

Selected Aspects of U.S. University/ Industry Relationships in Biotechnology

University/industry relationships in biotechnology were the focus of the discussion in *Chapter 17: University/Industry Relationships*. Material on selected university/industry agreements is presented below. Also described are guidelines for university/industry research adopted by the National Association of Land Grant Colleges and the 1982 Pajaro Dunes Conference, selected statements on patent rights and commingling of research funds, and university policies on patents, consulting, and sponsored research in the United States.

Selected university/industry agreements in biotechnology

Selected university/industry arrangements in biotechnology are discussed below. The arrangements were selected for discussion because they represent different approaches to university/industry relationships, because they are relatively large agreements, and because some of them have raised issues central to university/industry agreements. The agreement between the Whitehead Institute and the Massachusetts Institute of Technology (MIT) is not strictly a university/industry agreement, but has been included because it raises issues in university/industry relationships and because it is a product of industrial interest in biotechnology research.

RESEARCH PARTNERSHIPS

Monsanto/Washington University. -Washington University and Monsanto (U. S.) have a 5-year renewable contract totaling \$23.5 million. Under the contract, individual research projects in biotechnology will be carried out by cooperative arrangements involving Washington University faculty and Monsanto scientists. About 30 percent of the research will be fundamental research (terminology of the agreement) and 70 percent will be special research directly applicable to human disease. The contract between Washington University and Monsanto establishes an 8-person advisory committee made up of 4 members from each institution. This committee will solicit research proposals from the faculty of Washington University and from researchers at Monsanto, review and approve the proposals on the basis of individual merit, distribute appropriate funding, and act as a liaison between the university and Monsanto.

Monsanto's participation in the program will begin with a \$3 million grant the first year (1982) and rise annually to accommodate expansion in the number and scope of research projects involved. Washington University faculty members will have liberty to publish results of any research done under the Monsanto funding. Monsanto will exercise the right of prior review of draft materials, because they may contain potentially patentable technical developments. If they contain patentable developments, Monsanto can request a short delay of submission for publication or other public disclosure in order to begin the patent process. Monsanto will pay for and carry out the entire patent application process. If Monsanto does not elect to license a patent, the university is free to license the patent to others.

Washington University will retain patent rights, while Monsanto will have exclusive licensing rights. Royalties will go to Washington University for support of its education and research programs-not to individual researchers. The portion of royalty normally going to the individual will instead be channeled to his/her laboratory to support more research.

During the third year of the 5-year agreement, the entire program will be reviewed by a panel of distinguished scientists who are independent of both Monsanto and Washington University.

The schedule for funding in millions of dollars is as follows (11,13):

The schedule for funding in millions of dollars is as follows (11,13):

Contract year	Exploratory projects	Specialty projects	Contract year total budget
1982 -83	\$1.5	\$1.5	\$3.0
1983 -84	1.6	2.2	3.8
1984 -85	1.7	3.0	4.7
1985 -86	1.8	3.8	5.6
1986 -87	1.9	4.5	6.4
Total	\$8.5	\$15.0	\$23.5

The process by which the agreement between Washington University and Monsanto came about had some major strengths. First, individuals from Monsanto and Washington University met continually over a period of 2½ years to discuss the project. Second, members of the university faculty and administrative staff and representatives of the company held a 3day retreat to discuss the interactions and what form they should take. Furthermore, the Washington University/Monsanto agreement is unlike other agreements in that it is intended to be a cooperative research agree-

ment with industrial and university scientists working together on research projects. In other agreements, the explicit purpose has been to allow industry to gain a window on the technology and educate its personnel.

Hoechst/Massachusetts General Hospital—A \$70 million agreement between Massachusetts General Hospital, a teaching hospital associated with Harvard University, and the West German company Hoechst will create a department of molecular biology at Mass General and will provide support for the department for 10 years. The department of molecular biology will be headed by Dr. Howard Goodman and will eventually have a staff of about 100 persons. Hoechst will fund basic research in eukaryotic cell gene regulation, somatic cell genetics, microbial genetics, virology, immunology, and plant molecular biology.

The department faculty will be regular members of the staff of Mass General and will be nominated for membership on the faculty of the Harvard Medical School. Faculty duties will primarily consist of research for the department of molecular biology. Faculty may “also devote a reasonable amount of time to faculty duties other than research and to consulting for non-profit-making entities so long as such activities do not interfere materially with their research activities under the agreement.”

Hoescht has the right to send up to 4 individuals to work and be trained in the department at any one time and to send up to 40 individuals over the life of the contract. The individuals that Hoechst sends, however, must have qualifications acceptable to the department.

