UNIVERSITY-INDUSTRY RESEARCH RELATIONSHIPS: THE RESEARCH AGREEMENT

DONALD R. FOWLER*

I. SOME BACKGROUND

Since World War II, sponsored research at American universities has been so dominated by federal funding that actual cooperative or contracted research agreements between universities and industry have been relatively rare and, in the case of some institutions, virtually nonexistent. This can be seen from the statistics. By 1953, research funding relationships between the federal government and the nation's universities had already grown to the point where 54.1% of total research and development expenditures at universities was coming from the federal government. By contrast, only 7.5% was coming from industry.[1] By 1966, the peak year of federal funding in percentage terms, the federal portion of research and development funding at universities had risen to 73.5%, while industry's share had fallen to 2.4%.[2] From this peak, federal funding has gradually dropped off to an estimated 65.1% in 1981, while industry's contribution has increased to an estimated 3.8%.[3]

A continued relative decrease in federal funding is seen (or at least feared) by most observers and a steady increase in industrial funding is seen (or at least hoped for) by most universities. Any such increase, of course, has to be kept in perspective. Knowledgeable observers have recently predicted that the short-term potential limit of industrial funding, depending on the source of the estimate, is probably somewhere on the order of $600 million annually[4] (up from an estimated $240 million in 1981);[5] is no more than 15% of federal funding[6] (up from 5.85% in

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* General Counsel, California Institute of Technology. B.A., 1950; L.L.B., 1951; J.D., 1967, University of New Mexico; M.A., 1979; Ph.D., 1983, Claremont Graduate School.

[1] See NATIONAL SCIENCE FOUNDATION, NSF 81-311, NATIONAL PATTERNS OF SCIENCE AND TECHNOLOGY RESOURCES 1981, at 21 (1981) (hereinafter referred to as NATIONAL SCIENCE FOUNDATION, NSF 81-311). The percentages shown are calculations made by the author from the NSF data.

[2] Id.

[3] Id.

[4] Culliton, *The Academic-Industrial Complex*, 216 SCIENCE 962 (1982), quoting Edward E. David, Jr. of Exxon.

[5] See NATIONAL SCIENCE FOUNDATION, NSF 81-311, supra note 1, at 21.

[6] Culliton, supra note 4, at 962, again quoting David.

UNIVERSITY POLICIES ON CONFLICT OF INTEREST AND DELAY OF PUBLICATION:

REPORT OF THE CLEARINGHOUSE ON UNIVERSITY-INDUSTRY RELATIONS ASSOCIATION OF AMERICAN UNIVERSITIES, FEBRUARY, 1985*

APRIL BURKE*

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** This report of the Association of American Universities' Clearinghouse on University-Industry Relations was prepared by April Burke, Esq. Ms. Burke graduated from Stanford University in 1974 (A.B.) and the George Washington University National Law Center in 1978 (J.D.). Before joining the Association of American Universities, Ms. Burke was associated with the law firm of Ballard, Spahr, Andrews and Ingersoll. She began her legal career with the Office of Legislative Counsel of the United States

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PART I—INTRODUCTION

A. *Purpose of the Report*

The purpose of this report is to discuss the results of the first university survey conducted by the Clearinghouse on University-Industry Relations. The subject matter of the request was conflict of interest and delay of publication policies of universities engaging in collaborative research efforts with business. The principal focus of the report is not the form of the collaboration but rather how the institutions have prepared for and managed the constraints of entering into such ventures.

The Clearinghouse appreciates the willingness of all respondents to participate in the survey, particularly those who provided copies of policies and supplemental materials.

B. *Background: The Growth of University-Industry Collaborative Research*

The federal government provides most of the support for basic research at universities. Only a small percentage of university research is sponsored by corporations. There continues to be a great deal of reliance upon corporate philanthropy, but increasingly, universities and industry are establishing collaborative research relationships, more like partnerships. These relationships are based on a *quid pro quo*: the corporate sponsor provides financial support of specific research in exchange for certain rights to use the results or to maintain an exclusive relationship with the research activity.

Collaborative arrangements have flourished because competition has increased in recent years, increasing the pressure on industry to develop new technologies and be at the forefront of innovation. Concurrently, university and industry scientists find their work more closely linked as the boundaries between "basic" and "applied" research become blurred,

especially in areas of new technologies. In general, universitie research collaboration with industry meets their research nee compromising fundamental academic principles. The universi benefit of research support, valuable research experience for stu broader research opportunities for faculty who might otherwis from the academic environment to industry.

Further, there is growing support for the involvement of u in the technological and scientific growth of the business com the fourteenth annual report of the National Science Board st the interdependencies between good science and good develop been long recognized, but because of the changing character o lems, more direct research interactions between science and ir now occurring."[1]

Federal, state and local governments encourage universit relations. State economic development programs and legislative promote collaboration among government, industry, and unive the federal level, the National Science Foundation funds start-u centers in which federal support is phased-out as industry s is established. Other federal agencies, such as the Departme merce, encourage universities to develop research relationshi dustry. The National Academy of Sciences is sponsoring the G University-Industry Research Roundtable to "foster strong science through effective working relationships among g universities, and industry."[2]

Generally, universities have been responsive to establ laborative research arrangements with industry. The form of th tion varies, even within a single university. The most highly arrangements are multi-year, multi-million dollar projects b university and one company. However, there are many mor in which several universities and several corporations join to research center or project in which the universities jointly numerous research tasks. Some industries have formed non-pr tion or foundations to provide support for basic research at u

Despite the growth of corporate support for university res support is not expected to provide more than a small suppleme assistance. Even so, many universities welcome the additio ment to research. Although the federal government's suppo research is strong, it is not always reliable. Most glaring is the l of federal funding to remodel and replace inadequate resear and instrumentation.

