Appendix C

A Comparison of the U.S. Semiconductor Industry and Biotechnology*

Introduction

A parallel is sometimes drawn between the early development of the U.S. semiconductor industry and biotechnology. There are similarities. Semiconductors and biotechnology each showed promise for major advances. Whereas semiconductors immediately showed promise for major advances in electronics, biotechnology shows promise for major advances in many industries, from agriculture to oil recovery. Furthermore, developments in semiconductors and in biotechnology have both been characterized by the pioneering efforts of small startup companies, which have played a major role in technological innovation. Another reason for drawing a parallel between the U.S. semiconductor industry and firms using biotechnology is probably the hope that the development of biotechnology will be accompanied by the same kind of intense competition, continuing innovation, wide commercial diffusion, and spectacular financial returns that characterized the U.S. semiconductor industry.

As will be seen in this appendix, the early history of the U.S. semiconductor industry and the history of biotechnology to date are in fact characterized more by differences than by similarities. Nevertheless, studying the history of the U.S. semiconductor industry may aid the healthy development of biotechnology in the United States. Some of the actions that fostered the development of the U.S. semiconductor industry could be applied to the further development of biotechnology, thereby increasing its similarity to the semiconductor industry. The clear success of the U.S. semiconductor industry suggests that such actions deserve consideration for their applicability to biotechnology, although biotechnology is not an industry, but a set of technologies that can potentially be used by many industries.

The purpose of this appendix is to clarify the similarities and differences between the early history of the U.S. semiconductor industry and the development of biotechnology, to identify factors contributing to the successful development of the semiconductor industry, and to consider the relevance of these factors to the further development of biotechnology.

*The primary source for this comparison was a contract report prepared for OTA by Michael Borrus and James Millstein (2).

Semiconductor devices: terminology and evolution

Semiconductors are materials such as silicon and germanium with electrical conductivities intermediate between good conductors, such as copper, and insulators, such as glass. By appropriate manipulations, these materials can be made into *semiconductor devices* that have special properties. Such devices include diodes and transistors.

One of the most important properties of a *transistor* is its ability to amplify an electrical current flowing through it. A transistor is a compact, reliable replacement for the vacuum tube, which was the foundation of the early electronics industry. While transistors substantially improved the reliability and performance of electronic devices such as computers, they were simply components in electrical circuits connected by wires to other components.

Integrated circuits were the next major advance in semiconductor technology. Integrated circuits are "chips" or single components that perform functions that had previously required groups of components wired together.

The next step in"semiconductor technology involved increasing the density of circuit elements on each chip. The integrated circuit era began in the early 1960's. By the end of the decade, medium-scale integration (MSI) had been achieved (10 to 100 digital logic gates on one chip). Large-scale integration (LSI) (100 to 1,000 gates) was achieved in the mid-1970's, and the industry is now working on very large-scale integration (VLSI) (circuit complexity exceeding 1,000 gates) (9).

Advances in semiconductor technology have resulted in extraordinary gains in reliability and performance, with simultaneous reductions in component size and cost. In the 1950's, for example, the cost of computer memory capacity was about $1 per bit, but by 1981, a bit could be purchased for only $0.0001 (9).

The U.S. *senu"conductor industry is* comprised of the companies that manufacture semiconductor devices such as transistors and integrated circuits. Two types of firms can be differentiated: 1) firms that develop and manufacture semiconductor devices for sale to other firms that use them to manufacture computers and other end products; and 2) firms that develop and manufacture semiconductor devices for in-house use in the manufacture of final products. Both types of firms have been important to the development of the industry.

The following material describes the early development of the U.S. semiconductor industry and compares it to the short history of biotechnology. For the semiconductor industry, the period covered is from 1947 (the invention of the transistor) to the early 1960's. For biotechnology, which began in the mid-1970's, the period covered is from the mid-1970's to the present. In part because of the different time periods in which the semiconductor industry and biotechnology initially developed, an immediate difference between the two can be identified. The early development of the U.S. semiconductor industry occurred primarily in the context of the U.S. domestic market, whereas biotechnology is evolving in a world marketplace. International competition, which is an important factor in the development of biotechnology, is a far more important factor in the semiconductor industry now than it was in the early history of the industry. Both differences and similarities between the development of the U.S. semiconductor industry and biotechnology are indicated in the material that follows.

Development of the U.S. semiconductor industry

Two major influences in the development of the U.S. semiconductor industry were Bell Telephone Laboratories (Bell Labs) and the U.S. Government. These two influences are intimately related, because the Federal Government played a major role in shaping Bell Labs' contribution to the preeminence of the United States in high-technology electronic products including semiconductors, lasers, and computers. These industries have been built, in large measure, on the results of research undertaken at Bell Labs.

The role of Bell Labs in the development of the U.S. semiconductor industry is briefly described below. The multifaceted role of the Federal Government is discussed in the section that follows.

