Chapter 17

University/Industry Relationships

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Introduction

The recent spectacular advances in molecular biology in the United States have arisen from basic research, most of which is federally funded and carried out in university laboratories. Led by the promise of biotechnology's commercial potential and the need for technical expertise, U.S. and foreign companies have been developing closer ties with universities, thus intensifying the process of university/industry technology transfer. At least in the United States, concerns have been raised about industrial sponsorship of university research (1,4,8,13,25,26). Some of these concerns are actually not new. What is new is that biology, rather than chemistry or engineering, is suddenly commercially promising.

This chapter focuses on university/industry relationships as a factor influencing the competitive position of the United States vis-a-vis other countries in the commercialization of biotechnology. Issues in university/industry relationships are not confined to relationships in biotechnology, so the chapter also includes some discussion of broader university/industry issues that have implications for competitiveness in biotechnology. The resolution of issues in U.S. university/industry relationships in biotechnology is extremely important, because the manner in which these issues are resolved will help determine the pattern of basic and applied research in the field for the next decade or so. Furthermore, research is likely to be critical to the development of biotechnology for some time.

Closer ties between universities and industry can be advantageous to the institutions involved and are important for the national innovative process. Industrial research questions can enrich the university research process, and there are financial benefits from increased industrial funding of university research. Industrial support of university research and development (R&D) in the United States currently represents about 6 to 7 percent of the total research budget of universities, although the percentage of industrial funding in some departments of universities may be much higher or lower (19). It is unlikely that industrial support will ever equal Federal support of university research, but increases in industrial funding could have significant effects on the types of research performed, especially in high-technology areas such as biotechnology.

American universities can expect some financial benefit from royalties derived from the licensing of patents, although it is unlikely that royalty income will ever be a significant portion of support. The Wisconsin Alumni Research Foundation (WARF), for example, has been instrumental in generating royalty income for the University of Wisconsin. It should be noted, however, that 39 of the 58 income-producing inventions assigned to WARF since 1925 have earned less than $100,000, and only 7 have earned more than $1 million (3,9). As shown in table 66, royalty income as a proportion of total Federal support is far less at nine other leading research universities in the United States than at the University of Wisconsin. If Public Law 96-517, the 1980 law that allows universities and small businesses to retain patent rights for federally funded research, encourages the development and marketing of products, U.S. universities' royalty income may increase. Stanford University and the University of California at Berkeley have already benefited from royalties (approximately $2 million) for the Cohen-Boyer patent for the basic recombinant DNA (rDNA) process. However, university income from biotechnology may be more dependent on whether the firms developing and marketing biotechnological products or processes rely primarily on patents or on in-house research.* If the more usual operating mode becomes in-house industrial research, then royalty income to universities may not be significant.

*The advantages and disadvantages of relying on patents or trade secrets to protect intellectual property are discussed in *Chapter 16: Intellectual Property Law*.

Table 66.—License and Patent Activity at 10 Leading U.S. Research Institutions

Institution	Fiscal year 1980 Federal R&D support: Total ($000)	Life sciences ($000)	Type of activity	Current annual number of disclosures	Current annual royalty income (thousands of dollars)
1. Johns Hopkins	$239,869	$60,275	Licensing program	20	$ 9 0
2. MIT	141,011	24,200	Licensing program	164	1,500
3. Stanford University	104,011	43,712	Licensing program	140	2,500
4. University of Washington	100,567	54,968	Research foundation	28	120
5. University of California, San Diego	90,703	37,327	Licensing program[a]	320[a]	1 ,700a
6. University of California Los Angeles	87,073	52,606	Licensing program[a]		
7. Harvard University	83,997	53,962	Licensing program	60	50
8. Columbia University	81,361	49,383	—	20	Minimal
9. University of Wisconsin	80,460	43,342	Research foundation	75	6,000 (with investment income)[b]
10. Cornell University	74,761	37,900	Research foundation	50	1,300

~University of California system.
Investment income is the substantial portion

SOURCE: G. S Omenn, "University-Corporate Relatlons in Science and Technology: An Analysis of Specific Models," *Parfrrers irr the Research Errterprise*, T, W, Langfitt, S. Hackney, A. P. Fishman, et al. (eds.) (Philadelphia: University of Pennsylvania Press, 1983)

There are potential disadvantages to closer university/industry relationships, but some problems can be avoided if participants are aware of potential difficulties and adequate safeguards are in place. One potential disadvantage of closer relationships might be a tendency to increased secrecy on the part of university faculty; it should be noted, however, that some secrecy has always existed when a particular faculty member is close to a new discovery. A second potential disadvantage is the danger that basic research in universities will be directed toward profitable lines of inquiry instead of toward interesting questions raised by past or recent findings. This might occur if there were a precipitous decline in Federal support for research in universities and universities had to turn increasingly to industry for financial support. A third potential problem is that some universities might be associated with products and processes linking them to lawsuits for damages, causing subsequent impairment of the universities' impartiality and credibility, Finally, there is the danger that universities that traditionally have competed for the best faculty might compete instead for the most lucrative industrial contracts.

In general, the purposes of universities in the United States are education, the conservation of knowledge, and the pursuit of unrestricted knowledge. The ends of a university and its faculty are pursued in a relatively open environment that allows the exchange of ideas and unrestricted publication of research findings. This does not mean that there is no competition among scholars, nor is it to deny that secrecy can accompany the desire to be first to announce a discovery (31). Similarly, it does not mean that the pursuit of knowledge for its own sake cannot be diverted by the funds currently available for particular kinds of endeavors (e.g., a "war on cancer" or secret government research). Generally, however, the pursuit by universities of the principles of openness, aided by generous Federal funding for basic research, has enabled the United States to build the greatest research capability in the world.

In contrast to the purposes of universities, the goal of industry is to make a profit, and the mode of achieving this goal is competition. Industry is output oriented, i.e., industry aspires to the efficient production of goods and services. When a company pays for research, it may expect ownership of the results long enough to justify the investment to bring the product to market. In an industrial setting, there is less willingness than there is in a university setting to share research materials; such materials are often kept as trade secrets. The reason for greater secrecy in industry is that development of a product is often risky, costly, and fraught with many obstacles along the route to success. Although the costs of developing and marketing a product vary among industries and products, the development of a pharmaceutical product in the United States can cost from $50 million to $75 million, with no guarantee of profit (27). Thus, in industry, achieving a competitive edge in a market necessitates guarding communication and intellectual property, an operating mode quite opposite from that of universities (6,13).

Industries and universities undertake partnerships in biotechnology for a variety of reasons, ranging from the desire by industry to gain access to new technology, to gain a lead time in basic knowledge, or to obtain trained personnel, to the need by universities to fill shortfalls in funding. Ultimately, it is hoped, the effect of the partnerships in the United States will be to facilitate and speed up the process of domestic technology transfer, since this is critical to the maintenance of a competitive position by the United States. Examining U.S. university/industry relationships in biotechnology is necessary in order to gain insight into the process of technology transfer and to determine if technology is being transferred in a spirit of cooperation and without compromising the goals of two very different institutions.