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[1] *University-Industry Research Relationships: Myths, Realities, and P* teenth Annual Report of the National Science Board, October 1, 1982, p. 1. [Th resources cited in this Article are available from the author].

[2] Government-University-Industry Research Roundtable letterhead, Na of Sciences.

C. *Congressional Response to the Emerging Collaborative Relationships and the Establishment of the Clearinghouse on University-Industry Relations*

In light of these new collaborative relationships, it was not overlooked that universities and industry have missions that are different, and in some cases, divergent. Policy-makers and university administrators are concerned that university-industry research relationships could damage the research enterprise. Interested observers, including members of Congress and the press, have also expressed concern. Their fear is that universities engaged in these arrangements may compromise their goals of free inquiry and open dissemination of ideas. The *Report of the University-Industry Relations Project* at the University of California (1982) summarizes the concern of universities: to provide diversity of research activities while preserving the university's independence from undue influence from a single source.[3]

In 1981, the Oversight Subcommittee of the House Committee on Science and Technology asked the Association of American Universities (AAU) to develop ethical guidelines to govern university-industry collaboration. That request stated, ". . . the ethical dilemmas posed by the metamorphosis of our scientific research force from educators to entrepreneurs have not been resolved. Changes in research priorities, allocation of resources, faculty-student and faculty-university relationships, as well as diminishing scientific openness may soon be evolving from a shifting value system."[4]

A Committee on University-Industry Relations was formed by AAU to respond to the Congressional request. The Committee determined that uniform guidelines appeared unnecessary. However, it did conclude that universities, industry, Congress, and the public would benefit greatly from the sharing of information regarding research collaboration. The responsibility for establishing a clearinghouse for such information was undertaken by the AAU. Thus, the Clearinghouse on University-Industry Relations was established by AAU in September, 1983.

D. *The Clearinghouse's Initial Project: Establish an Information Source and Conduct a Study of Conflict of Interest and Delay of Publication Policies*

Since the establishment of the Clearinghouse, university administrators and industry managers have expressed a great deal of interest in information sharing. The Advisory Committee to the Clearinghouse recommended how best to address that interest. As a result, the Clear-

[3] Report of the University-Industry Relations Project, The University of California, October, 1, 1982.

[4] Letter to Dr. Thomas A. Bartlett, President of the Association of American Universities from Representatives Gore and Fuqua, House Committee on Science and Technology, United States House of Representatives, November 18, 1981, p. 1.

inghouse now actively collects and disseminates information r
university-industry relations.

The Clearinghouse also has established a program of gathe
mation on a systematic basis from universities concerning activ
industrial sponsors of research. The first request, made during
of 1984, focused on two specific problem areas: conflict of in
delay of publication. The request was made in writing to fifty-s
sities. A detailed description of the requested information was
to each respondent (see Appendix A). The universities were ask
vide copies of relevant documents and examples of cases that ar
campuses. The information was reviewed and analyzed in det
fifty-one universities responded.

Conflict of interest and delay of publication are policy issue
in almost every type of research arrangement with industry. Ea
on a different aspect of the university's policies with regard to
sity and the faculty. Knowledge about the content of the policie
tices and when and how they are implemented are important too
institutions to use in evaluating their own activities. In additio
terns of establishing policies and procedures provides insight i
tent to which universities have developed their own structure
cedures for research collaboration, and the extent to which u
accommodate the interests of business entities.

PART II—CONFLICT OF INTEREST POLICIES

A. *Background*

Universities rely on faculty to make decisions concerni
propriateness of research, both substantively and procedurally,
out the purposes and goals of the institution.

Overwhelmingly, this arrangement is a success for faculty
stitution. Nevertheless, there is not always a single view of the
balance between outside activities that enhance the knowle
perience of the faculty member, and his or her commitm
university.

The university itself must recognize its goals and objectives
At most universities, consulting and sponsored research activ
couraged. They provide intellectual stimulation and financial s
line is drawn, however, when that support becomes an improp
over the faculty member and as a result, university respons
neglected or the faculty member becomes biased in favor of inc
prietary goals.

Conflict of interest within a university can have two mea
conflict of interest arises when the faculty member's commit
or her responsibilities in the university are not met as a resu
activities. The conventional solution to this conflict is to prov
which describes the faculty member's teaching, researc

ministrative duties, and limits outside research and consulting activities to one day per week. Within the past twenty years, the issue of faculty consulting prompted many universities to develop such a policy.

Second, conflict of interest arises where a faculty member uses influence within the university to advance his or her own personal gain. For example a faculty member could promote a research relationship with an outside sponsor in which he or she has an equity interest, managerial role, or consulting relationship. The university would be adversely affected if the faculty member subordinated his or her university teaching and research to the activites of the outside company or used university facilities, equipment, and instrumentation, or graduate students for that purpose.