The contract between Hoechst and Mass General states that the scientists in the department of molecular biology are free to collaborate with others but that “research collaborations funded in part by the Company and in part by others shall take into account the interest of the Company in obtaining exclusive, worldwide licenses.” If Hoechst cannot obtain an exclusive license from such collaboration, it must be assured of a nonexclusive license.

All faculty in the department have the right to publish but must submit early drafts of all manuscripts from Hoechst-sponsored research not less than 30 days prior to the submission of the manuscript for publication.

Mass General will hold any patents that may arise out of the Hoechst-sponsored research. The hospital will grant Hoechst an exclusive worldwide license for the life of the patent. Hoechst will pay the hospital royalties at rates that give “due consideration” to the fact that Hoechst paid for the research (2,10).

The exclusive funding may preclude department scientists from seeking grants from the U.S. National Institutes of Health (NIH), thereby taking them out of

the peer review process. The department will report to a scientific advisory committee of two members from Mass General, two from Hoechst, and two from elsewhere. The committee’s review, however, may not be the equivalent of the critical peer review of proposals at NIH. The department will be physically separate from Mass General, and all equipment and physical plant will be paid for by Hoechst. Department scientists will generally be free to collaborate with others but will have to obtain written permission from Hoescht. Dr. Goodman hopes to collaborate with Dr. Philip Leder who has a 5-year \$6 million research agreement with DuPont, Whether Hoechst will grant this request will probably depend on the nature of the collaboration.

Whitehead Institute/Massachusetts Institute of Technology—Whitehead Institute, a biomedical research institute administratively separate from MIT, has been provided for by Edwin C. Whitehead, the President of Technicon Corporation. Whitehead has bequeathed about \$20 million to build the structure, \$5 million annually to operate it through the year 2003, and a gift of \$100 million upon his death. Whitehead has also given \$7.5 million to MIT plus support moneys estimated to be worth about \$1 million a year for faculty, graduate students, and research assistants in MIT’s biology department.

The Whitehead Institute is headed by a 14-member board of directors that includes 3 MIT directors, 3 of the Whitehead children, and David Baltimore, the director of Whitehead Institute who is serving a renewable 5-year term. Whitehead Institute faculty will have joint appointments with MIT but will be paid entirely from Whitehead Institute funds. Faculty appointments will be proposed by Whitehead Institute according to the research needs of the institute and in consultation with the appropriate MIT department. Appointees will follow the rules and regulations of MIT with regard to teaching, consulting, tenure, benefits, salaries, etc. It is expected that 10 to 15 appointments will be made during the first 7 or 8 years, Graduate students will also be supported.

Whitehead Institute will retain the patent rights on any inventions arising from the research. After deduction for expenses, the royalty will be shared according to the following formula: one-half to the inventor and one-half shared by Whitehead Institute and MIT. The term of the agreement is 10 years, with a 5-year renewal and 2 years written notice necessary for termination. If the agreement should be terminated, faculty will be given the choice of joining the MIT or Whitehead Institute faculty.

Prior to the signing of the agreement, the agreement was extensively discussed by MIT faculty and administrators. Some were concerned that an imbalance in

the MIT biology department might result from the addition of 15 new faculty members in molecular biology; other important specialties would have less representation. Since the members of the faculty of Whitehead Institute, though approved by MIT, would be chosen for their research contributions to Whitehead Institute rather than to MIT's educational or research needs, there was also concern over the possibility that the loyalty of the Whitehead Institute faculty would be divided. Other concerns centered on conflict of interests. Some faculty thought that the findings of Whitehead Institute could turn up in the investment portfolio of Whitehead Associates, Edwin H. Whitehead's venture capital firm. Furthermore, since David Baltimore has equity in the Collaborative Research Company, and several other proposed faculty of Whitehead Institute consult for the company, there were concerns that the link between Collaborative and Whitehead Associates might be too close. After extensive discussions, the MIT faculty decided that the positive aspects of the arrangement outweighed these concerns and voted overwhelmingly to approve the agreement. MIT's Board of Trustees would not have approved the arrangement without faculty support. Furthermore, a special committee will be appointed to monitor the arrangement so that any misunderstandings can be avoided (3).

PRIVATE CORPORATIONS

Engenics/Center for Biotechnology Research and Stanford University.-The for-profit company Engenics was established in September 1981, along with the nonprofit Center for Biotechnology Research (CBR). The purpose of CBR is to support basic and applied biotechnology research at universities, disseminate the results of such research to the public, and facilitate the conversion of knowledge into products and processes. The purpose of Engenics is to carry out research and process development and to establish new businesses. Although the two organizations are separate, they have the same six corporate sponsors and will work in close cooperation.