E. David has described the fundamental characteristic of optimal technology transfer between universities and industry as a two-way synergistic process between equal partners (6). Basic research, usually carried out in universities, is essential to the process. It is important to note, however, that basic science itself cannot progress without advances in technology, which often is developed by industry. Just as, for example, Galileo and Newton could not have made their contributions to astronomy without the invention of the telescope, the recent advances in molecular biology could not have been made without advances such as the electron microscope, X-ray crystallography, radioisotope Iabeling, and chromatography. Thus, universities and industry alike must accept the requirements of the other institution and enter into agreements that maximize the ability of each to maintain its standards and goals.

The effectiveness of university/industry relationships in biotechnology transfer

Since most of the university/industry relationships in biotechnology are new, it is difficult to ascertain how effective the relationships in the United States will be in transferring the technology between universities and industry. An estimate of their effectiveness can be made however, by considering the following questions:

- Why are university/industry relationships in biotechnology being formed?
- Are the relationships working smoothly?
- Has the way research is done in university laboratories or the quality of university research been affected by the relationships?
- Has collaboration among university researchers been affected?
- Has the quality of education been affected?
- Are there lessons to be learned from university/industry relationships in fields such as microelectronics?
- What forms are university/industry relationships in biotechnology taking and what are the associated issues?
- Are university policies with respect to university/industry relationships (e.g., patent and royalty agreements, handling of tangible research property, and conflicts of interest) being formulated?
- What is the likely future of university/industry relationships in biotechnology?
- And finally, how effective is universit,y/industry technology transfer in countries likely to compete with the United States in biotechnology?

At the request of OTA, two contractors interviewed university administrators, faculty, and graduate students (principally in biotechnology) from the University of California, Berkeley, the University of California, San Francisco (UCSF), Stanford University, Harvard University, Massachusetts Institute of Technology (MIT), and Johns Hopkins University, and representatives from 15 companies (a mix of new biotechnology firms and other companies moving into the biotechnology area) to obtain their opinions. Although this sample was not statistically representative, it included some of the major U.S. companies and research institutions working in biotechnology; thus, the opinions came from individuals active and knowledgeable in the field.

Why are university/industry relationships in biotechnology being formed?

OTA found an almost unanimous consensus among both university and industry representatives in the United States that universities are seeking money from their relationships with industry, motivated in part by a reduction or fear of reduction in Federal funding. Industry representatives believe that universities want to gain more real-world exposure for faculty and students and offer them a look at "economic reality" (18), In addition, some faculty stated that industrial funding requires less administrative work and is longer term than Government-funded renewable grants.

Are the relationships working smoothly?

The perception of most of the respondents in OTA'S survey is that university/industry arrangements in the United States are working well. The initial administration of agreements between universities and industry in the area of biotechnology was inefficient, because new policies were being formulated and new players (biologists, in contrast to engineers or chemists) are now involed in interactions with industry. In addition, some research administrators have had to learn how to administer technology transfer agreements (18). Some individuals have speculated that agreements are working well because there are almost no biotechnology products yet. Disagreements may arise, especially in limited partnerships, when product sales revenues are generated (18).

Has the way university research is done or the quality of university research been affected by the relationships?

Respondents in OTA'S survey were asked to consider two potential effects of university/industry relationships on U.S. university research: effects on the way research is done (its focus or methodology) and effects on the quality of the research. Nearly 85 percent of those responding believed that university/industry relationships in biotechnology have had no effect on the way research is done, and virtually all believed there has been no change in the quality of research.

Has collaboration among university researchers been affected by the relationships?

Almost 85 percent of the respondents in OTA'S survey who had an opinion about this issue believed that university/industry relationships in biotechnology have had no substantial effect on the exchange of information or the collaboration that has existed among U.S. university researchers. Most respondents believed that there is only limited collaboration in rapidly evolvring areas of science anyway and that levels of communication vary among faculty. Industry representatives commented that faculty having consulting arrangements should keep proprietary information confidential (18).

Has the quality of education students receive been adversely affected by the relationships?

Slightly more than half of those who responded to this question said there has been no change in the quality of education students receive, The others said that if there has been any effect, it has been to enhance the quality. Two forces will probably keep the quality of education at American universities unaffected by university/industry relationships in biotechnology. First, the goal of the faculty and university administrators to protect and maintain standards of academic excellence will continue to influence the arrangements that universities make with industry. Second, students themselves can be expected to monitor the situation and act to prevent any deterioration in the quality of education they receive. Some students have encountered problems at the University of California, Davis and Stanford University campuses, for example, and seminars and meetings have been held to address them. Faculty and university administrators have been involved in efforts to address the problems and to ensure that students' education is not compromised.

Are there lessons to be learned from university/industry relationships in fields such as microelectronics?

The development of the U.S. semiconductor industry is often suggested as a comparison for the development of biotechnology (see *Appendix C: A Comparison of the U.S. Semiconductor Industry and Biotechnology*). Virtually all of the basic research in electronic engineering carried out by U.S. universities during the 1950's and 1960's was supported by the Federal Government. In addition, however, a specific program in electronics research was funded by the Joint Services of the U.S. Department of Defense (DOD). DOD's program had four specific aims:

- extending basic knowledge in electronics;
- strengthening the scientific qualifications of electrical engineering faculty;
- training students to enter research positions at industrial, government, and university laboratories; and
- developing new ideas that could be exploited in the development of new systems and devices in applied research and development labs.

Because of the infusion of capital from DOD's program, there developed at U.S. universities a research and training infrastructure that facilitated the growth of the U.S. semiconductor industry. From the mid-1950's on, this infrastructure generated increasingly open cooperative ties between university electrical engineering departments and private companies. By 1961, nearly half of the 400 graduate students in Stanford's electronics program were employees of local industry who attended Stanford on a part-time basis and whose education was paid for by private company contributions. Moreover, members of Stanford's electrical engineering faculty sat as directors on the boards of 13 corporations (including one board chairman and one half-time company president). Nearly all of the 30-odd electrical engineering faculty members spent one-half to 1 day per week consulting for private industry. Moreover, four or five faculty members were virtual millionaires as a result of equity participation in companies with which they were associated as either board members or consultants. During the intensifying Cold War atmosphere surrounding the launching of Sputnik in the late 1950's, most individuals in academia, government, or industry were not troubled by these overt cooperative ties between the semiconductor industry and university electrical engineering departments. Neither the quality of the education nor academic freedom appeared to suffer substantially; in fact, all were probably enhanced (2).

The impact of Federal research funding at universities during the 1950's and 1960's thus had intended and unintended effects. Federal moneys purposefully developed the research and training infrastructure at universities necessary to feed industrial growth, and, in turn, laid the basis for widespread but largely unintended collaborative ties between American universities and the U.S. semiconductor industry. Major universities seized on Federal funds to become the concentrated locational foci for the rapid growth of the dynamic, new U.S. semiconductor industry. However, few semiconductor innovations emerged directly from federally funded university research.