THE ROLE OF BELL TELEPHONE LABORATORIES

As part of the American Telephone& Telegraph Co. (AT&T), Bell Telephone Laboratories does fundamental and applied research in many areas to benefit its parent company. Bell Labs also serves a broader constituency. During World War II, for example, Bell Labs undertook about 2,000 research and development (R&D) projects for the U.S. Army, U.S. Navy, and National Defense Research Council (11). Federal funding of research at Bell Labs and AT&T's manufacturing arm Western Electric from 1949 to 1959 amounted to about $609 million-or about 48 percent of all AT&T research (17). The quality of research at Bell Labs and the level of funding available from corporate and Government sources attracted the most competent electronics scientists and engineers to work there.

In the late 1930's, the electronics industry depended on the vacuum tube for amplification of electric currents. The advantages of a smaller, more reliable device that would generate less heat were obvious, however, and because of military and aerospace needs, there was strong motivation to invent an alternative. Also clear was the potential importance of the transistor to commercial communications and computer applications. It is not surprising, given Bell Labs' commanding position in fundamental and applied electronics research, that the first new device that could compete with the vacuum tube in the marketplace, i.e., the transistor, was invented in 1947 at Bell Labs. This invention gave Bell Labs a lead in what would ultimately become the semiconductor industry.

Semiconductor R&D by Bell Labs was supported with corporate funds from AT&T. Between 1946 and 1964, Bell Labs' annual expenditures on semiconductor R&D rose from less than $1 million to about $22 million. In 1959, the funding of semiconductor R&D at Bell Labs represented about 30 percent of all privately funded semiconductor R&D in the United States (14).

The fact that Bell Labs was part of AT&T also contributed to Bell Labs' leadership in the semiconductor industry (2). The research done at Bell Labs was linked to real-world problems through AT&T's manufacturing arm, Western Electric. Western Electric involved Bell Labs in the solution of engineering problems associated with conversion from vacuum tube to semiconductor technology in communications systems. Western Electric also involved Bell Labs in research to improve *production* of semiconductor devices. In addition to conducting research that led to new devices, therefore, Bell Labs did research that led to process innovations. It was these process innovations that dramatically decreased the cost of semiconductor devices (2).

Federal and corporate investment in Bell Labs produced significant return. Between 1947 (invention of the transistor) and 1959 (invention of the integrated circuit at Texas Instruments and Fairchild), Bell Labs obtained 339, or more than 25 percent, of the patents related to the development of semiconductors. During this period, Bell Labs also was responsible for a disproportionate share of the most important product and process innovations (14).

In summary, market pull for an alternative to the vacuum tube favored the development of the semiconductor industry. The key invention, the transistor, arose from fundamental R&D in an industrial laboratory. That laboratory was an arm of a major corporation that also would be a significant user of the new technology.

The history of biotechnology is quite different from the early history of the U.S. semiconductor industry. Biotechnology arose from basic research in universities—research supported by Federal funds for basic biomedical research. Probably most significant were Federal funds for research associated with the '(war on cancer. " Because of the "war on cancer, " a great deal of research was done on tumors and tumor viruses. One of the simplest viruses, SV40, causes tumors in hamsters and mice. Researchers went to great effort to locate the genes in sv4o that enabled it to cause tumors. A need to improve on tedious genetic selection procedures for mapping genes led to the identification and use of restriction enzymes that cut DNA in specific locations, and thus enabled physical mapping of genes. Restriction enzymes also produce the "sticky ends" that are fundamental to recombinant DNA (rDNA) experiments. Physical mapping of an entire genome (an organism's complete set of genes) using restriction enzymes was first accomplished with SV40. And it was a proposed rDNA experiment using SV40 that gave rise to the Asilomar meeting that eventually led to the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules. *

Other researchers concentrated on myelomas (neoplastic growth of certain white blood cells). Thus, cancer research probably also contributed to the discovery of hybridomas * * and the monoclinal antibodies they make possible.

In summary, cancer research played a significant role in the history of biotechnology and is another example of how fundamental research may produce unexpected results. In the development of biotechnology, "science push," rather than the "market pull" that gave impetus to the U.S. semiconductor industry, was particularly important.

THE ROLE OF THE U.S. GOVERNMENT

The actions of the U.S. Government that influenced the development of the U.S. semiconductor industry were many and diverse. Undoubtedly, not all the effects of the Federal Government's actions were intended or anticipated. With the benefit of hindsight, however, it is apparent that these actions helped to produce a dynamic, healthy U.S. semiconductor industry. Similar actions by the Federal Government could encourage the development of companies in other high-technology fields such as biotechnology.

Federal Funding of Semiconductor Research and Development To Encourage Competition.—In the late 1940's, the U.S. Department of Defense (DOD) wanted to miniaturize and increase the reliability of electronic devices so that a new generation of defensive weapons could be developed. Defensive missile systems, in particular, required these advances. To ensure achievement of its objectives, DOD distributed R&D funds to many research houses, including Bell Labs. The provision of funding to many research houses encouraged the competitive development of semiconductor technology throughout the U.S. electronics industry. It also had the effect of leveraging private funding of semiconductor R&D (2).