CBR is receiving \$2.5 million from its six corporate sponsors over a period of 4 years. The six sponsors of CBR are Elf Technologies, Inc. (a U.S. venture capital subsidiary of Elf Aquitaine), General Foods, Koppers Co. Inc., Bendix Corp., Mead Corp., and McLaren Power and Paper Co. (a subsidiary of Noranda Mines). CBR holds about 30-percent of the equity in Engenics, equity that was issued to Engenics in exchange for options to licenses under university patents. The same six corporations that sponsored CBR paid \$7.5 million for a total of about 30 percent of the equity in Engenics.

The remaining 30 percent of the equity in Engenics is shared by the line officers and the consultants Charming Robertson (Chairman of the Chemical Engineering Department at Stanford), Abdul Matin (Professor at Stanford's Medical School), and Harvey W. Blanch (Professor of Chemical Engineering at the University of California, Berkeley).

CBR can use all capital appreciation or dividends from the equity in Engenics only for the support of university research. Any patents resulting from CBR-sponsored research will be held by the university at which the work was performed, with CBR, Engenics, and the six corporate sponsors receiving royalty-bearing licenses. Negotiations at the time of the patent will determine the terms of the license. Investigators performing CBR-sponsored research will retain the right to publish their findings.

CBR is currently funding three university research contracts. One is a 4-year \$970,000 contract with Drs. Robertson and Matin, both of Stanford, as principal coinvestigators. The second contract is a 5-year \$783,000 contract with Dr. Blanch, of the University of California, Berkeley, as the principal investigator. This contract is funded by both CBR and Engenics, because University of California policy stipulates that licensing agreements cannot be made with nonprofit organizations. The third contract is with Anthony Sinsky at MIT. No data on the amount of this contract are available. Dr. Sinsky is on the Scientific Advisory Board of Engenics (68).

Neogen/Michigan State University Foundation and Michigan State University.-Neogen was founded in July of 1981 by the Michigan State University (MSU) Foundation, an independent nonprofit fundraiser and disbursing of donations and royalty income to MSU. Neogen, which was organized to seek venture capital for limited partnerships to develop and market innovations arising out of research at MSU, was formed for several reasons: MSU wished to retain faculty members who are getting lucrative offers from other small companies; MSU would like to allow faculty to develop their entrepreneurial talents and remain at the university; and a company such as Neogen can help diversify Michigan's economy. The company was organized with full knowledge of the board of trustees, the administration, and the faculty of MSU.

Neogen limited partnership purchases are being managed by an investment firm in Detroit. The MSU Foundation, which purchased \$100,000 of stock when the company was founded, will soon purchase another \$130,000 of stock, and Doan Resources is buying \$250,000 in stock.

One project (a parasite diagnosis project) is ready to begin (funded at \$455,000) and two projects are awaiting funding. Neogen will be able to buy title to any resulting patents from MSU for the parasite diagnosis project. The money will be paid through the MSU Foundation to Neogen.

Patents will usually be applied for by MSU. The patents will be assigned by MSU to the MSU Foundation for subsequent sale to Neogen in exchange for stock. Inventors will receive a 15-percent royalty or can exchange this for a 1-to 2-percent stock option in Neogen.

Because Neogen is tied to the MSU Foundation, MSU receives moneys from successful commercialization of products or processes and the individuals are rewarded commensurate with their efforts. The basic research takes place on the campus of MSU, but commercialization will be moved off-campus to a nearby research park in order to avoid conflicts of interest.

The MSU faculty and administration were aware of and/or participated in the founding of the company, and there is a scientific advisory board that reviews the projects, thus preserving the principle of peer view.

Guidelines for industrial sponsorship of university research in biotechnology

NATIONAL ASSOCIATION OF STATE UNIVERSITY AND LAND GRANT COLLEGES, DIVISION OF AGRICULTURE

A document titled "Genetic Engineering Policy for the State Agricultural Experiment Stations" was adopted by the Experiment Station Committee on Policy (ESCOP) in November 1981 at a meeting held in conjunction with the fall meeting of the National Association of State University and Land Grant Colleges (NASULGC). ESCOP, headed by Dean Clarke of Texas, was brought together after Clarke and several other members observed that several State Agricultural Experiment Stations (SAES) were being simultaneously approached by industry to do genetic research. Since there were no policy guidelines for the new field of biotechnology, SAES often found themselves in a weak position during contract negotiations. Thus, ESCOP was formed to draw up guidelines.