Of course, conflict of interest is not a new problem. In 1964, the American Association of University Professors (AAUP) and the American Council of Education (ACE) jointly issued a statement entitled *On Preventing Conflict of Interest in Government-Sponsored Research at Universities*, which has been endorsed by most research universities. The joint statement provides a detailed discussion of conflict of interest and encourages individual universities to establish procedures to address it.

According to the AAUP/ACE statement, conflicts may arise when a faculty member undertakes or orients his or her university research to serve the needs of a private firm, purchases equipment from a firm in which the faculty member has an interest, transmits to a private firm otherwise unavailable information, influences negotiation between the university and a private firm with which the faculty member has a relationship, or accepts gratuities or special favors from a private firm which might be interpreted as an attempt to influence the recipient's conduct of his or her duties.

The joint statement also addresses a faculty member's conflict of commitment. It states that a researcher has a responsibility not to mislead the sponsor of research or the university about the amount of time and effort to be devoted to the research project. Precise time accounting is recommended.

With respect to the university's responsibilities, the AAUP/ACE statement recommends that each university develop and disclose its accounting procedures to inform the university about the outside professional work of faculty members, procedures to inform faculty members about the standards relating to conflict of interest, and the availability of advice and guidance to faculty members regarding potential conflicts.

The joint statement concludes:

> The above process of disclosure and consultation is the obligation assumed by the university when it accepts Government funds for research. The process must, of course, be carried out in a manner that does not infringe on the legitimate freedoms and flexibility of action of the university and its staff members that have traditionally characterized a university. It is desirable that standards and procedures of the kind discussed be formulated and administered by members of the university community themselves, through

> their joint initiative and responsibility, for it is they who are the bes
> of the conditions which can most effectively stimulate the se
> knowledge and preserve the requirements of academic freedom. Ex
> indicates that such standards and procedures should be develo
> specified by joint administrative-faculty action.[5]

B. *Results of the Survey*

As one might expect from the attention drawn to the probl AAUP/ACE statement issued over twenty years ago, most univ the sample have procedures within the university to direct the and management of sponsored research. Since the university mu sponsored research projects, the approval process includes a rev activity for potential conflicts of interest. It is not surprising tha of the respondents have established written conflict of intere which are applicable to business-sponsored research as well. been revised in the last five years (See Appendix B).

Twelve conflict policies (out of twenty-one public institutio ding) are based upon existing state law applicable to public employees. For example:

> 1. A university officer or employee is forbidden to participate official capacity with respect to any transaction between the unive a business entity in which the officer or employee has a substantial
> 2. A university officer or employee is forbidden to receive c tion (in addition to regular budgeted salary or wages for services to th sity) as a result of, or in connection with, any transaction between th sity and a business entity in which the officer or employee has a interest.
> 3. A university officer or employee is forbidden to accept em or engage in any business or professional activity which he/s reasonably expect would require or induce him or her to disclose tial information acquired by reason of the officer or employee's u position.
> 4. A university officer or employee is forbidden to disclose tial information acquired by reason of his/her university position, such information for his/her or another's gain or benefit.
> 5. A university officer or employee is forbidden to accept othe ment which he/she might reasonably expect would impair h dependence of judgment in the performance of university d responsibilities.
>
> * * * *
>
> 7. A university officer or employee is forbidden to have pe vestments in any business entity which will create a substantial co tween his/her private interests and university duties.[6]

The distinctions among the various policies on conflict of inte

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[5] "On Preventing Conflict of Interest in Government-Sponsored Resea sities," joint statement of the American Association of University Professors an Council on Education, December, 1964, p. 3.

[6] University of Utah Policy and Procedures Manual, January 22, 1981, Public Officers' and Employee's Ethics Act, 1953 Utah Code Annotated, Sec. 6

less dramatic than one might expect. Appendix C categorizes the principal focus of the various conflict policies.

The most significant difference among the policies was the mechanism within the university for disclosure of outside activities. One distinction lies in which party, university or faculty member, initiates the disclosure. Nineteen institutions provide for a faculty-initiated disclosure when the faculty member determines that a sponsored research arrangement to which he or she is a party may present a conflict. Many of these policies require a disclosure by the faculty member only if he or she intends to take an equity interest or management position with the sponsor entity.

For example, a typical policy statement in this category reads, in part:

> Responsibility for establishing that activities in business ventures do not conflict with Institute commitments rests first with the Faculty member. Further, on request from cognizant Division Chairmen, the Provost, or the President, the Faculty member shall make a full disclosure of all such ventures including the names of companies, the nature of agreements, the responsibilities assumed by the Faculty member, and the time involved.[7]

Twenty-six universities have conflict of interest policies that provide a university-initiated disclosure or annual report from each faculty member engaged in sponsored research or require approval to be granted before the faculty member may undertake a consulting or sponsored research project. Many annual reporting requirements were similar to the following:

> D. Reporting. All faculty members must report through their chairman to both the Dean and the Office of Science and Technology Development all outside professional activities at their inception and shall amend these reports as circumstances change . . . Such reports shall include consulting arrangements as well as equity holdings, board memberships, managerial positions, etc. in relevent organizations.[8]

A summary of a sample financial disclosure procedure at a state university further illustrates:

> A. Principal investigators disclose *whether or not* they have a financial interest in the sponsor of a proposed research project when funding in whole or in part is through a contract or grant from a non-governmental entity;
>
> B. Principal investigators disclose *whether or not* they have a financial interest in the donor of a gift when the gift is from a non-governmental entity and is earmarked by the donor for a specific principal investigator or for a specific research project;
>
> C. Disclosure statements be filed (1) before final acceptance of such a contract, grant or gift; (2) when funding for such a contract or grant is renewed;

[7] "Conflict of Interest and Conflict of Commitment," California Institute of Technology Faculty Handbook, chapter 7, p. 12.