The same forces driving military interests—miniaturization and reliability–also applied to the U.S. aerospace program. In addition to DOD, therefore, the National Aeronautics and Space Administration (NASA) also became a major source of funding for semiconductor R&D.

It is important to note that the early development of semiconductor technology was dominated by the interests of the U.S. military and NASA (2). Civilian applications followed. This early predominance of military interests driving the development of semiconductors contrasts with the development of biotechnology, for although there are military applications of biotechnology, civilian commercial interests have driven its development.

Federal Funding of Demonstration Projects, Production, and Consumption of Semiconductor Device% —Demonstration projects using semiconductor technology were financed by the Federal Government. The U.S. Air Force, for example, funded a demonstration in which a small digital computer using integrated circuits was built by Texas Instruments (l). Demonstration projects such as this convincingly demonstrated to both military and civilian users the feasibility of using integrated circuits in electronic systems (2).

In addition to funding demonstration projects, the Federal Government funded the development of semiconductor production capability and provided a market for semiconductor products under industrial preparedness contracts in 1952-53 and 1956-57. In 1952-.53, $11 million of DOD funds were used to build pilot transistor production lines at five sites operated by Western Electric, General Electric (GE), Raytheon, RCA, and Sylvania (10). In 1956, DOD provided major assistance to production technology with $4o million

• "I heseU S guidelines for rDNA research are discussed In *Chapter 15 Health, Safety, and En vironmental Regulation*

● "*Hyhndomas* are made by fusing an antibody-producing spleen cell with a my eloma cell in transistor production contracts to 12 firms. Because early production was often faulty and about 90 percent of the devices produced could not meet Federal specifications, the 12 firms had to build production facilities potentially capable of manufacturing 10 to 12 times the number of devices the Government wanted, thus assuring the Government of the number of devices it needed (19). As processes improved, more and more usable devices came off each assembly line, and the search for new commercial markets was stimulated by the need to absorb increases in production capacity.

The actions of the Federal Government just outlined helped to demonstrate the value of semiconductor technology to users other than the Federal Government, greatly reduced the risk of developing and producing semiconductor devices, and helped to develop industry capacity to produce semiconductor devices at levels that would meet the needs of new users as well as those of the Federal Government.

The Federal Government could support in biotechnology, just as it did in the semiconductor industry, the development of process and production technology. These are the very areas in biotechnology where needs for funds and for innovation are high. It is also in process and production capability and capacity that the United States is least competitive with Japan, its major competitor in biotechnology (2). One area of biotechnology that might be stimulated by a bioprocess production and demonstration project is the production of commodity chemicals. Large-scale bioprocess facilities, and hence large financial investments, will be necessary for U.S. firms using biotechnology to successfully enter the commodity chemical market. Cetus Corp. made an attempt to enter this market with its fructose-alkene oxide process using Standard Oil of California (SOCal) as financial backer. The attempt was frustrated when SOCal decided to terminate its backing (2). Federal funds could help new biotechnology firms (NBFs)* enter commercial markets requiring large-scale production. Alternately, rather than funding specific projects at particular firms, the Federal Government could support R&D in generic technology underlying bioprocessing. Regardless of the particular form of support, the Government should ensure that new knowledge of bioprocess technology gained with the assistance of Federal funding is made available to other potential users.

Federal Government support of field and clinical trials necessary for approval of some products of biotechnology by the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) would be somewhat analogous to the federally funded semiconductor demonstration projects. Such trials are very expensive and beyond the financial resources of many small firms.

The 19S6 Consent Decree.—In the development of the semiconductor industry, the Federal Government provided more than dollars, useful as these were to fund R&D, build production lines, demonstrate their products, and provide a first market. Substantial Federal dollar investments were accompanied by less direct policy decisions that helped shape a highly competitive U.S. semiconductor industry. The 1956 consent decree is a case in point.

In 1949, the U.S. Department of Justice initiated an antitrust suit against AT&T. Resolved in 1956, the consent decree (20) required AT&T's manufacturing arm Western Electric to license existing Western Electric patents to U.S. firms without royalty and to establish reasonable rates for licenses under future patents. AT&T was permitted to retain its vertically integrated structure but was prohibited from entering new product markets; in other words, AT&T was restricted to its existing markets of basic common carrier communications and Government defense and aerospace. Thus, AT&T was prohibited from using the results of research at Bell Labs to enter additional commercial markets that semiconductor technology promised to advance, such as commercial electronic computers.