Because the field of "genetic engineering" is changing rapidly, the November 1981 ESCOP policy document is regarded by ESCOP as an interim document subject to annual revision, if necessary. In addition, Clarke is collecting copies of legal documents from SAES institutions and will develop an aggregate summary of appropriate components of general agreements to be made available to all members of

NASULGC's Division of Agriculture. Work is now underway to draw up guidelines for NASULGC'S Division of Agriculture. The committee that is drawing up these guidelines is headed by Dean F. A. Wood of the University of Florida.

The ESCOP document of November 1981 is summarized below because it addresses issues that are common to most industry/university relationships in biotechnology. As noted in that document, the SAES have five general concerns (5):

1. As publicly supported institutions, the SAES will need to assure that industrial relationships generate an end result in the interest of the general public. This end result should reward the industrial investor but avoid placing such an investor in an unwarranted position of financial advantage through privileged use of information or technology partly derived from research using public funds; nor should a curtailment of new information to the public occur.
2. The SAES are greatly concerned about the curtailment of communication on early research results and about the constraints on sharing of germplasm emerging due to concerns . . . for protecting potentially patentable research results. . . .
3. There is general concern in the academic community about the drain of scientific manpower from the universities to industry. . . .
4. There is concern that individual scientists may place themselves in the positions of compromise or conflict of interest as they establish personal relationships with industry as contractors, consultants or institutional officers.
5. There is concern on the Part of both scientists and the SAES that through industrial sponsorship of research, there may be introduced an undesirable level of direction of effort by industry.

The guidelines set forth in the ESCOP document are subsumed under the three major issue areas outlined below (5):

A. Institutional relationships

1) *Maintain SAES management control of research:*

Consensus: SAES should retain the ability to manage research programs, and control the direction of new investigations, regardless of the source of support, including situations in which one or several firms may sponsor research at several institutions.

2) *Strong basic research and graduate education capability:*

Consensus: SAES should maintain and expand the basic research capability in genetic engineering and related areas within the domain of publicly supported institutions.

3) *Faculty-industry relations@:*

Consensus: Scientists should maintain close communication with institutional administrators in development of relationships and commitments with the commercial sector. Institutional guidelines

should be developed which assist the scientists in avoiding institutional or personal conflicts of interest.

B. Technical relationships

4) Publication and communication:

Consensus: The ability to publish and exchange information is essential and must be secured in agreements. In some instances, publications or information exchange may need to be temporarily delayed to allow time for an institution or sponsor to assure adequate patent protection. The final decision to defer or modify a publication should reside with the public institution.

5) Trade secrets and confidential information:

Consensus: Protection of "trade secrets" or "confidential information" for more than a very limited period should be avoided by public institutions. Advance review by a private sponsor, to avoid premature release of information, may be advisable but should not become a mechanism to "shelve" useful information or unpatentable technology.

6) Patent rights and premature disclosure:

Consensus: SAES should retain the right to participate in the decisions related to the disposition of intellectual and real property and patent rights resulting from research. Retained ownership of patents by the SAES is preferred. In any agreement, the SAES should retain the right to use discoveries and inventions from SAES research to extend and enhance public research and education. The need of private sponsors to obtain a return on investment must be recognized, and agreements may provide for special licenses for patents originating from sponsored research.

7) Biosafety of recombinant DNA:

Consensus: SAES must retain responsibility for review and decisions in the release or distribution of laboratory research products, although some research may be supported by outside sponsors.

C. Fiscal and management relationships

8) Grants and income earnings:

Consensus: Extending knowledge and developing new technology while serving the public interest should be the prime motivations in agreements between SAES and the private sector. Royalty income from discoveries originating under such agreements should be recognized as a secondary consideration.

9) Licensing responsibilities and performance expectations:

Consensus: SAES should assure that "due diligence" clauses are included in contracts to assure that new technology is not shelved and the public interest is served while private investment in commercialization is respected. Assignments of rights or licensing of patents for commercial use should be considered separately from contractual definition of research to be conducted. Initial or developmental processes and pervasive technology ultimately leading to improved biological materials

generally should not be assigned for sole use by a sponsoring firm.

10) Tax code implications:

Consensus: When sponsored research is motivated by certain interpretations of Tax Code Section 1235, exclusive licensing or co-ownership of patent rights is a preferred alternative for the institution, since the institution maintains a vested interest and some ownership of patent rights involving the scientist, the institution, and the firm may require unique documentation. Careful attention to these rights and relinquishments is suggested.

