. industry in biotechnology and advocated measures to protect and enhance that position.

During Congressional hearings industry representatives argued that any restrictions would hamper the competitive position of the U.S. industry. And the NBFs argued that they would suffer a competitive disadvantage with their corporate competitors if there were restrictions because the corporations have the

ability to shift activities to foreign facilities (which these corporations, in fact, testified would be considered if restrictions were imposed). The industry also argued that simply having to continually address the possibility of governmental restrictions was also taking a toll. These arguments were not only politically persuasive but also indicated the political advantages which the established corporations have over the NBFs, which have limited financial and managerial resources to respond to recurring political demands.

While debates over the regulation of testing continue, there have been few restrictions on the production and distribution of new pharmaceutical products. One can point to the attitude of the Food and Drug Administration which has generally accepted the industry argument that the FDA should focus on the safety of the product and not be concerned with the process (genetic engineering) which created it. The industry also has received support from recent legislation -- with strong competitiveness overtones -- to relax the restrictions on product exports and from the Orphan Drug Act, which the FDA has interpreted to give significant protection to manufacturers (in the form of exclusive market rights). The FDA rulings have, in fact, split the biotechnology community because some NBFs argue that they have been locked out of lucrative product markets, and these firms have sued the FDA.

Thus in 1988 there exists no coherent body of federal regulation of the biotechnology industry and the prospects of such regulation, barring a significant public "disaster," are not imminent. The history of the debates reveals that a continuing theme in the business-government relationship has been international competitiveness, which has resulted in the political resistance to biotechnology regulation and the creation of political supports for the industry.

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