Given the consent decree, one option for AT&T would have been to redirect Bell Labs' research so that it would not benefit fields AT&T could not enter. However, semiconductor R&D directed to enhancing AT&T's major interests in the telecommunications, military, and aerospace markets was not separable from R&D applicable to areas such as commercial computers from which AT&T was prohibited. In addition, Bell Labs had a history of open communication regarding its research. As a result, AT&T conformed not only to the letter but also to the spirit of the 1956 decree. The effect was to transform Bell Labs, for a time, into a sort of national laboratory for semiconductor R&D.

Continuing its open practices begun prior to the consent decree, Bell Labs actively contributed to the diffusion of the technology that it helped develop. Symposia to educate Government users and small and large firm licensees were begun in 1951, and a liberal license policy was begun in 1952. Also important, Bell Labs and Western Electric personnel moved freely to new employment in firms exploiting the results of Bell Labs R&D without fear of suit for theft of trade secrets (18). Such movements transferred know-how developed at Bell Labs and Western Electric to other firms.

*NBFs, as defined in *Chapter 4: Firms Commercializing Biotechnology*, are new, generally small firms that have been formed specifically to capitalize on new biotechnology.

Liberal licensing, the educational activities of AT&T, and personnel mobility encouraged by Federal antitrust activity resulted in wide diffusion of semiconductor technology. Diffusion was facilitated by the fact that data acquired under DOD R&D contracts were subject to unlimited use by the Government, including their supply to other contractors working in related areas. Various DOD offices and agencies, and DOD-funded centers at universities, served as information centers for research findings. The U.S. Department of Commerce (6), National Science Foundation, National Bureau of Standards (4), and NASA (13) served as clearinghouses for semiconductor information and transferred knowledge derived from military contracts to civilian users. Government agencies held symposia and colloquia to inform industrial contractors of the results of federally funded research and of future military and space requirements. The result was an acceleration in the pace, and hence the competitiveness, of the U.S. semiconductor industry, in civilian as well as military markets. In 1961, the Army Signal Corps estimated that defense R&D had made possible many civilian applications of semiconductor technology in a period perhaps 75 percent shorter than that which would have occurred without Government support (17).

In biotechnology, there is no institutional equivalent to Bell Labs, which served as a national resource for semiconductor research, development, education, and personnel. Furthermore, the scope and magnitude of Federal actions facilitating diffusion of knowledge and know-how in the area of semiconductors have no parallel in biotechnology at present. Finally, the diffusion of technolo~ by personnel mobility that occurred in the semiconductor industry because of the commanding position of Bell Labs, which was restrained by the 1956 consent decree, is unlikely to occur to the same degree in biotechnology, where knowledge is spread among many competing firms.

Federal Loan and Tax Policies.—In the 1950's and 1960's, the U.S. Government also encouraged the development of the U.S. semiconductor industry through Federal loan guarantees and tax policies. Although not developed specifically for the semiconductor industry, these general policies made funds available for operations, plant investment, and new equipment.

The Defense Procurement Act of 1950 established the V-loan program and was a major source of Federal loan guarantees to defense contractors from 1950 to 1958. This act provided Federal loan guarantees that obligated the Federal agency guaranteeing the loan to purchase a stated percentage of the loan if the borrower defaulted. Thus, the Federal agency shared any potential losses up to the amount of the guaranteed percentage (16). Such guaranteed loans accomplished several things:

- They encouraged private investors by decreasing their risk of loss.
- Because they were granted at lower than prevailing interest rates, they decreased the cost of capital.
- They served as a system of revolving credit. Guarantees were not tied to particular loans but instead were guarantees against loss of a particular level of debt. As periodic repayments reduced outstanding debt, therefore, additional loans could be taken out as long as repayments kept debt within the face amount of the authorization. Thus, authorizations of only $2.9 billion allowed loans totaling about $11.6 billion to be made to defense contractors.
- They returned a net profit to the Federal Government of about $24.5 million (15). This profit resulted because the Federal guaranteeing agent was entitled to a portion of the interest paid on the loan.

Most of the funding leveraged by the V-loan program was used for working capital rather than facilities. Other Government financial aids produced additional working capital. Progress payments, advance payments, and direct loans were made to companies involved in defense production (16).

A particularly important financial instrument encouraging investment in defense production capability was a program permitting accelerated depreciation. In the 1950's, the Office of Defense Mobilization awarded Certificates of Necessity that provided a 5-year writeoff (compared to the usual 20- to 25-year amortization schedule) of the percentage of the cost of certified production facilities that could be attributed to major defense production needs. From November 1950 through April 1957, 21,925 Certificates of Necessity permitted the accelerated writeoff of almost $23 billion on facilities costing $39.2 billion (15). Although these figures include more than semiconductor firms and data do not permit isolation of their share, semiconductor firms definitely received Certificates of Necessity and their writeoff was surely substantial (5).

The growth of the U.S. semiconductor industry was further spurred in 1962 by two changes in general U.S. tax policy (2). One change was that the Revenue Act of 1962 permitted all manufacturing industries an investment tax credit of up to 7 percent of qualified investment in machinery and equipment. This investment tax credit stimulated investment in semiconductor production capacity just when integrated circuit procurement began to expand. The second change was adoption by the U.S. Treasury Department in 1962 of new regulations that shortened depreciation guidelines by 15 to 20 percent.