PAJARO DUNES CONFERENCE, MARCH 1982

The March 1982 Pajaro Dunes Conference on **university/industry relationships in biotechnology**, which was financed by the Henry J. Kaiser Family Foundation, was organized principally by Donald Kennedy, the President of Stanford, and included the Presidents of Harvard, Derek Bok; California Institute of Technology, Paul Gray; and the University of California, David Saxon. Also invited were an administrator and two faculty from each university. Leading industrialists were also invited, among them representatives from Beckman Instruments, Inc.; Syntex Corp.; Cetus Corp.; Cabot Corp.; Applied Biosystems, Inc.; Damon Corp.; Gillette Corp.; Eli Lilly and Co.; E. I. du Pont de Nemours; and Genentech Corp. A statement drafting guidelines and principles emerged from the conference, although Kennedy and others stressed its role as a draft of the process of policy formation rather than a statement of policy.

The premise of the Pajaro Dunes Conference was that collaboration between universities and industry will benefit all parties, including the general public, if the university's ideals are not distorted. The general consensus was as follows (9):

... research agreements and other arrangements with industry (must) be so constructed as not to promote a secrecy that will harm the progress of science; impair the educational experience of students and postdoctoral fellows; diminish the role of the university as a credible and impartial resource; interfere with the choice by faculty members of the scientific questions they pursue, or divert the energies of faculty members and the resources of the university from primary educational and research missions.

The consensus of the Pajaro Dunes Conference with respect to specific issues is discussed further below.

Disclosure of Research Agreements—On this topic, the following views were expressed (9):

In order to satisfy the faculty and general public that the role of the university is being maintained, contracts should be made public. This could involve publication of relevant provisions of research contracts with industry or, alternatively, examination by a facul-

ty committee or some other competent body of all research contracts to assure that terms are consistent with university values.*

Patents and Licenses.—The consensus on patents and licenses was as follows (9):

The traditions of open research and prompt transmission of research results should be maintained. However, it is appropriate for the institution to file for patent coverage; actions which might require brief delays in publication or other public disclosure. Receipt of proprietary information may occasionally be desirable to facilitate research. These situations must be handled on a case-by-case basis so as not to violate the educational process or the traditions of openness.

There was a disagreement on the issue of whether exclusive rights should be given, although the document does appear to favor the granting of exclusive licenses (9):

Some people fear that allowing a single firm the sole right to develop a patent will necessarily remove competition, slow the development of the patent, or even prevent development altogether. This fear is exaggerated. . . . Thus, universities should be able to negotiate exclusive licenses provided that exclusivity seems important to allow prompt, vigorous development of the patent to occur.

In license negotiations, the consensus was that the university should insist on a requirement of due diligence on the part of the licensee in developing and using the patent.

The situation is more difficult when a sponsor requests the right to exclusive licenses on all discoveries made as a result of the research funded by the company (9):

Some of us believe that such exclusive rights are an appropriate *quid pro quo* for the funds provided for research. Others believe that the university should be willing to agree to provide instead nonexclusive royalty-free licenses to the sponsor, but should not give up its right to examine the appropriateness of exclusivity for each invention on a case-by-case basis.

Conflict of Interest—Discussion focused on two aspects of the problem. The first was the propriety of a university's taking an equity position in a company in which one of its faculty is a major stockholder or officer. Most were against such investments (9):

It is not advisable for universities to make such investments unless . . . there are sufficient safeguards to avoid adverse effects on the morale of the institution . . .

The second and really complex issue, conflict of interests, was avoided by participants entirely. Issues related to university/industry relationships are not new, and the Pajaro Dunes Conference participants were all experienced with and knowledgeable about

these relationships. Rather than producing some definite guidelines regarding the structuring of such relationships, however, Pajaro Dunes Conference participants provided only general principles underlying general university policies.

Selected statements on patent rights and commingling of research funds

Since one of the purposes of the 1980 U.S. patent law (Public Law 96-517) is to foster cooperative research arrangements among government, universities, and industry, one question that immediately arises is how the establishment of patent rights is affected by potential commingling of funds. Circular A-124 issued by the U.S. Office of Management and Budget (OMB) sets out some guidance on this (4):

Notwithstanding the right of research organizations to accept supplemental funding from other sources for the purpose of expediting or more comprehensively accomplishing the research objectives of the government sponsored project, it is clear that the Act would remain applicable to any invention "conceived or first actually reduced to practice in performance" of the project. Separate accounting for the two funds used to support the project in this case is not a determining factor.