The potential industrial applications of biotechnology, by contrast, have emerged directly from publicly funded academic biomedical research. As biotechnology has been moving to the market, universities have been buffers in commercializing the fruits of public funding, because they are virtually the *sole source* of basic know-how. Many of the new firms in the field of biotechnology have sprung out of academia, whereas in the semiconductor field, ample DOD procurement helped to create *industrial* know-how and encouraged *industrial* spinoff. In the area of biotechnology, the traditionally distinct roles of the university as source of research and training and of industry as source of commercialization are blurred. Though the consulting arrangements, equity arrangements, and research contracts between U.S. universities and industry in the field of biotechnology resemble in form the cooperative ties that emerged between U.S. universities and industry in the field of semiconductors, their timing, substance, and scale are significantly different (2).

What forms are university/industry relationships in biotechnology taking and what are the associated issues?

The major issues in university/industry relationships, though derived in part from the differences between the two institutions, are also set in a context of broader social and economic issues. Thus, the discussion of types of university/industry arrangements below is set in this context of broader issues. First a caveat: industry and universities are not monolithic institutions. The variability within each of these two institutions is as least as great as, if not greater than, the variability between them. This diversity is essential to the health of both and must be borne in mind in any discussion of university/industry arrangements, because no two arrangements are identical.

In the following discussion, five broad types of university/industry arrangements in biotechnology are considered:

- consulting arrangements,
- industrial associates programs,
- research contracts,
- research partnerships, and
- private corporations.

Additional information about specific university/industry relationships in biotechnology is presented in ***Appendix H: Selected Aspects of U.S. University/Industry Relationships in Biotechnology.***

By far the most common form of interaction is personal interaction among scientists. Personal interactions can include consulting arrangements, personnel and publication exchanges, seminars, and speaker programs. Issues arise most often with regard to consulting arrangements.

CONSULTING ARRANGEMENTS

Consulting is important for several reasons. It allows direct technology transfer between universities and industry that goes in both directions. Academicians agree that consulting keeps them apprised of new innovations in industrial R&D and that their knowledge can be applied to new kinds of problems related to, but outside of, their on-campus research. University faculty who consult publish more than faculty who do not consult (this may be a chicken and egg situation); they also do more research and participate as actively in their administrative duties as faculty who do not consult (17). Furthermore, consulting plays a significant role in faculty salary supplementation: 44 percent of calendar year faculty at doctoral granting institutions in the United States report that consulting is their first or second largest source of supplemental income (17). Consulting relationships have led to longer term industrial support of U.S. university research such as that provided by Monsanto to Washington University (see below) and Harvard and that provided by Exxon to MIT.

Industry views consulting arrangements with university faculty essentially as having an expert on retainer. Most U.S. universities have policies on consulting, but the policies vary. Some examples of university policies on consulting are presented in appendix H.

University consulting policies typically have provisions regarding conflict of interest, time regulation, disclosure, and policy enforcement. In most cases, policy enforcement is based on an honor system; each faculty member who consults is personally responsible for adhering to this. Although some faculty members may not always observe the rules, with incentives to carry on good research, train graduate students, and publish findings, most university faculty are not motivated to pursue consulting activities to the point where conflicts of interest occur on a regular basis. Disclosure policies are of interest for public access to objective scientific information. An argument could be made that because the public has supported research in universities, it has a right to know whether a particular university faculty member who is giving testimony, for example, has a consulting relationship with a company that manufactures a particular potentially harmful chemical. The negative side of disclosure policies is that "objective" information maybe judged "subjective" because of guilt by association. If a faculty member's consulting arrangement with industry is declared openly, it is not necessarily the case that his or her testimony is biased. In fact, the expert may have a more objective view because he or she understands both the research and development aspects of the technology.

INDUSTRIAL ASSOCIATES PROGRAMS

Industrial associates programs usually involve entire university departments or groups of specialists within a department. Companies pay a set annual fee that allows them to participate in seminars, interact with graduate students and faculty, and preview publications.

Industrial associates programs allow university/industry contacts and at the same time avoid conflict of interest problems and patent agreements. These programs exist at several U.S. universities, and some ongoing programs now include biotechnology. At MIT, for example, the Industrial Liaison Program has begun to include biotechnology as a subject of its symposia and seminar series. One of Stanford's 19 industrial affiliates programs is a program in biochemistry. And Pennsylvania State University has just initiated a Cooperative Program in Recombinant DNA Technology.

Industrial associates programs facilitate technology transfer between universities and industry, open up opportunities for further consulting and contract arrangements, provide funding for graduate students and faculty research, and give industry access to graduate students for future employment. Industrialists generally view these programs as useful. However, some industrialists believe that a few university programs tend to give the impression that research results are being sold to members only. Exclusivity is not the purpose of these programs; rather, their purposes are support of research activities and continuing open lines of communication of research results.

RESEARCH CONTRACTS

University research contracts with industrial sponsors have been and continue to be an important type of university/industry relationship in biotechnology. Research contracts differ from consulting arrangements in that the industrial sponsor is usually paying for a specific piece of research or supporting general research activities. Contractual arrangements often grow out of consulting or industrial associates programs and are usually motivated by industry's need for research that complements research being done in-house or for some expertise in a new area.

Several of the university research contracts with industrial sponsors in biotechnology have been large and have elicited questions regarding issues such as commingling of funds, patent rights, and disclosure of equity or other financial arrangements between the industrial sponsor and the principal investigator. The larger agreements have received extensive press coverage.

Issues of conflict of interest, invention rights, commingling of funds, and university policies regarding the processing of contractual arrangements are all important. It is interesting to note that MIT, which traditionally has had a close relationship with industry and has a relatively larger (7 percent) share of industrial sponsorship than other American universities, has the most explicit guidelines for consulting, disclosure, and processing of industry-sponsored contracts. other universities, notably, Johns Hopkins, Harvard, and the University of California, are moving toward more explicitly stated policies. See appendix H for descriptions of selected university policies on sponsored research and patents.

RESEARCH PARTNERSHIPS

Another type of university/industry arrangement taking place in biotechnology is the joint establishment of a research foundation, institute, or long-term collaborative arrangement by an industrial sponsor and a university. Three recent ones, further described in appendix H, are well known: the Hoechst/Massachussetts General Hospital agreement, the Monsanto/Washington University agreement, and the Whitehead Institute/MIT agreement. These arrangements raise several issues, some of which are pertinent to only one or two of them, others to all three.

The agreement between the West German company Hoechst and Massachusetts General Hospital, for example, raises the issue of foreign investment in and foreign benefit from U.S. Government-funded research. This agreement also raised the issue of commingling of funds (see below). For both the Hoechst and Whitehead Institute agreements, faculty selection is an issue because of the need for balance in subdiscipline in biology in Massachusetts General Hospital's medical school and MIT's biology department, respectively. Other issues raised by these agreements are external peer review of projects and controls on rights to publish. Another issue is the terms of termination of the agreements and whether adequate notification provisions have been made for the university to seek other support.

In the Hoechst/Massachusetts General Hospital agreement, the company will pay for all equipment and other expenses in order to ensure that there will be no Federal support of the research. Questions will arise if faculty cooperate with other researchers who are funded, for example, by the National Institutes of Health. Provisions have been made in both the Hoechst and Whitehead agreements to separate faculty selection and consulting. Choice of directions of research is the responsibility of the Whitehead Institute's directors and scientific board, all of whom have high academic reputations. Provisions for termination of the agreements vary, but they have been clearly stated.