Clearly, Federal tax and loan policies can stimulate substantially the growth of emerging industries. Consideration might be given to whether current tax and loan policies are stimulating development of biotechnology adequately or whether additional Government financial instruments are needed.

Defense Laboratory Research.–During the 1950's and early 1960's, each branch of DOD developed intramural programs for semiconductor R&D. Although these defense facilities produced relatively few significant semiconductor discoveries (with some major exceptions) (21), they nonetheless played a major role in the development of the semiconductor industry. In addition to serving as centers for information and technical liaison, these laboratories tested theories and ideas considered too speculative by private industry. Those that turned out to be practical were then developed by industry (7). Furthermore, personnel movements from defense establishments to private industry served to transfer knowledge, sometimes at critical points in the development of the U.S. semiconductor industry (23). Especially important, defense laboratory researchers provided the Federal Government with an independent view of the state-of-the-art of semiconductor technology and the capacity to verify, assist, and at times lead industrial efforts.

In terms of level of expertise and dynamic interaction between Federal agencies and industry, the closest analogs in biotechnology are NIH and FDA. Because it issues the U.S. guidelines for rDNA research, however, NIH is a quasi-regulator of biotechnology. This role puts NIH in a conflict of interest position vis-a-vis both its substantial funding of basic research in biotechnology and any additional role it might assume in commercialization. NIH, which has been forced to be aware of developments in the commercialization of biotechnology by the guidelines, however, nevertheless has a major potential role in biotechnology transfer. The degree to which and how best to involve NIH in commercial development of biotechnology deserve consideration.

FDA has developed expertise in biotechnology because of its regulatory function. Its major contribution to the development of biotechnology to date has been in providing a favorable regulatory climate for new products. However, the present regulatory climate is highly subject to administration views on industry regulation. Whether U.S. regulatory agencies should be better insulated from the effects of changes in administrations so that biotechnology evolves in a relatively stable environment deserves thought. In any case, an increased role for FDA in fostering the development of biotechnology is probably prohibited by conflict of interest with its significant regulatory responsibilities.

Other relevant U.S. Government agencies, such as DOD, the Environmental Protection Agency (EPA), the National Bureau of Standards, the National Science Foundation, the Occupational Safety and Health Administration (OSHA), and USDA have so far been less involved in the development of biotechnology than either NIH or FDA.

In sum, the substantial role that DOD and NASA played in encouraging the early development of the U.S. semiconductor industry is a role that is not being played by the U.S. Government in the commercial development of biotechnology.

THE ROLE OF UNIVERSITIES

During World War II, the successful funding of defense developments at universities gave rise to a conscious national policy of U.S. Government funding of university basic research. Although Federal funds for joint research at universities and industrial laboratories in solid-state physics and materials helped provide the basis for the U.S. semiconductor industry (22), the key discovery leading to the transistor was made in an industrial laboratory.

In the early 1950's, university electrical engineering departments lagged behind industry in the area of semiconductors by a considerable margin. * Federal funds were provided to universities to help reduce this gap and build the university expertise and training capacity that would be needed to support the expansion of the U.S. semiconductor industry.

These Government expenditures were fruitful. By roughly 1960, the major research universities in the United States had highly trained electronics personnel, creative basic research programs, and faculty members who served as expert consultants to industry.

Furthermore, the U.S. semiconductor industry became concentrated geographically around the major university recipients of Federal dollars, in particular, in Boston and San Francisco. The geographic proximity of semiconductor firms and these universities fostered productive interchange and insured the continued buildup of university expertise.

Increasingly cooperative ties between U.S. universities and the semiconductor industry resulted in the part-time employment by the industry of significant numbers of students. Many university faculty mem-

*Massachusetts Institute of Technolo&v's Lincoln Laboratories is an exception bers served as directors of semiconductor corporations, and some even held positions such as board chairman and part-time company president (2). Some faculty members became millionaires through equity participation in the companies with which they were associated (2). In comparison with the protests that have been raised in reaction to similar arrangements in biotechnology, public protests against these arrangements were small.

In sum, in the early history of the U.S. semiconductor industry, few innovations emerged from federally funded university research. The universities used Federal dollars to bring their expertise up to a level commensurate with industry's and to become geographic foci for the development of the new semiconductor industry. In the case of biotechnology, by contrast, innovations have emerged directly from university research. New semiconductor firms tended to locate near major university research institutions. This collocation occurred fairly gradually as Federal dollars flowed to universities and helped build their expertise. In the case of biotechnology, the collocation of new firms and universities occurred immediately, because the universities were the site of biotechnology expertise (2).