To the extent that a non-government sponsor establishes a project which, although closely related, falls outside the planned and committed activities of a government funded project and does not diminish or distract from the performance of such activities, inventions made in performance of the non-government sponsored project would not be subject to the conditions of the Act. An example of such related but separate projects would be a government sponsored project having research objectives to expand scientific understanding in a field with a closely related industry sponsored project having as its objectives the application of such new knowledge to develop usable new technology. The time relationship in conducting the two projects and the use of new fundamental knowledge from one in the performance of the other are not important determinants, since most inventions rest on a knowledge base built up by numerous independent research efforts extending over many years. Should such an invention be claimed by the performing organization to be the product of non-government sponsored research and be challenged by the sponsoring agency as being reportable to the government as a "subject invention," the challenge is appealable . . .

An invention which is made outside of the research activities of a government funded project but which in its making otherwise benefits from such project without adding to its cost is not viewed as a "subject invention," since it cannot be shown to have been "con-

*Harvard has elected to keep its contracts confidential and Stanford is following an informal policy of full disclosure (1).

ceived or first actually reduced to practice" in performance of the project. An obvious example of this is a situation where an instrument purchased with government funds is later used, without interference with or cost to the government funded project, in making an invention all expenses of which involve only non-government funds.

Members of the Advisory Committee to the Director of NIH asked Mr. Dietrich of OMB for some guidance on problems posed by commingled funds. Dietrich noted that application of OMB and the Department of Health and Human Services cost-accounting and auditing principles can resolve some of the issues. He stated that one good way to distinguish between commingled funds is to determine whether a project was supported through direct costs (in which case the patent regulations would likely apply) or by indirect costs (in which case the regulations would likely not apply). He then provided an assessment of some specific cases (12).

- In a situation where privately supported work is done in a building previously constructed with Government funds, the Government obtains no patent rights in inventions developed through those private funds.
- Similarly, in a situation where privately supported work is done using equipment previously purchased with Government funds, the Government obtains no patent rights in inventions developed through those private funds; however, it does if the equipment is currently operated under Government support.
- If a single individual spends one-half time on a project supported with Government funds and one-half time on a privately supported project, the Government obtains patent rights only if the privately supported project is directly dependent on ideas or materials generated in the publicly supported project.
- Similarly, if a scientist spends 10 years on a publicly supported project and then 10 years on a privately supported project, the Government obtains no patent rights to the invention developed under private support unless it is clear the idea was conceived with public funds.
- In the case of a team working on a single project with both public and private support, the Government would obtain patent rights.
- For inventions resulting from normal intellectual intercourse in which two individuals, one privately and one publicly supported, exchange information, the Government would obtain no patent rights unless there is intent to commit fraud (e.g., the scientist on public funds provides information to the scientist in the private sector to increase the marketability of an invention and then shares in the profits).

Selected university policies

UNIVERSITY PATENT POLICIES

To analyze the patent policies of universities in the United States, OTA reviewed documents on the patent policies of the following 32 universities:

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| 1. Alabama/Birmingham, University of | 16. Miami, University of |
| 2. Arizona, University of | 17. Michigan, University of |
| 3. Boston University | 18. Minnesota, University of |
| 4. California Institute of Technology | 19. Northwestern University |
| 5. California, University of | 20. Ohio State University |
| 6. Case Western Reserve University | 21. Pennsylvania, University of |
| 7. Colorado, University of | 22. Purdue University |
| 8. Connecticut, University of | 23. Rochester, University of |
| 9. Cornell University | 24. Rockefeller University |
| 10. Georgia, University of | 25. Rutgers University |
| 11. Indiana University | 26. Southern California, University of |
| 12. Iowa, University of | 27. Stanford University |
| 13. Johns Hopkins University | 28. Vanderbilt University |
| 14. Maryland, University of | 29. Virginia, University of |
| 15. Massachusetts Institute of Technology | 30. Washington University |
| | 31. Washington, University of |
| | 32. Wisconsin, U. of |

In general, the patent policies of the 32 universities OTA sampled define the obligations and rights of the university and the university researchers who produce inventions that have commercial potential. They also recognize the rights of outside sponsors. Typically, university patent policy documents state that the relationships defined between the university and inventor are subject to the obligations that the inventor has made in return for outside support from either private or government sources. In some cases, an industrial sponsor may have retained the right to the invention (because most universities grant only nonexclusive licenses if they own the patent, subject to a short exclusive licensing period to help commercialize the invention) and also may have defined how royalties are to be shared. Thus, for example, the Stanford patent policy document notes:

In practice, the great majority of inventions arise from externally funded research covered by agreements containing patent provisions. Some agreements permit the University to retain title and grant license rights to the sponsor; some provide for the reverse or defer allocation of rights.