[8] "Guidelines for Situations Involving Potential Conflicts of Interest Between Scholarly and Commercial Activities," Columbia University, Draft, May 21, 1984, p. 6.

> and (3) within 90 days after expiration in the case of a contract or or after funds have been completely expended in the case of a gift
>
> D. When disclosure indicates that a financial interest exists, an ind dent substantive review of the disclosure statement and research proje place before the contract, grant, or gift is accepted; and
>
> E. Department chairs disqualify themselves from approving a researc posal for a project to be funded in whole or in part by a non-governm entity in which they have a financial interest.
>
> Failure by a principal investigator to make the required disclosure a department chair to disqualify himself or herself may result in st forcement proceedings against him or her as an individual, as well as U sity sanctions.[9]

With regard to equity interests and faculty managerial invo in businesses providing research or development, twenty-one ins have developed specific policies to address this issue. None of the prohibited such activities. Rather, the involvement of a faculty in an outside business is recognized as a potential conflict of inte commitment for the faculty member which should be disclosed to proved by the dean. Several state institutions have ceilings beyon no faculty member may have an ownership interest in a compan does business with the university. For example:

> (e) No member of the faculty or academic staff or members of th mediate families and no business in which they own or control at le interest of the outstanding stock, or at least 5% interest in such bu or in which they are an officer or director may enter into any comm contract with the university unless the contract has been awarded th a process of public notice and competitive bidding under section 16 Wis. Stats., or unless the member of the faculty [or] academic staff in a position to approve or influence the university's decision to gra contract.[10]

Appendix D lists the respondents that have equity interest provi their conflict policies.

Many institutions responded to the survey by providing supp materials illustrating recent guidelines or memoranda addressing of interest issues directly related to industry-sponsored resea following excerpt is an example of one institution's treatment of arising from equity ownership and management participation i mercial entity:

> 1. *Participation of the University and its faculty in commercial org tions.* The University, or a faculty member, may of course invest, own or other equity in a commercial enterprise. However, if the Universi its faculty holds a controlling interest, participates in the managem

[9] "Guidelines for Disclosure and Review of Principal Investigators' Financia in Private Sponsors of Research," University of California, April 9, 1982, p. 2.

[10] Wisconsin Administrative Code, University of Wisconsin System, UWS

the conduct of affairs of the commercial organization, or if the work of the University and its faculty is being funded by the organization, conflicts of interest are likely to exist, and the matter should be referred to the Policy Committee. Faculty members may own a controlling interest in a commercial enterprise, and may participate in its management or conduct of affairs, as long as such participation does not interfere with their ability to fulfill their University commitments, and as long as the activity of the commercial organization is not closely related to the area of the faculty member's University research. If there is a close relationship between the two, the question should be referred to the Policy Committee. The University does not participate in the management or conduct of affairs of a commercial organization.

A faculty member may own significant stock or equity in a commerical enterprise, but a conflict of interest may exist if the faculty member's University research is closely related to the activity of the enterprise, especially when the faculty member participates in management, in which case the question should be referred to the Policy Committee.

* * * *

2. *Funding of research or conduct of research at the University by commercial organizations.*

* * * *

If a faculty member has significant stock or other equity interest in a commercial corporation and/or participates in the management or the conduct of its affairs, it is not normally permissible for the University and the faculty member to receive funding from that organization for the faculty member's research at [this] University. These rules apply with particular force when faculty members in question hold administrative positions which permit them significant control of space and other resources at the University.[11]

A few institutions have policies relating to the protection of graduate students. For example:

(4) STUDENT RESEARCH PROTECTION. A member of the unclassified staff shall inform students engaged in research under his or her supervision of any financial interest which the unclassified staff member has in the research activity, including, but not limited to, financial arrangements involved in the direct support of the activity, agreements made by the unclassified staff member to obtain data for the research, or agreements concerning copyright or patent rights arising from the research.[12]

Finally, several universities responded to the survey with examples of possible conflicts that were reviewed and resolved. One state university with a mandatory disclosure procedure required by state law provided an interesting example:

It was the unanimous opinion of the ISRC [independent substantive review committee] that Professor A's project be recommended for disapproval. The Committee's decision was made on the basis of an extensive and thorough

[11] "Guidelines for Situations involving Potential Conflicts of Interest Between Scholarly and Commercial Activities," Columbia University, Draft, May 21, 1984, p. 3-5.

discussion of the issues raised in Professor A's Disclosure of Finan terest and in his personal appearance before the Committee. The pr reason for recommending disapproval of the project is the absence of a length relationship in determining the amount of monies to be p university as between Professor A, the Principal Investigator (and t individual who determines the amount of such monies on behalf University) and Dr. A, the President and 100 percent owner of Th pany, who must pay such monies.