The lack of public and congressional concern over equity ownership of semiconductor companies by university professors is in stark contrast to the reaction to similar arrangements in biotechnology. Some of the factors that may account for the differences include the following:

- The locations from which biotechnology and semiconductor technology emerged and the source of their expertise, coupled with patterns of Federal spending, are different. Semiconductor R&D was dominated by industry, especially in its early years, and Federal funds went to industry for the development of the technology. Federal funds to the universities were used very differently from Federal funds to industry, namely, to build the scientific infrastructure necessary to support the new industry. Thus, the roles played by universities and industry and the use of Federal funds in the two sectors were more distinct in the early years of the semiconductor industry than they have been in biotechnology.
- Many recent advances in research in biotechnology immediately suggest commercial products. Although there are many problems to be solved between, for example, cloning the gene for human insulin and market success, the potential marketability of the product of the research is obvious immediately, In addition, the DNA organism that makes insulin, is, in a sense, itself the product. A transistor, on the other hand, is of no value unless it is used with other electronic components to make an end product such as a missile guidance system. Thus, in biotechnology, the contributions of the universities and industry are less distinct than they were in the semiconductor industry.
- The semiconductor industry had obvious contributions to make to aerospace and defense. Defense and aerospace are seen as national objectives and national commitment to them tends to be stronger and more focused than commitment to other sectors of the economy, where biotechnology is making its first contributions. Actions that would be protested otherwise may be tolerated when they relate to meeting defense and aerospace needs.

Structure of the U.S. semiconductor industry

Industries develop unique structures in response to their own characteristics and the effects of external forces acting upon them. The forces that have been described in this appendix shaped the U.S. semiconductor industry so that its particular structure evolved from a myriad of possible structures, much as biological systems evolve in response to pressures of selection. The structure that emerged in the semiconductor industry consisted of three types of companies:

- small, new entrepreneurial firms that developed and manufactured semiconductor devices, the so-called "merchant" firms;
- generally larger, established companies that obtained most or all of their semiconductor devices from the merchant firms and incorporated them into electrical systems; and
- one very large, vertically integrated company, AT&T, t-hat manufactured semiconductor devices for use in its telecommunications systems but was constrained by antitrust policy from dominating other markets. *

The role of AT&T, along with its affiliates Bell Laboratories and Western Electric, has already been discussed. The rest of this section describes the relationships between the other two groups of firms.

The emergence of new entrepreneurial firms in the U.S. semiconductor industry was facilitated by U.S. Government policies and actions, such as the 1956 consent decree and military and aerospace demands. Information on semiconductor technology was widely available, and personnel mobility was not effectively discouraged. AT&,T's liberal licensing policy, a U.S.

*Later in the history of the semiconductor industry a second vary large vertically integrated firm, IBM, was added to this group IBM manufactured semiconductor devices for its own use In the computer industry

Government market for new products, and the fact that transistors could be *substituted* for vacuum tubes meant that an entrepreneur could start a new semiconductor firm and move immediately to market with a few million dollars of capital, a license from AT&T, and a DOD or NASA contract.

Larger U.S. companies were helped in establishing their position in the semiconductor industry by the patterns of DOD development and procurement established during World War 11 that favored large corporations. "Even as late as 1959 the old-line vacuum tube companies were awarded 78 percent of the federal R&D funds devoted to improving the performance and reducing the cost of the transistor although they accounted for only 37 percent of the product market" (3). In contributing to the development of transistors and integrated circuits, the large defense electronics companies were speeding the obsolescence of a technology in which they had a very large investment, vacuum tubes. The large companies were forced into this position, however, by the presence of small entrepreneurial firms that managed to obtain DOD funds by their more flexible and rapid response to DOD's demands for miniaturization and reliability. The small, new firms undoubtedly contributed to the speed of entry of the large companies into semiconductor technology.

Small entrepreneurial firms did contribute to innovation in semiconductors, but preeminence in that role went to Bell Laboratories. In the development of the U.S. semiconductor industry the major contributions of small firms were to diffuse semiconductor technology and to stimulate competition. Diffusion of semiconductor technology occurred because the small firms exploited new markets. It was they who most "quickly and successfully (took) new technology from the laboratory and adapted it for large-scale production" (14). The small firms also stimulated-competition. In effect, the small firms, as independent sources of advanced semiconductor technology, introduced an element of dynamic uncertainty into the US. semiconductor industry. And because Federal policies helped them to *produce and market* their products, the small firms stimulated semiconductor R&D among all companies in the industry, large and small.

Biotechnology, as it now stands, presents a very different picture. Small NBFs in the United States, in order to spread risk and raise capital, have had to turn to complex cooperative arrangements with large domestic and foreign companies. * On the surface, the arrangements between NBFs and established companies may appear analogous to the relationship between the small new semiconductor firms and the Federal Government. An essential difference, however, is that small new semiconductor firms and the Federal Government did not compete for markets; NBFs would like to compete with established companies.