The crucial issue, therefore, seems *not* to be the patent agreements between universities and their researchers (i.e., what is covered in the documents OTA reviewed), but the terms of contracts from external sponsors to individual researchers.

Most university patent policies cover anybody working with university facilities, although individual universities vary in the degree of specific identification of personnel types. Most of them also cover students, although MIT excepts students from the provision and Johns Hopkins invites students to "take advantage of the mechanisms set forth herein." University employees who produce inventions on their own time and without substantial use of university resources own their inventions, but all 32 universities invite them to use the university's commercialization mechanism,

All 32 universities require researchers to report inventions with potential commercialization promptly so that the university can assess their potential and file for a patent. Some universities (e.g., University of Pennsylvania) also require delay in publication of the findings to allow for filing of a patent. Since publications prior to patenting can make an invention nonpatentable, the practice of requiring a delay in publication is probably common even at universities whose documents do not explicitly mention it.

University administrative mechanisms have been set up to evaluate inventions, to settle disputes, and to attempt commercialization. Many universities use the services of commercialization firms such as Research Corporation of New York and Battelle Development Laboratories. Other universities have their own commercialization ventures (e.g., the Wisconsin Alumni Research Fund at the University of Wisconsin).

The sharing of royalties varies with each university. Almost all the universities use the U.S. Government's stipulation that no more than 15 percent of gross royalty income is to go to the inventor, but they usually set this as the minimum share (i.e., many give the inventor a bigger share if the stipulations of outside sources do not apply). Private universities have a greater propensity than public universities to give ownership of the invention to the inventor, while the university is given a license. This may not be a substantive difference, as the other provisions in university policies (commercialization, royalty sharing, etc.) do

not seem to be related to whether the inventor rather than the university owns the invention. On the question of ownership, universities having the right to take ownership have the option to do so. Conversely, the inventor can petition to have the invention assigned to him/her if the university does not diligently pursue its commercial applications.

Royalties, after deduction for expenses and the inventor's share, may be assigned to a number of university activities. Some universities place the remaining royalty income in their general operating funds; often, however, royalties are assigned to "research" or to "research and training" either through stipulation or through a separate fund set up for that purpose (e.g., Cal Tech's California Institute Research Foundation). Some universities also allocate a share to the inventor's department, division, and/or area of activity (e.g., the University of Colorado allocates a 25-percent share each to the discoverer, to an account for support of the discoverer's research, to the discoverer's department or primary administrative unit, and to the university).

The crucial issue is the commercialization stipulations that are attached to funds provided by outside sponsors, public and private. The patent policies discussed here are subject to these external conditions, and, as the Stanford document states, external sponsorship of university research is more the rule than the exception.

UNIVERSITY POLICIES ON CONSULTING

The policies on consulting of five major U.S. universities (Harvard, MIT, Johns Hopkins, Stanford, and the University of California) are summarized in table H-1 below.

UNIVERSITY POLICIES ON SPONSORED RESEARCH

The policies on sponsored research of three major U.S. universities (Harvard, MIT, and Johns Hopkins) are summarized in table H-2 below.