A second serious concern of the Committee was that the employe actually do the work funded by the contract are performing 'secret That is, they are conducting analyses of chemical compounds whi been provided to the Company by outside sponsors who have insis the results of the analyses not be disclosed. While the agreement b the University and the Company did not contain a restriction on the tion of research findings, Professor A indicated that all decisions c ing publication will be made by him. He stated that he would ho commitments made by the Company to its sponsors not to disclose t dings. Thus, a conflict of interests exists between Dr. A's role as a U ty Professor, with the obligation to disclose the findings of his w Dr. A's role as the President of a private corporation which has a treat his findings as confidential. It is Dr. A who will determine or not the findings of these projects will be published and therein conflict of interest.[13]

In some cases, detailed conditions have been imposed members. For example, a letter from a university official to member sets forth conditions under which the faculty member allowed to proceed with a project:

The purpose of this letter is to respond to your inquiry concern participation in the commercial development of certain prior res forts . . . . It is my further understanding that your participation wo the form of an investment or some receipt of an equity interes corporation.

* * * *

It is further understood that you agree to the following specif sions regarding your participation in the above described corpor

1. Your equity interest shall not exceed 26 percent and the cu equity interest of all members of your department shall not exceed cent of total equity in the new corporation.

2.You do not, and will not in the future, have any involvem responsibility for the operation of the new corporation.

3. . . . you are under no obligation to make present or future results available to the corporation, nor will you undertake such an ob

4. You will not allow the interests of the corporation to hav fluence whatsoever on the current or future directions of you research.

5. You will not allow the interests of the corporation to hav fluence whatsoever on the current or future directions of the College of members of the Department.

[13] Letter from the Vice Chancellor to Professor A, re: Positive Disclosur Interest from Professor, University of California, Los Angeles, March 4, 198

6. You agree to disclose immediately to the Dean any real or apparent conflict of interest that may arise in relation to your interest in the corporation and your position on the [University] faculty.

7. The terms of any consulting agreement or other form of business agreement or relationship between you and the corporation shall be disclosed to the University and be subject to prior University approval.

8. Any use of funds of the new corporation to support your College research will require the prior approval of the Dean.

9. No resources of the University will be committed to the furtherance of the purposes of the corporation without the prior review and approval of the Dean and the negotiation of a written University contract.

10. You will initially provide to the Dean a report of all aspects of your participation in the corporation and you will disclose any proposed changes or modification in the relationships between you and the corporation and your on-going University research.[14]

C. *Summary*

In general, it can be concluded that universities responding to the survey have developed conflict of interest policies that address the faculty problems arising out of university-industry relationships. A key feature of most of the policies is reliance on disclosure as a mechanism to deal with conflicts. Perhaps this reflects a conclusion that disclosure will inhibit the formation of inappropriate relationships at the outset. Or, it could be based on the theory that so long as the business relationship between a faculty member,and an industrial sponsor has the informed consent of the university, the faculty member may proceed with confidence. In the final analysis, however, should policies based on disclosure actually reveal serious conflicts, the test of the effectiveness of such policies will be in the ability of institutions to use the information that is in their possession.

PART III-DELAY OF PUBLICATION POLICIES

A. *Background*

Delay of publication relates to the issue of openness. Exchange of ideas, including research results, is an integral part of increasing knowledge. Free communication also allows scholars and scientists to verify and critique research of others and lessen duplication of effort. Further, each faculty member relies on the freedom to select a research path regardless of whether it is likely to produce commercial success.

The federal government has often asserted the sensitivity of research results for national security reasons and requested or required that it be embargoed. In the case of industry-sponsored research, the sponsor is interested in protecting the proprietary nature of the research and may not want competitors to have access to the information resulting from the sponsored research. Within this context, sponsors of research sometimes request restriction of openness.

The opposing views about information are often a subject c
tion in university-industry relations. Most frequently, the reso
contract provision which allows a specified delay of the pub
the research results in order to permit the sponsor to protect it
by filling a patent application with th U.S. Patent Office. Pat
are based on the premise that the owner of the rights should di
invention in exchange for the right to exclude others from
manufacturing it. Thus, the end result of a patent is openne

In addition to patent rights, some universities allow a speci
of publication to permit the sponsor to review the publicatio
prietary data. Most frequently, proprietary data means inform
sponsor supplied to the research enterprise which was not
public. If the sponsor supplied that information to the research
be determined by the parties, in advance, that such information
tended to be made available when the results of the research are

B. *Results of the Survey*

Forty-nine universities responding to the survey provided
on delay of publication. Thirty-two universities have writte
stating the institution's position on freedom to publish. Mos
statements were general admonitions that the university is con
free publication and open dissemination of ideas. Some provide
in publication is permissible under specific circumstances, bu
delay may not be unreasonable. The length of time permitted
is rarely stated, but is determined on a case-by-case basis. For