Several States have established institutes for biotechnology development that encourage interactions between industry and universities. The North Carolina Biotechnology Center and the Molecular Biology Institute in Michigan have already been established; other States are in the process of establishing such centers. *

*For a list of State government initiatives for high-technology industrial development, see *Technology, Innovation, and Regional Economic Development: Census of State Government Initiatives for High-Technology Industrial Development-Background Paper* (28).

PRIVATE CORPORATIONS

Innovative approaches to connecting university research to commercial developments in biotechnology are being initiated. The establishment of Engenics (with Stanford and the University of California, Berkeley) and the establishment of Neogen (with Michigan State) are examples of two different approaches. For descriptions of these arrangements, see appendix H.

The Engenics arrangement is funded by six corporations, with money flowing through the simultaneously established nonprofit Center for Biotechnology at Stanford. The Center for Biotechnology funds contract research on the campuses of the University of California, Berkeley, and Stanford (and also funds one contract at MIT) and will funnel royalty income back into the university to fund more research. Neogen was established to utilize limited partnerships and tax benefits as a vehicle to allow Michigan State University faculty to remain on campus and simultaneously allow entrepreneurial ideas to flourish. Neogen's royalties are funneled back to the university through the nonprofit Michigan State University Foundation.

It is too early to evaluate the Engenics and Neogen arrangements. It should be noted, however, that potential challenges could arise with respect to adequate mechanisms for peer review of projects, applied research being done on campus, conflicts of interest of professors, and a private company doing the same type of work as is being done on campus with the on campus principal investigator having ties (equity, consulting, board membership) to the company.

Are university policies with respect to university/industry relationships being formulated?

The control of intellectual property, commingling of funds, tangible research property, and conflicts of interest are issues that cut across all university/industry arrangements and ultimately affect technology transfer and the U.S. competitive position in biotechnology. University policies with respect to these issues are addressed in the discussion that follows, and additional information about university policies is presented in appendix H.

INTELLECTUAL PROPERTY

Different traditions have developed in the United States to deal with different kinds of property. Although some U.S. universities allow the faculty member who developed the invention to retain any patent rights, most require those rights to be transferred to the institution. Created works are subject to copyright laws. Most institutions assert that ownership, but universities do not assert rights to books written by faculty (14).

Patent&—Issues relating to patent agreements can be divided into two kinds: those dealing with retention of rights to an invention and those dealing with decisions regarding exclusive or nonexclusive licenses.

The rights of small businesses, universities, and other nonprofit organizations to inventions made under research sponsored by the U.S. Government are addressed in the 1980 U.S. patent law, Public Law 96-517. An Office of Management and Budget (OMB) circular, Circular A-124, "establishes a standard Patent Rights clause to be included in all Government grants and contracts with such organizations, which gives these inventing organizations the right to retain title to the inventions. The Circular also requires agencies to modify existing regulations to bring them into conformity with the Circular" (7). Public Law 96-517 was passed with the recognition that the public interest can in most instances be promoted by allowing exclusive licenses under those circumstances. In a competitive economy, private enterprise will not invest funds to develop ideas that can be duplicated with impunity. Without exclusive licenses, important investigations made at Government expense would remain undeveloped because development costs are high. Thus, these inventions would never be available to the public (lo).

The consensus expressed in recently developed university guidelines for industrial sponsorship of academic research is that granting of exclusive or nonexclusive licenses will be on a case-by-case basis to the corporate sponsors of research. Summaries of State Agricultural Experiment Stations (SAES) and Pajaro Dunes Conference guidelines are presented in appendix H. In some cases, an exclusive license is given to allow time for development of the product. There is a division of opinion on whether exclusive licenses should be granted on all discoveries that result from university research funded by an industrial sponsor: some university representatives believe that an exclusive license should be granted, while others believe that the university should provide a nonexclusive royalty free license (see Pajaro Dunes Conference guidelines in appendix H). Most agree, however, that if a faculty member's research is being sponsored by a company in which the faculty member has substantial interest and/or equity, the university should grant only a nonexclusive license. In most of the major multimillion dollar university/industry agreements being struck in biotechnology, the corporate sponsor is receiving some exclusive rights to inventions developed as a result of the funding. In all arrangements between industry and universities, it is essential that the patent issues be carefully thought out in advance. *

COMMINGLING OF FUNDS

Since one of the purposes of the 1980 U.S. patent law (Public Law 96-5 17) is to foster cooperative research arrangements among Federal Government agencies, universities, and private industry, one question that immediately arises is the potential for commingling of funds. Currently, for agreements struck after 96-517 became law, no exemption for Government de minimus provisions has been made. Where the Government has funded a small percentage-even 1 or 2 percent of direct costs—then the provisions of Public Law 96-517 and OMB Circular A-124 apply.

The Comptroller General of the United States, in his reply to Congressman Albert Gore concerning the possibility for commingling of funds in the Hoechst/Massachusetts General Hospital agreement stated, "MGH must account separately for all expenses leading to an invention, including the cost of research itself as well as indirect or overhead costs, t. be able to show that the

"For a discussion of patent issues in surh agreements, see P. Hutt, "University/Corpo rat" Research Agreements" (10) expenses were paid with funds provided by Hoechst" (23). After reviewing the terms of the contract, the Comptroller General ruled that it is possible for Massachusetts General Hospital to separate the funds properly.

TANGIBLE RESEARCH PROPERTY

A basic principle among scientists is that research findings should be communicate promptly to the scientific community by written and oral means. Written and oral processes, however, are not sufficient to disseminate tangible products of research such as the antibody-producing cell lines and plasmids used in biotechnology.

Stanford University developed in March 1982 a specific policy on tangible research property (TRP), defined as "tangible (or corporeal) items produced in the course of research projects, " including items such as "biological materials, computer software, computer data bases, circuit diagrams, engineering drawings, integrated circuit chips, prototype devices and equipment, etc." (16). Stanford's policy was promulgated to protect the university's ownership in such property consistent with the policy of promoting the prompt and open exchange of TRP and associated research data with scientific colleagues outside the investigator's immediate laboratory. Controlling the distribution of TRP, subject to provisions of applicable grants or contracts and university policy, is the responsibility of the principal investigator. Such control includes determining if and when distribution of the TRP is to be made beyond the laboratory for others' scientific use.

WARF has developed a confidential disclosure agreement in order to disseminate or license intellectual property, tangible or intangible property, and products arising from work conducted at the University of Wisconsin. In order for the receiver to obtain the materials, the following conditions must be met (3):

- The materials will be received and held in confidence by the receiver. Only persons within the receiver's organization and only those essential in the evaluation of the materials will be permitted access to the materials.
- If opinions or services of other persons outside the receiver's organization are needed, then the receiver will notify WARF and the confidential disclosure agreement will be executed with that person.
- The receiver will not commercially utilize the material or any part thereof without written consent of WARF or prior to entering into a licensing arrangement with WARF.