In the absence of support from the Government for producing and marketing its products or processes, an NBF is likely to turn to a large established company that has expertise in scale-up technology and regulatory clearance procedures. The established company is likely to have gained this expertise by developing a product similar to the one the NBF wants to bring to market. If the new product threatens an existing product of the established company, the established company's marketing of the new product is likely to be less than optimal. This is not to say that the established company will refuse to undertake the clinical trials, marketing, and distribution of the new product developed by the NBF. Indeed, the motivation of the established company is just the opposite. By obtaining a license for the NBF's new product, the established company ensures that another large competitor does not obtain the biotechnology product that threatens its own market. Furthermore, the established company can control the market environment of the new product. By entering into an agreement with an NBF, the established company also gains access to the new technology.

The arrangements between Eli Lilly and the NBF Genentech with respect to the new biotechnology product Humulin" are illustrative. * Eli Lilly has licensed this rDNA-produced human insulin product from Genentech. Humulin" is a competitor of insulin obtained from animals, and Lilly currently holds about 85 percent of the U.S. insulin market. Thus, the pace of market development in Humulin" can be controlled by the very company whose monopoly position Humulin" sales otherwise might challenge. A consequence of arrangements of this kind could be to slow market development and to reduce the flow of royalties to NBFs. Yet royalties maybe necessary to NBFs' survival and certainly are anticipated by the new firms to assist them in expansion. Arrangements like that between Eli Lilly and Genentech in biotechnology go against the lessons to be learned from the evolution of the U.S. semiconductor industry. Both the pace of technological development and the growth of small, innovative semiconductor firms such as Texas Instruments might have been quite different had Texas Instruments found it necessary to license GE or RCA to get its transistor products on the market.

● These arrangements are discussed in *Chapter 4: Firms Commercializing Biotechnology.*

● These arrangements are discussed in *Chapter 5: Pharmaceuticals*

Like the semiconductor industry in its early stages, biotechnology currently is restricted by its need for process technology. The history of process development in the evolution of the U.S. semiconductor industry is of relevance to biotechnology. As has been shown, large electronic defense contractors such as GE were assisted in developing production lines for semiconductor devices by large infusions of DOD dollars. But the history of the U.S. semiconductor industry demonstrates that small firms are not automatically foreclosed from process advances. Thus, the early growth of Fairchild Semiconductor, for example, was tied largely to its development of the planar process, which dramatically increased the firm's production yield and helped compensate it for its lack of production experience,

In the case of biotechnology, firms that exploit possibilities in both new product development and process innovation clearly will have more growth opportunities than those that restrict themselves to one or the other. In biotechnology, as in semiconductors, process know-how is probably transferable across a range of potential products and markets. Thus, if NBFs can surmount the financial hurdles to commercial production, the pace of technological advance and market development likely will be accelerated significantly, and the competitiveness of U.S. firms using biotechnology probably will be increased.

Other differences

Two other differences between the early history of the U.S. semiconductor industry and biotechnology are noteworthy. The first difference is the range of economic sectors each technology was perceived potentially to affect. For semiconductors, military, aerospace, communications, and computer applications were foreseen. All these draw primarily on the disciplines of electronics and engineering. The applications of biotechnology are perceived to be broader—pharmaceuticals, plant and animal agriculture, chemicals, pollution control, energy production, mining, oil recovery, and biosensors/biochips are areas where applications are being pursued. Not only is the array of sectors expected to be affected by biotechnology broader, the technical disciplines required for effective application of biotechnology are more numerous. Developing an effective infrastructure to support the commercialization of biotechnology, therefore, may be more complex than was developing an infrastructure to support the semiconductor industry.

The second difference is the prominent role of Federal regulation in biotechnology. NIH, through the rDNA research guidelines, is in a quasi-regulatory position with regard to both R&D and scale-up to commercial production. And for specific products of biotechnology, FDA, which regulates food ingredients and human drugs and biologics, and USDA, which regulates animal biologics, are particularly important. EPA and OHSA also may have significant regulatory authority, although their exact authority is somewhat unclear. * U.S. Government regulation in research, development, and marketing of many products of biotechnology, for which there is no parallel in the semiconductor industry, makes effective commercialization of the products of biotechnology relatively more complex.