Table H-1.—Summary of Selected University Policies on Consulting

Harvard University	Harvard Medical School	Massachusetts Institute of Technology	Johns Hopkins University	Johns Hopkins Medical School	Stanford	University of California (all campuses)
Conflict of <i>interest</i>:						
<ul style="list-style-type: none"> • Time for outside involvement regulated • Primary commitment to the university required • Disclosure of potential conflict required 	<ul style="list-style-type: none"> • Time for outside involvement regulated • Primary commitment to the university required • Disclosure of potential conflict required 	<ul style="list-style-type: none"> • Outside activities may not conflict with their obligations to the institute • For all those in decisionmaking roles required annual acknowledgment in writing of the policy • Required disclosure of all outside activities, including financial interests, to institute officers • Requirement: To seek advice of department head if a potential conflict exists 	<ul style="list-style-type: none"> • No formal policy 	<ul style="list-style-type: none"> • Time for outside involvement regulated • Primary commitment to the university required • Financial gain regulated 	<ul style="list-style-type: none"> • Overriding professional allegiance to the university • Disclosure of potential conflict situations urged • Prewritten clause to be inserted into all agreements stating that university conditions of employment prevail before all other agreements 	<ul style="list-style-type: none"> • Primary responsibilities to university stressed • Outlines specific examples of conflict-of-interest situations
Time regulation:						
<ul style="list-style-type: none"> • 200/0 	<ul style="list-style-type: none"> • 2x salary 	<ul style="list-style-type: none"> • 1 day/week • No dollar amount 	<ul style="list-style-type: none"> • 200/0 	<ul style="list-style-type: none"> • 200/0 	<ul style="list-style-type: none"> • 13 days per academic quarter (13-week quarter) 	<ul style="list-style-type: none"> • No limit on consulting days unless time conflicts with primary responsibility to the university
Disclosures:						
<ul style="list-style-type: none"> • Not required, unless potential conflict exists 	<ul style="list-style-type: none"> • Required annually—reported to the dean's office 	<ul style="list-style-type: none"> • Faculty are required to keep their department heads continuously informed on all outside activities 	<ul style="list-style-type: none"> • Not required 	<ul style="list-style-type: none"> • Monthly reporting 	<ul style="list-style-type: none"> • Disclosure of names of companies you request of dean, provost, etc. 	<ul style="list-style-type: none"> • California Political Reform Act of 1982, requires disclosure of faculty member financial interest in industrial sponsor of his/her research • Annual reports of consulting activities to be supplied to heads of units

Table H-I.—Summary of Selected University Policies on Consulting (Continued)

Harvard University	Harvard Medical School	Massachusetts Institute of Technology	Johns Hopkins University	Johns Hopkins Medical School	Stanford	University of California (all campuses)
Policy enforcement:						
<ul style="list-style-type: none"> ● Essentially self-enforced ● Minimally by department chairman 	<ul style="list-style-type: none"> ● Essentially self-enforced ● By dean ● By department 	<ul style="list-style-type: none"> ● Department heads are required to register once yearly faculty members outside commitments in terms of: <ul style="list-style-type: none"> — number of days spent — nature of the relationship — any significant financial interest the faculty member may have in the company 	<ul style="list-style-type: none"> ● Self-enforced 	<ul style="list-style-type: none"> ● By department director and dean 	<ul style="list-style-type: none"> ● Essentially self-enforced 	<ul style="list-style-type: none"> ● By department dean, variable enforcement among campuses and departments

SOURCE: Management Analysis Center, Inc., "Study of University/Industry Relationships in Biotechnology," contract report prepared for the Office of Technology Assessment, U.S. Congress, January 19S3; and P.R. Lee, W. Levinson, L.H. Butler, et al., "Industrial-Academic Relationships in Biotechnology at Stanford University, University of California, Berkeley, and University of California, San Francisco," contract report prepared for the Office of Technology Assessment, U.S. Congress, July 19S2.

Table H-2.—Summary of Selected University Policies on Sponsored Research

Harvard University (includes Medical School and Mass. General Hospital)	Massachusetts Institute of Technology	Johns Hopkins University (includes Medical School)
Patent rights:		
● Retained by the university	● Retained by the university	● Retained by the university
License:		
● Generally nonexclusive encouraged	● Generally nonexclusive encouraged	● Generally nonexclusive encouraged
Publication rights:		
● Guaranteed	● Guaranteed	● Guaranteed
● Sponsor preview	● Sponsor preview deferrals up to 30 days	● Sponsor preview deferrals up to 120 days
Confidentiality:		
● No confidentiality of results	● No confidentiality of results	● No confidentiality of results
Choice of research topics:		
● Selected by researcher	● Selected by researcher	● Selected by researcher
● Reviewed by department chairman	● Reviewed by department head	● Reviewed by committees (by Biosafety Committee at the Medical School)
Policy enforcement:		
● Review by the department chairman. Approval by the Committee on Patents and Copyright required	● A three-stage approval process is utilized. The stages are: — review by department head — review by the Office of Sponsored Programs — review by dean or provost	● Review by the dean and Office for Sponsored Research (Office of Research Administration at the Medical School)
● Required disclosure to dean of faculty of all personal and remunerative commitments to potential industrial sponsor		
Policy development:		
● Currently underway at all faculties	● Centrally developed policies already in existence	● Being developed by divisions under the direction of central administration
● Decentralized development, moving toward greater centralization		

SOURCE: Management Analysis Center, Inc., "Study of University/Industry Relationships in Biotechnology," contract report prepared for the Office of Technology Assessment, U.S. Congress, January 1983.

Appendix H references

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