Recently, a dispute over the ownership of a cell line that produces interferon arose between the University of California and the Swiss company Hoffmam-La Roche. The University of California, as the institutional home of the scientists who created the cell line, claimed ownership of the cell line and the right to future royalties. Hoffmann - La Roche also claimed ownership on the grounds that it had funded the university research that increased interferon production by the cell line and filed a patent application covering this interferon production process. Lawyers from the university sued the company, arguing among other things that the firm had made unauthorized use of the material, taking commercial advantage of the open exchange of information and material among academic scientists. This suit was settled out of court, but the settlement has not been made public.

Another recent case has left unresolved the issue of ownership of a cell line (24). H. Hagiwara, a visting Japanese researcher at the University of California, San Diego, took, without permission, a hybridoma fused from cancer cells taken from his mother and used the resulting monoclinal antibodies to treat her for cancer. Although the usefulness of the treatment has not yet been evaluated, the cell line may have commercial potential, so the issue of ownership is important. The University of California sued Hagiwara, stating that, as the research institution, it owned the cell line. This case has been settled with the Hagiwara Institute of Health (Hagiwara's father is the director) obtaining exclusive license in Japan and other Asian countries and the patent rights assigned to the University of California. Some argue that a hybridoma is a newly created entity, so the donor has no rights of ownership; others contend that cell donors should automatically be given a share of any subsequent profits (24).

CONFLICT OF INTEREST

Conflict of interest situations have both financial and intellectual components. A potential conflict of interest could arise if a university held equity in a company in which a faculty member of the university also held equity interest as a line officer. This situation arose in a Harvard proposal to establish a firm to commercialize the research of one of its professors. The proposal was subsequently withdrawn, and Harvard President Derek Bok described the potential problems with the arrangement (l):

- The administration could be exposed to disagreements not only with the faculty partners but also with other nonpartner faculty who might also want support.
- Commercial ventures could impose responsibilities on the university it doesn't have when its endowment invests only in shares of many companies.
- Conflicts could arise if the university were associated with particular products and a public that expects high standards from the university were dissatisfied with the standards of marketing or the products.
- The arrangement could inevitably change and confuse the relationship of the university to its professors. A faculty member who joins with the administration in founding a new company is no longer valued merely as a teacher and scholar; he becomes a source of potential income to the institution.
- There could be more doubt concerning decisions made with respect to qualifications for tenure, extra leave, larger laboratory space, more graduate students, salaries, etc.
- Professors might become so involed with the challenges of seeing an enterprise grow and develop that their work commitment to university duties might be diminished. The university would be in a prejudiced position regarding assessment of that person's performance of work since that person's commercial success would be linked to that of the university.
- Participation would increase the risk of secrecy, and the university could have a stake in supporting that secrecy.

A potential conflict of interest and commitment arises when a professor holds equity within a company that engages in the same type of activities as the university. This issue has been raised in the activities of Calgene. The State Agricultural Experiment Station (SAES) at Davis helps develop new varieties of plants for California growers. University of California professors, including Ray Valentine, have part-time employment at the station. Calgene, a company Valentine founded, is undertaking for profit the same kinds of activities as the SAES undertakes for growers. Thus, there is a potential source for conflict and for taking the results of work off campus and marketing them through the company.

University conflict of interest policies and consulting policies vary, but university policies are becoming more explicit, in part because universities are responding to developments in biotechnology. It is interesting to note that MIT, which has traditionally had extensive contacts with industry, has explicit policies on industrially sponsored research. In addition, several organizations are setting guidelines for industrial sponsorship of academic research (see app. H).

At the request of Representative Albert Gore, the American Association of Universities (AAU) reviewed the ethical dilemmas posed by increases in industrial support for research. AAU suggested that it serve as a clearinghouse and monitor activities at the major American universities with regard to the formulation of policies. AAU decided not to develop policies, because "conditions exist [in the universities] for intelligent and thoughtful decisionmaking on these issues and policies that are informed by wide experience and that are tailored to individual circumstances are preferable to injunctions broady enough cast to cover the multitude of local circumstances that exist among many universities" (15).

Also, representatives from universities, industry, and the legal community are now meeting to review issues and communicate more effectively. Recent meetings have been hosted by Columbia University, the Gulf Universities Research Consortium, the Industrial Biotechnology Association, Florida State University, Harvard, and the Bar of the City of New York, and a meeting in Philadelphia in December 1982 was hosted by eight major research universities (15).

It is clear that recent activities to formulate explicit policies are advantageous in helping to define the role of the university and ultimately facilitating effective technology transfer between universities and industry. Technology transfer will be most effective if both sides are strong, vibrant, creative, and have something to offer each other.

What is the likely future of university/industry relationships in biotechnology?

A comparison of the responses to OTA'S survey of university and industry groups in the United States shows that both groups see the future of university/Industry relationships in biotechnology as depending largely on the success of biotechnology companies in getting products into markets. There was divergence of opinion among the respondents, however, on what kind of research assistance—broad basic research or more specialized research-industry would seek from universities, In biotechnology as in other fields, an increase in the actual number of industry/university relationships and an increase in the total amount of funding made available by industry can be expected to develop over the short term (18).

U.S. university/industry relationships in biotechnology will most likely follow the same pattern that they have in other high-technology areas. First, scientific breakthroughs generate a period of hyperactivity in university/industry relationships. This hyperactivity phase is characterized by the promise of "big bucks," which leads to a short-term faculty and post-graduate drain. After the industry goes through its initial phases, an equilibrium state is reached and a fairly healthy symbiotic relationship emerges.

How effective is university/industry technology transfer in countries likely to compete with the United States in biotechnology?

The countries identified in this assessment as being the most likely major competitors of the United States in biotechnology are Japan, the Federal Republic of Germany, United Kingdom, Switzerland, and France.

JAPAN

Japan has a mixed situation with regard to university/industry relationships in biotechnology. First, a distinction should be made between institutions and individuals. At the national universities, which are at the top of the Japanese university hierarchy, institutional ties are very strictly regulated. At the level of individual professors, however, there is considerable opportunity for interaction. A second distinction is between the basic and applied sciences. The distinction and separation of basic and applied science departments at Japanese universities is strong. Japanese professors in disciplines such as biology, biochemistry, and medical science are proud of their independence from industry. Professors in applied disciplines such as bioprocess engineering, on the other hand, have ongoing contacts with industry. Japanese professors in applied science departments are considered to have a moral obligation to place their students as employees. Consequently, they tend to maintain good relationships with industry. Furthermore, because former students are members of industry, informal contacts continue.

Even though Japanese professors in applied sciences have contacts with industry, the level of exchange of information between universities and industry in Japan is not as high as that in the United States. Japanese professors at the national universities are forbidden to take other positions simultaneously with their university work, and all donations toward their research must be made through formal university channels. No fees for consulting can be accepted, and offers of stock options are unheard of. Japanese professors were not allowed to hold patents or collect royalties until 1981. Because of the restrictions on both professors and industry, Japanese professors often quit their posts to work in industry or private laboratories where facilities-and salaries are better than in the universities. They do this in spite of the fact that there is a great deal of social prestige attached to being a professor.