Conclusions

Certain differences between the early history of the U.S. semiconductor industry and biotechnology are particularly important from a policy perspective:

- The U.S. semiconductor industry arose from a fundamental invention (the transistor) made at a major industrial laboratory, AT&T's Bell Telephone Laboratories, in 1947, and most of the subsequent product and process innovations in the period from 1947 to the early 1960's also were made by industry. Biotechnology arose from fundamental biomedical research in universities, and its early subject matter experts were primarily unversity professors.
- The need for development of the U.S. semiconductor industry to meet military and aerospace needs was clear. The tie between biotechnology and national objectives is less clear. The U.S. Government's role in support of basic biomedical research has been, and remains, clear, but its role in the commercialization of biotechnology is far less defined.
- At Bell Labs, early commercial exploitation of semiconductor discoveries was strictly limited to one industrial sector, communications (despite the much wider applicability of semiconductor technology). In effect, Bell Labs became, for a time, something like a national laboratory for the semiconductor industry. There is no equivalent in biotechnology.
- Many new semiconductor firms in the United States were formed to market a definite product, and, because of the availability of Federal contracts, relatively little capital was required to enter the market. Most NBFs were started as R&D houses, with the objective of determining how to make a product. With certain exceptions (e.g., in vitro monoclinal antibody diagnostic products),

*This issue is discussed in *Chapter 1.5: Health, Safety, and Environmental Regulation.*

the capital required to produce a biotechnology product and bring it to market will be greater than that needed by early semiconductor firms. For NBFs attempting to commercialize a new drug or biological for human use, capitalization requirements may be $50 million to $100 million. *

- The early U.S. semiconductor industry was characterized by multifaceted Federal encouragement of commercialization through a variety of policies ranging from antitrust to Federal loan and tax policies. There is no parallel to this in biotechnology.
- Biotechnology differs from the U.S. semiconductor industry in that the Federal Government is not providing substantial funds for process engineering and development of pilot and production facilities. Nor is the Federal Government serving as a "creative first market" for the products of biotechnology as it did for the semiconductor industry.
- Biotechnology also differs from semiconductor technology in the wider array of economic sectors it is perceived potentially to affect and in the larger role of the Federal Government in regulating many products of biotechnology.

Thus, NBFs currently face a very different, and much more complex, market environment than did the new entrants in the semiconductor industry. The industrial sectors in which biotechnology appears to be making its first contributions are human and animal health care, and the pharmaceutical sector has special characteristics. The market for a particular pharmaceutical product is often dominated by one or a few major corporations, as, for example, the U.S. insulin market is dominated by Eli Lilly.** The product of the dominant corporation is supported by extensive advertising in medical journals, by a complex distribution system involving detail men who provide product samples and are recognized by the physicians they serve, and by the reluctance of physicians to switch to a product with less familiar properties. The established company is also skilled in the clinical testing procedures necessary to obtain market approval. An NBF with a competing product, but without production capacity, experience in regulatory compliance, and an established marketing and distribution system within the medical community, has little choice but to license the new product to an established company that already produces a similar product. Such licensing, however, will tend to reduce the competitive stimulation to the industry that the NBF might otherwise provide.

The Federal Government was clear about its role in the development of the U.S. semiconductor industry. DOD and NASA funded the industry to produce products needed in military and aerospace applications. The Federal Government has funded basic biomedical research in university settings, but as yet it has no explicit role in the commercialization of biotechnology. Unlike semiconductor technology, biotechnology has sprung primarily from academia. As biotechnology moves to the market, universities of necessity have played a role in commercializing the fruits of public funding of research, because they were the sole source of basic knowledge. Moreover, the role of the universities has been further complicated in biotechnology by the close association between basic and applied research in this area. The traditionally distinct roles of the university as source of research and training and of industry as source of commercialization, which were clear with respect to semiconductors, are blurred for biotechnology. *

In the early history of the U.S. semiconductor industry, the Federal Government and industry were partners, with industry providing know-how and the Federal Government supplying public funds for R&D, demonstration projects, production, and consumption of semiconductor devices. Direct returns to the Federal Government, in the form of advances in defense and aerospace electronics, were obvious. In the case of biotechnology, however, not the Federal Government but the public health organizations and universities that were the sources from which biotechnology arose have been industry's partner in commercialization, As a result, an impression is left that the public is ceding the biotechnology research infrastructure and discoveries brought about by public moneys to private industry without corresponding return. The problem has been exacerbated because biotechnology emerged so quickly from the academic setting. Basic biomedical research nourished by Federal dollars is applicable suddenly to the development of commercial products.

Consideration of the differences between the early history of the U.S. semiconductor industry and biotechnology suggests several areas of need for biotechnology:

- One need is for the Federal Government clearly to distinguish basic research from commercialization and to define its different roles with regard to each.

* For discussion of the financial needs of firms using biotechnology, see *Chapter 12: Financing and Tax Incentives for Firms,*

** A profile of Lilly's share in U.S. and foreign insulin markets is presented in *Chapter 5: Pharmaceuticals.*

*University/industry relationships in biotechnology are explored at greater length in *Chapter 17: University/Industry Relationships.*

- **A second need, suggested by the successful history of the U.S. semiconductor industry, is for the Federal Government to facilitate the development of NBFs so that they can compete effectively in the marketplace. As in the semiconductor industry, small firm competition would stimulate innovation by all companies, large and small.**
- **Related to the above is the need to develop effec -** tive **mechanisms for the diffusion of knowledge developed in biotechnology.**

The last is very important and is really the central issue with respect to ensuring a return to the public for the financial investment that the public has made in biotechnology.

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