3. *Publication*. In order to fulfill our educational objectives, and
status as a tax-exempt education institution, research at [the Univers
to serve a public rather than a private purpose. Results are disse
broadly and on a non-discriminatory basis. Thus [the University]
undertake studies whose results cannot be freely published. W
however, recognize legitimate proprietary concerns of sponsors w
propriate. Publications may be deferred for an agreed upon limite
of time to protect patent rights, and sponsors may review our pub
before release so that they are aware of the contents. On occasio
[the University] may have accepted a sponsor's proprietary inform
necessary background data for a research project, we will allow a
tion review in order to identify any inadvertent disclosure of data
a reasonable-efforts basis, we agreed to keep confidential.[15]

All of the institutions responding to the Clearinghouse re
mit publication to be delayed. Appendix E summarizes the r
which the respondents will agree to delay publication. Overwl
the most common reasons given for permitting delay of public
to permit the sponsor to review the proposed publication for
subject matter or confidential information and to permit the ur

the sponsor to file a patent application in the United States (and sometime abroad) to protect the sponsor's interest in such subject matter. Nineteen universities specified patent review and filing as the only reason fo delay. Twenty-one institutions specified both patent review and filing and review for confidential information supplied by the sponsor.

Delay of publication provisions tend to fall into three categories. Some merely state that the university will permit a delay. Others specify the total length of time that the university will delay. Others specify a two-tiered delay procedure involving a specified review period and a subsequent delay for patent application preparation and filing. This last category may be subdivided based on when the delay may commence. Some calculate the delay from the time that the proposed publication is submitted to the sponsor regardless of when it would have been published. Others calculate the delay from the time that the proposed publication would have been published. Publication includes any presentation of the research results to the public.

The following is an example of a publication provision in a contract between a respondent and an industrial sponsor:

> a. The University reserves the right, subject to the provisions of this Agreement, to use the results of all work provided by the University under this Agreement, including but not limited to, the results of tests and any raw data and statistical data generated therefrom, for its own teaching, research and publication purposes only. The University agrees, on behalf of itself and its employees, students, assistants or associates, not to cause said results to be knowingly used for any commercial purpose whatsoever except as authorized by Sponsor in writing.
>
> b. Any proposed publication by or on behalf of the University, its employees, students, assistants, or associates, involving work hereunder shall be submitted to Sponsor for review and comments at least ninety (90) days prior to submission for publication or presentation. At the end of ninety (90) days after said submission to Sponsor, the University shall be free to proceed with publication. However, if Sponsor believes patentable subject matter is inadvertently disclosed in any publication submitted for review, Sponsor shall immediately identify such subject matter to University. University shall use its best efforts to promptly file or assist Sponsor to file a patent application covering such subject matter with the United States Patent and Trademark Office or through the Patent Cooperation Treaty prior to publication.[16]

The length of time that universities will delay publication varies among institutions and among arrangements within institutions. Among the respondents, the shortest delay was thirty days, the longest more than one year. Appendix F summarizes the time periods during which the respondents would delay publication.

[16] Sample publication contract clause, University of California at Los Angeles.

C. *Summary*

In general, all respondents allow some form of delay of pub Clearly, then, a reasonable delay is considered by institutions g to be within the scope of free and open publication. Publication confined to patent protection and pre-disclosed proprietary dat that are easily defined. Other types of intellectual property protecti as trade secrets, do not appear in institutional policies as legitimate for interfering with open dissemination of research results.

PART IV—CONCLUSION

All of the universities sampled in the Clearinghouse requ developed policies and practices relating to industry sponsored r Whether particular policies are too narrow or too broad is a matter institution, and each interested person, to evaluate. The sampl clearly that the issues relating to industry-sponsored research a addressed by university administrations and faculties, and that ge procedures are in place to provide adequate disclosure of the arran between universities and industry.

The natural extension of the issues addressed in this report c the entrepreneurial activities of the university itself. Increasingly, sities are establishing business entities to provide technology tran development services for the university. The Clearinghouse's next which is scheduled to commence in May, 1985, will focus on ur entrepreneurial activities, as well as intellectual property polici For further information or materials, contact:

April Burke, Esq.
The Clearinghouse on University-Industry Relations
Association of American Universities
Suite 730
One Dupont Circle, N.W.
Washington, D.C. 20036

APPENDIX A

March 20, 1984

CLEARINGHOUSE ON UNIVERSITY-INDUSTRY RELATIONS

This is a request for information about some specific university policies and practices in the area of university-industry relations. We would like to receive a response regarding your institution. The thoroughness of each response is crucial to the success of our effort. The purpose, simply stated, is to gather information about policies and practices affecting these relationships and to make it available in ways that will improve the quality of decisions university officers make.

Potential problems associated with university-industry research collaborations have become a subject of concern among interested observers, including members of Congress and the press. The fear is that the universities engaged in these arrangements may compromise the goals of free inquiry and open dissemination of ideas.

In 1981, the AAU was asked by the Oversight Subcommittee of the House Committee on Science and Technology to develop ethical guidelines to govern university-industry collaborations. That request stated, ". . . the ethical dilemmas posed by the metamorphosis of our scientific research force from educators to entrepreneurs have not been resolved. Changes in research priorities, allocation of resources, faculty-student and faculty-university relationships, as well as diminishing scientific openness may soon be evolving from a shifting value system."