There are only two mechanisms through which Japanese industry can channel funds to a university. One of these, the "itakuhi," is commissioned research on a particular topic. The company supplies a researcher and some funds, usually only $500 to $1,000 (Y 125,000 to * 250,000), to a university professor. This mechanism allows the company to have its researchers trained by the professor and the professor's staff; the professor, in turn, gets extra help in doing his research. The second mechanism, the "shogaku kifukin," is a scholarship grant donated to a specific university researcher but not for a specific topic. The grant money must be used only for equipment and other direct costs, not personnel costs; no overhead is charged by the university, and there is no limit on the amount. Money for these grants must be channeled through the Ministry of Education. Within this framework, there are a number of administrative obstacles in terms of hierarchy of approvals necessary, different policies on patents among departments, etc. In spite of the tight control of channels of funds and lack of consulting opportunities for Japanese professors, about 10 percent of all university funding for research in Japan does come from industry. Most of this is probably channeled to applied research (22).

The Science and Technology Agency (STA) has established the New Technology Development Fund in order to subsidize Japanese companies that develop and commercialize university research findings. The fund will probably be used to transfer technology between applied science departments and industry, which already have good relations, rather than between basic science departments and industry.

Another STA program is designed to cross traditional barriers between university basic science departments and industry and between the Ministry of Education and the Ministry of International Trade and Industry (MITI). Research responsibilities in STA'S program are allocated between university and corporate laboratories. The success of the program will depend in part on getting MITI, the Ministry of Education, and basic research departments to work together. Basic researchers have already asked the Ministry of Education to supervise the project, so there is some doubt as to whether the program will be successful. If supervision stays in Ministry of Education, the link with industry will be weakened.

Research in Government institutes makes up for the lack of technology transfer from the heavily regulated Japanese universities. In almost every major industrial sector in Japan, there are a number of governmental research institutes that do background research for MITI policy makers and where professors, industry representatives, and Governrnent officials meet for discussion. Mitsui Information Development and Normura Research Institute have been used for background research in biotechnology.

In addition, the Japanese Government is building two biotechnology centers, each with a P4-level laboratory facility: one in Tsukuba (a new university research community) and one at osaka University. The P4 facilities will be available to private sector corporations via contacts with university professors. Four other universities were designated by the Ministry of Education to have P3 level facilities and received $640,000 (* 160 million) in fiscal year 1981 to help build them: 1) Tokyo University Medical Research Institute; 2) Kyoto University Chemistry Research Institute; 3) osaka University Microbial Disease Research Institutes; and 4) Kyushu University Medical Department. These large-scale biotechnology facilities administered by the Japanese Government will provide a place for university professors, Government researchers, and company researchers to work together.

The applied science departments of Japanese universities have been instrumental in Japan in providing training and information exchange in biotechnology. At present, university basic research in Japan is peripheral to Japanese industrial activities. If Japan intends to develop a greater basic research capacity that industry can draw on, funding for basic research will have to be increased and mechanisms to increase communication between researchers and industry will have to be implemented, Japanese companies look to other countries to make up for the weaknesses in the technology transfer from Japanese universities. Whether the Japanese will have a competitive edge in biotechnology will rest, in part, on the differences in industrial relationships in applied and basic research. If biotechnology develops such that most research moves into industry, then the present system will be adaptive. If strong basic research and effective domestic technology transfer by universities is important to the development of biotechnology and if international technology transfer proves ineffective, then the Japanese system will have to change (22).

FEDERAL REPUBLIC OF GERMANY

Biotechnology research in the Federal Republic of Germany is carried out at the federally supported, private Max Planck institutes as well as in German universities. * Critics have charged that the Max Planck institutes may be depriving the universities of talent by drawing away promising researchers and that they are "ivory towers" conducting research of little relevance to the nation's technological well-being. The Federal Ministry for Research and Technology (BMFT, Bundesministerium fur Forschung und Technologies) would like to see closer connections between the Max Planck institutes and industry. One successful outcome of its strategy is the recent cooperative agreement between the Max Planck Institute for Plant Research and Bayer Leverkusen.

The university system is in flux. Beginning in the 1960's, West German universities were subjected to a series of reforms that left the system in turmoil. According to one recent analysis (11):

> The underlying trouble is that West Germany has sought to reconcile several irreconcilables—the principle of open access to any university in the country, the doctrine that all universities are equal, the practice that the universities are run by the ministries of culture in the Lander in which they happen to be sited, and the phenomenal increase in the demand for higher education in the past twenty years.

The result is a university system in which litigation about the rights and duties of students and faculty sometimes seems to take precedence over research and teaching,

A lack of money has recently added to the administrative and legal conflicts created by the West German university reforms. Biotechnology in the universities, both because of financial cutbacks and because it is a new discipline, depends on outside sources of funding. Probably the largest single source of funding is the German Research Society (DFG, Deutsche Forschungsgemeinshaft), a nonprofit institution that serves as a German National Academy of Sciences and as a conduit for Government funding of basic research. The approval by DFG of a "special collaborative project" on bioconversion in Munich will give a boost to academic work in this area.

Other sources of funding for biotechnology in universities include the Fraunhofer-Gesellschaft and the Volkswagen Foundation, as well as private industry. Relations with industry in the past have largely taken the form of contracts or consulting agreements between individual professors and interested firms. Hoechst's arrangement with Massachusetts General Hospital (see app. H), however, has prompted BMFT to seek more systematic university/industry collaborations within West Germany. One product of BMFT's initiatives in this area is an agreement between the German chemical company BASF and the University of Heidelberg whereby the chemical company will give the university $450,000 per year for research over a 5-year period. BASF'S commitment is more modest than Hoechst's support for Massachusetts General Hospital. Nevertheless, it marks an important step in the German Government's effort to engage the private sector in building up fundamental research in biotechnology inside Germany.

Among the factors cited to explain West Germany's slow entry into commercial biotechnology is an educational system that prevents the kind of interdisciplinary cooperation that is viewed by most experts as essential to the development of this field. In particular, the traditional separation of technical faculties from their arts and sciences counterparts means that process technicians, usually located in the technical schools, rarely come into contact with colleagues holding university appointments in biochemistry or microbiology.

One of BMFT's professed aims since the adoption of its performance plan for biotechnology has been to bridge this institutional gap.** A significant contribution toward meeting this objective is made by the German Society for Chemical Engineering (DECHEMA, Deutsche Gesellschaft fur chemisches Apparatewesen). DECHEMA played a crucial role in the original formulation of BMFT's biotechnology program. Its working group on "technical biochemistry" was charged in 1971 with preparing a study on biotechnology that established the framework for the BMFT program.

* For a description of Federal applied research carried out through the Society for Biotechnological Research, GBF, see *Chapter 13: Government Funding of Basic and Applied Research.*

** BMFT's performance plan, *Leistungsplan: Biotechnologie*, is discussed in *Chapter 20: Targeting Policies in Biotechnology.*

DECHEMA continues to further interdisciplinary exchanges through a variety of means. Its expert group on biotechnology is a standing body that brings academics and industrial scientists into regular contact at seminars on biotechnology for small groups of experts. Attendance at these is by invitation, and one of their functions is to further a fruitful dialog between industry and academia. The confidential character of these meetings permits research scientists to discuss their results at prepublication stages. At the same time, industry representatives can present their own problems with the hope of interesting academic groups in their resolution. Finally, DECHEMA also organizes continuing education courses in various aspects of biotechnology, such as the use of immobilized enzymes or measurement and control of bioreactors (11).

UNITED KINGDOM

A traditional weakness in the united Kingdom has been a gap between university research and industry. This gap in the area of strategic applied research has been termed the "pre-development gap." Them is consensus that the National Enterprise Board set up to foster university/industry relationships failed. The National Enterprise Board is now called the British Technology Group (BTG), and measures have been taken to improve its efficiency. Also, new institutions for biotechnology have been developed. Furthermore, direct contacts between British universities and industry have recently increased, in part because of economic conditions.

To stimulate the transfer of university basic science research in health-related fields to industrial applications, the British Government and four industrial partners created a new company, Celltech, Ltd., in 1981. In the original agreement, Celltech received the right of first refusal* on all work in hybridoma technology conducted by the Medical Research Council. Celltech also plans to commercialize the results of basic research in rDNA technology. Currently, the British Government owns 28 percent of the company and private companies hold the other 72 percent. Celltech's initial capitalization was $20 million (<11.4 million). Celltech currently maintains a staff of 130 persons, two-thirds of whom are scientists. It is likely to increase this number to 180 persons in the near future.

In an arrangement similar to that of Celltech, the British Government, through BTG and two private concerns (Ultramar and Advent Eurofund), recently established the company Agricultural Genetics. The objective of this company is to commercialize basic research results in nonconventional plant breeding, microbial resistance factors, and biological control products originating from research in the Agricultural Research Council. Agricultural Genetics has the right of first refusal on all work in the Agricultural Research Council. Though only about $1.2 miIlion (685,000) has been invested to date, the total initial capital promised approaches $28 million (16 million).

To encourage direct links between academia and manufacturers, the Cooperative Research Grant Scheme has been initiated under the Science and Economic Research Council (SERC). SERC will support the academic side provided that the company in a particular arrangement makes substantial contributions in effort, materials, and expertise. Patent rights, subject to a small royalty, will be assigned to BTG. The number of projects in biotechnology under this scheme increased from 3 to 14 in the last 6 months of 1982.

Industrialists are also beginning to invest in university centers. At the University of Leicester, four companies have put up $1.7 million YI million) to establish a new biotechnology center. SERC is granting $316,000 (#180)000) for capital equipment.

Another program has been started by industry to help academics in British universities develop their ideas into commercial realities. At the initiative of Monsanto (U. S.) and including the Universities of oxford, Cambridge, and St. Andrew, the Imperial College in London, and the Nuffield Foundation, $17.5 million (10 million) initial capital has been raised (Monsanto contributed half). The program will include most fields of high technology as well as biotechnology.

Imperial College in London, in order to transfer its technology to industry, has launched a private company to exploit the pilot plant built at Imperial

*This is the right to choose whether to produce any good or service without having to bid competitively.

College in the 1960's. The plant is in good condition, but has been underused because of lack of funds. Imperial College has reserved 20 percent of the time of the plant for its own use in lieu of shares. Thus, there will be a continuing contact between research workers, the associated Imperial Biotechnology Center, and industrialists. Imperial Biotechnology's first major contract is with the Swiss firm Biogen S.A. to scale-up the firm's interferon production to 3,000 liters.

Engineers in British universities have traditionally done consulting for industry; biologists in British universities are now adopting the same practice. The extent of this phenomenon is not known, but all the large British companies involved in biotechnology are using the services of consultants in the universities. No general rules apply to consultancies in British universities; arrangements are left to individual institutions and to the consciences of the individuals involved. There is some concern on the part of the British Government, however, that foreign companies are making more use than domestic companies of British biotechnology experts.

Most authorities agree that the United Kingdom has an excellent basic research base with well-trained researchers. Traditionally, however, the United Kingdom has had a problem translating this expertise to industry; the next 5 years will determine how effective the new British measures to effect domestic technology transfer are (30).

SWITZERLAND

The field of molecular biology is highly developed in Swiss universities, particularly in relation to the size of the population. Centers of excellence include the universities of Basel, Geneva, and Zurich. The quality of research in these institutions is all the more remarkable in view of the fact that they are under cantonal jurisdiction and thus derive support primarily from local revenues.

The channels for transfer of knowledge from the Swiss universities to industry appear well established in the area of biotechnology. The president of the Federal Institute of Technology (ETH, Eidgenossiche Technische Hochschule), which established a department of biotechnology in 1976, for example, has endorsed the practice of direct contracts between professors in the biotechnology department and industry. Joint funding by industry and the Commission for the Encouragement of Scientific Research provides another avenue for collaboration with the private sector, one that has been actively utilized by the ETH biotechnology group.

The Swiss firm Biogen S.A. is closely linked to the Swiss university research system and has built an important share of its competitive strength on the productivity of these ties. Two members of the company's scientific board, Drs. Weissmann and Mach, have done seminal work for the company in the Universities of Zurich and Geneva, respectively. Finally, the city of Basel, as the fountainhead of Swiss research in the chemical and biological areas, provides unique opportunities for communication and collaboration between the academic and industrial sectors, a potential that the BaseI-based pharmaceutical corporations clearly recognize and are prepared to exploit (12).

FRANCE

Universities in France are generally regarded as teaching institutions and not looked to for their research capabilities. Highly regarded research in France is usually funded by the National Center for Scientific Research (CNRS, Centre National de 1a Recherche Scientifique) or the National Institute of Health and Medical Research (INSERM, Institut National de la Sante et de la Recherche Madicale). Both of these are Government research institutes (grands organisms). CNRS operates its own laboratories, which are usually associated with universities. INSERM is concerned with the applied aspects of medical research. French universities that are important in biotechnology are those at Toulouse, Strasbourg, Marseille, Line, Montepellier, ParisOrsay, Grenoble, and Nancy. A newer university, the Technical University at Complegne (modeled after the American university structure), which is an important center for enzymology and bioprocess technology, has concentrated on some of the disciplines underlying biotechnology and has developed good relations with industry.

There is divided opinion in France as to whether relationships between academics and industrialists should be encouraged. The December

1980 Pelissolo report concluded that relations formerly were poor; this situation has changed, however, and the problem now is not whether university research results should be transferred to industry, but how best to accomplish the transfer (29).

There are no formal constraints in France on relationships between academics and industrialists. The National Agency for the Funding of Research [ANVAR, L'Agence Nationale de la Valorisation de la Recherche) is an independent organization that stimulates the transfer of public research results to industry and encourages applied research in industry. ANVAR does not have any rights of first refusal on the results of public research, which includes university research, and apparently encourages direct links between universities and industry by offering general advice on suitable contract terms and on patenting problems. Large French companies such as Elf Aquitaine and Rhone Poulenc have organizations to keep in touch with and seek out public sector university research of interest and appear to have no problems developing and maintaining these links (except for occasional conflicts between the firms' desire for secrecy and the researchers' legitimate desire to publish). In addition, some companies are locating their new biotechnology facilities near universities in order to benefit from proximity (e.g., Elf Aquitaine at Toulouse and Transgene at Strasbourg). The University of Compiegne is situated in an agricultural region and works closely with the local foodstuffs industry. Also, according to ANVAR, a phenomenon similar to the involvement of American professors in U.S. venture capital firms is developing in France, although along more traditional lines—top French scientists are either acting as consultants to private firms or leaving the public sector for industry (this kind of transfer is generalIy much more common in France than in, for example, the United Kingdom (29).