A committee on University-Industry Relations was formed by AAU to respond. That Committee determined that guidelines appeared unnecessary; however, it did conclude that universities, industry, Congress, and the public would benefit greatly from the sharing of information regarding research collaborations. The responsibility for establishing a clearinghouse for such information has been undertaken by the AAU.

Since the Clearinghouse was established in September, 1983, university administrators and industry managers have expressed a great deal of interest in information sharing. On November 28, 1983, the Advisory Committee to the Clearinghouse met in Washington to recommend how best to address that interest. The Committee recommended that the Clearinghouse request information from universities concerning activities with industrial sponsors of research, beginning with two specific problem areas: conflict of interest and delay of publication.

This is the first request for information and it is confined to those two topics. We are interested in receiving written information concerning university policies and practices, including documentation of policy, such [illegible] and discussions and documen-

tation of practices, including contracts and other agreements. W requesting confidential information. If it is necessary to delet dates, dollar amounts, or other specific details from documents, v be pleased to receive them in such form. We hope to receive inf covering the breadth and variety of university activities in this a including the details of specific arrangements.

The following hypothetical examples may make clearer th information we would like to get and the value that such informat have to university officers confronted with real cases.

University A has a conflict of interest policy which states that faculty should avoid situations involving conflicts of inte as financial dealings that are contrary to the University's best i which may obligate the faculty member to take actions adve University's interest. Faculty member X, following extensive c arrangements with a small biotechnology company, is asked t company as a stock holding partner in order to head a new d his area. X would only dedicate one day a week to the new com would have the new division contract with him at the Universi tinue to do research. He notifies his department chairman of to accept the offer, assuring him that the University's interests, the selection of research topics and the learning experience o students, would not be compromised.

What information about other universities' experiences in sir tions would you like to know to help you resolve University tion? For example:

1. Conflict of interest policies.
2. Faculty contracts with industrial sponsors.
3. How similar matters were resolved, including proc followed by other universities.

Corporation A and University Y are negotiating a contract u the university would receive $10 million over 5 years to con research in the area of X. The Corporation will be entitled to a license to develop patents owned by the university for produ cesses developed under the project, but has asked for very res cess and publication measures to be imposed by the universi to protect possible proprietary rights. As part of those restrictive no faculty member or graduate student involved in research ject may publish the results of the research without first sub proposed publication to the Company for review. The Com questing 120 days to determine whether the publication would patentable product or process, and a subsequent 120 days to f application. The University has no stated policy concernir publication; however, it has never agreed to delay publicatic than 90 days in the past.

What information about other universities' experiences in s

tions would you like to know to help you resolve University Y's situation? For example:

1. Contracts with delay provisions.
2. Restrictive measures requested by companies.
3. How similar matters were resolved, and whether their resolution treated faculty members differently than graduate students.

We know we are asking your institution to undertake a significant task in responding to this request. We are convinced that it will be in the university community's best interest to share this information. It is important to demonstrate to those who are concerned about university interaction with industry that universities are addressing the legal and ethical problems of entering into business relationships to perform research. We hope your institution can assist in this effort.

All responses should be received at AAU by June 1, 1984. Please direct any inquiries and responses to:

April Lewis Burke, Esq.
Director of the Clearinghouse on University-Industry Relations
Association of American Universities
One Dupont Circle, N.W., Suite 730
Washington, D.C. 20036
202-466-5030

Please let us know the name, address, and phone number of any member of the university's staff who will be assisting with this request.

Thank you.

APPENDIX B

Dates of Most Recent Revision of Conflict Policies at Respondent Universities

No date provided
University of Maryland
Northwestern University
University of Pittsburgh
University of Rochester
University of Southern California
Yale University

1982-1984
California Institute of Technology
University of California, Berkeley
University of California, Los Angeles
University of Chicago
University of Colorado
Columbia University
Duke University
Georgia Tech University
Harvard University
The Johns Hopkins University
University of Michigan
University of Missouri
University of Nebraska
New York University
University of North Carolina
University of Pennsylvania
Purdue University
Rensselaer Polytechnic Institute
Rockefeller University
Stanford University
University of Texas
University of Virginia
University of Wisconsin

1979-1981
Brown University
Case Western Reserve University
The Catholic University of America
Indiana University
Iowa State Unviersity
University of Kansas
Massachusetts Institute of Technology
Ohio State University
The State University of New Jersey, Rutgers

University of Utah
Washington University

1970-1979
Cornell University
Pennsylvania State University
Princeton University
Tulane University
University of Washington

1960-69
Vanderbilt University

APPENDIX C
PRINCIPAL TERMS OF CONFLICT OF INTEREST POLICIES AT RESPONDENT UNIVERSITIES

No written conflict of interest policy provided
Carnegie-Mellon University
University of Massachusetts
University of Minnesota
University of Oregon
Syracuse University

General statement
University of Maryland

Faculty-initiated disclosure of outside professional activitiers or equity required only of equity interest involved
California Institute of Technology
University of Colorado
Cornell University
Indiana University
The Johns Hopkins University
University of Missouri
University of Nebraska
New York University
Ohio State University
Rensselaer Polytechnic Institute
Pennsylvania State University
Purdue University
Rockefeller University
Stanford University
University of Texas
Tulane University
University of Utah
Washington University
Yale University