Despite the absence of formal constraints on relationships between academics and industrialists, there remains a problem in France in the exploitation of the results of public sector research by industry. Except for large companies, industry has an insufficient number of qualified personnel to seek out opportunities, and French research scientists as a whole have not been very active in the pursuit of commercial opportunities (29).

The French Government has recently taken steps to encourage cooperation between the grands organisms and French industry. The institutes participated through the Committee for the Organization of Strategic Industries (CODIS, Comite d'Orientation des Industries Stratdgiques)* in the establishment of the French pharmaceutical firm, Immunotech. More generally, in the recent law reforming these institutes, there are provisions for them to form profitable liaisons with industry (up until now they have been Iimited to contract research). This change is very recent, so it is impossible to judge its practical effect. But CNRS, in a change of statutes published on November 25, 1982, has for the first time appointed a scientific director of "Funding and Application of Research. "

Fields related to biotechnology have not attracted large numbers of French researchers in the past. Government policies and funding changes have been promulgated to change and to foster university/industry relationships. It is too early to determine the effectiveness of these policies.

*CODIS mobilizes State funds from multiple sources to produce packages for project development in strategic industries,

Findings

The United States has the most effective and dynamic university/industry technology transfer process of the six countries being examined in this assessment. The process in the United States is facilitated by the openness of the university system and the freedom of faculty to pursue research. It is also facilitated by the many mechanisms by which the process can occur. These include dissemination of publications, professional meetings, consulting arrangements, contract research, cooperative research agreements, and institutes within universities funded by industry. All these mechanisms are being exploited in biotechnology. U.S. universities and industry are benefiting from the present arrangements, and diffusion of knowledge is occurring.

University and industry representatives in the United States agree that Federal support of basic research is essential. Even if industrial support of university R&D were to rise to 15 percent of universities' R&D budget, it could never replace Federal funding. Furthermore, since the goals and philosophy of industry are different from those of universities, the focus of research in industry is different from that of research in universities. Of necessity, industry is mission oriented; the emphasis in industry is on applied research leading to products. By contrast, the purpose of university basic research is to extend knowledge itself.

Universities in the United States are formulating and implementing policies that are more consistent across disciplines and more specific with regard to consulting, conflict of interest, and disclosure than policies formulated in the past. There have been some cases of potential conflict of interests with researchers who have consulting or contract arrangements with firms in which they hold equity. University administrators, faculty, and students appear to be taking measures to reduce the potential for conflicts of interest and ensure quality research and education.

Although funding of large agreements between U.S. universities and industry in biotechnology has occurred, the consensus is that, after the initial excitement has dissipated and companies have developed in-house capabilities, most of the university/industry arrangements in biotechnology will be consulting and contract research as in other fields with close university/industry ties.

Universities are looking for financial support, but the promise of patent royalties from biotechnology may be premature. Especially if biotechnology becomes a rapidly moving process field where research is carried out primarily in industry, research in biotechnology will have to move off campus and royalty income to universities may not be significant.

Biotechnology has spawned a new kind of arrangement in university/industry relationships: for-profit companies established with nonprofit buffers to funnel contract research money and royalty payments between the university and the company. One arrangement (Neogen) takes advantage of new U.S. tax laws that permit funding of R&D through limited partnerships. The other (Engenics) is built on the support of six major corporations that are funding the research and have invested in the company. It is too early to predict whether these approaches will be viable.

Biotechnology is being transferred between industry and universities in the United States; most of the arrangements are working well. Some individuals have noted potential problems and administrative bottlenecks; these should lessen as individuals on both sides gain more experience and policies are formulated to standardize administrative procedures within universities. Some individuals believe that problems may arise when sales revenues are generated as a result of some of the limited partnership agreements.

The early history of the U.S. microelectronics industry can serve as a comparison for the commercialization of biotechnology. The U.S. semiconductor industry was fueled by and developed in a milieu of DOD support for basic research and training at universities, DOD procurement of the industry's products, and DOD's need for increasingly more sophisticated products from that industry. In the history of the U.S. semiconductor industry, relationships between universities and industry were very close. Many professors had equity in companies located close to campuses, and consulting was extensive, It appears that education in this field did not suffer; in fact, it was probably enhanced, and students gained an understanding of industrial career paths. The current leveling of Federal support for biology combined with the lack of consensus that biotechnology is a strategic industry (as was microelectronics in the instance of the space race) leads to the perception of more "potential conflicts" in industry/university relations in biotechnology than actually exist.

In countries other than the United States, there are varying degrees of cooperation between universities and industry. In Japan, the ties between university applied science departments and industry have always been close. Most people acknowledge that Japan already leads the world in bioprocess engineering research, and the close relationships that already exist between Japanese industry and university applied research departments benefit the commercialization of biotechnology in that country. Currently, the Japanese Government is implementing new policies to encourage closer ties between university basic researchers and industry.

In the Federal Republic of Germany, BMFT is encouraging domestic university/industry contacts, especially in light of Hoescht's agreement with Massachusetts General Hospital. After that agreement was announced, some West Germans were concerned because they felt that research money was being fumeled into American universities instead of into German universities.

The United Kingdom has an excellent basic research base. University ties with industry have been few in the past, but are now being encouraged by the Government. The British Government helped to establish two firms, Celltech and Agricultural Genetics, to capitalize on British university research in animal and plant molecular biology .

In Switzerland, the field of molecular biology is highly developed, and patterns of interaction between individuals in universities and industry are well established. ETH established a department of biotechnology in 1976 and endorses the practice of direct contracts between professors in the biotechnology department and industry.

In France, an ambitious program is underway to tie universities and industry closer together. One problem in France is that the country lacks a cadre of experts in molecular biology, because this field has not been considered an important one.

Issue

ISSUE 1: Should Congress set guidelines for university policies on industry-sponsored research?

At the request of Representative Albert Gore, the American Association of Universities (AAU) reviewed ethical dilemmas posed in the United States by increases in industrial support of university research. A select committee drawn from the AAU membership suggested that the AAU could serve as a clearinghouse and monitor of activities at major universities with regard to the formulation of university policies on industrially sponsored research. Because one policy formulated by the AAU or Congress would have to be broad enough to cover all circumstances, it might be too general to be useful. Furthermore, as the committee noted, informed decisionmakers within universities are formulating policies that fit each university's needs.

In addition, in a report of joint hearings on universityfindustry relationships in biotechnology, the Subcommittee on Investigations and Oversight and the Subcommittee on Science, Research, and Technology of the Committee on Science and Technology of the U.S. House of Representatives made the following recommendations: 1) universities should prepare guidelines for industrially sponsored research that require open disclosure of all faculty consulting and contractual agreements; and 2) full-time faculty should be discouraged from holding equity or directing such firms. The subcommittees further recommended that there be continued review by universities, industry, and the Federal Government of the ***benefits*** and problems resulting from large-scale corporate support for and involvement in university research programs in biotechnology.

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