University-initiated disclosure or annual disclosure or approval to undertake sponsored research activity
Brown University
University of California, Berkeley
University of California, Los Angeles
Case Western Reserve University
The Catholic University of America
University of Chicago
Columbia University
Duke University
Georgia Institute of Technology

Iowa State University
University of Kansas
Massachusetts Institute of Technology
University of Michigan
University of North Carolina
Northwestern University
University of Pennsylvania
University of Pittsburgh
Princeton University
University of Rochester
The State University of New Jersey, Rutgers
University of Southern California
Vanderbilt University
University of Virginia
University of Washington
University of Wisconsin

APPENDIX D

Respondents Having Equity Interest Provisions in Conflict of Interest Policies

The State University of New Jersey, Rutgers
Syracuse University
University of Texas
Tulane University
University of Utah
University of Washington
Yale University
University of Wisconsin
Columbia University
Cornell University (letter to faculty)
Purdue University
Rockefeller University
Duke University
Harvard University
The Johns Hopkins University
University of Michigan
University of Nebraska
New York University
University of North Carolina
University of Pennsylvania

APPENDIX E

Reasons Given by Respondent Universities for Permissible Delay of Publication

Review for disclosure of patentable subject matter and filing application
Brown University
California Institute of Technology
University of Colorado
Georgia Institute of Technology
Harvard University
Indiana University
Iowa State University
University of Maryland
University of Minnesota
University of Nebraska
University of North Carolina
Ohio State University
University of Pittsburgh
University of Rochester
Syracuse University
University of Texas
Tulane University
University of Virginia
Yale University

Review for disclosure of confidential information
University of Utah
University of Wisconsin

Review for disclosure of confidential information or patentable s ter and filing of patent application
Case Western Reserve University
The Catholic University of America
Columbia University
Cornell University
Duke University
Massachusetts Institute of Technology
University of Michigan
New York University
Northwestern University
University of Oregon
University of Pennsylvania
Pennsylvania State University
Princeton University
Purdue University

The State University of New Jersey, Rutgers
University of Southern California
Stanford University
University of Washington
Washington University

Review for confidential information and sponsor approval
Carnegie-Mellon University

Review for comment, patentable subject matter and confidential information
University of California, Los Angeles

Comment and patent filing
University of California, Berkeley

Review and deletion of sensitive information
Vanderbilt University

Reason not stated
University of Chicago
University of Maryland
University of Missouri

APPENDIX F
LENGTH OF TIME PERMITTED BY RESPONDENT UNIVERSITIES FOR DELAY OF PUBLICATION*

30-45 Days
Rockefeller University
Yale University

60-90 Days
California Institute of Technology
University of Chicago
Columbia University
Duke University
Georgia Institute of Technology
Massachusetts Institute of Technology
New York University
Princeton University
University of Rochester
University of Southern California
Stanford University
University of Texas
Vanderbilt University
University of Wisconsin

91-120 Days
University of California, Los Angeles
Cornell University
University of Michigan
Northwestern University
University of Oregon
University of Washington
Washington University

121-365 Days
Brown University
Case Western Reserve University
University of Colorado
Indiana University
University of Kansas
University of Maryland
University of Minnesota
University of Nebraska
University of North Carolina
Ohio State University
University of Pennsylvania
University of Pittsburgh
Purdue University

The State University of New Jersey, Rutgers
Syracuse University
Tulane University
University of Utah
University of Virginia

More Than 365 Days
Carnegie-Mellon University

Other
1. "short period"
   —California Institute of Technology
   —University of California, Berkeley
2. "long enough for sponsor to protect their patent application"
   —The Catholic University of America
3. "will not delay publication significantly"
   —Harvard University
4. "limited time"
   —Iowa State University

*Each institution is placed in the category reflecting the longest delay possible, as described in their response. If an institution stated that it typically delays for "x days, or longer," such institution was placed in the next longest delay category following x.

THE CATALOG IN THE COURTR
FROM SHIELD TO SWORD?

*DAVID DAVENPORT

My first month on the job as a university general counsel examining a familiar document in a new setting and a differe a student years before, I had passed several hours in my dorm r ing the thick listing of courses in the college catalog (in fact, it *Courses and Degrees*). As a faculty member only months before interests in the booklet, after the faculty profile section of co the beautiful photos and messages about the school itself. A at the shortened listing of courses in the back of the catalog rea that the subjects I taught were still being offered.

As a new university counsel, I was already in the courtroo catalog, looking not at the pictures in the front or the listing in the back, but at the many pages of promises, representations statements in between. And my concern was not recruiting s choosing classes with the document, but rather convincing a jur laymen that the University's understanding of the catalog, an of thirteen former students, was legally correct.

I. CHANGING ROLE OF THE CATALOG

In a sense, this changing personal experience with the catalo the evolving nature and role of the document itself. Originally or university catalog was simply what the term connotes, a lis case, the list was usually of courses and degrees, with perhaps a of other information and a sturdy statement about the school's As one commentator noted, the style of these early catalogs was they "were not respectable unless they were dull, set in type so that it was unreadable—and organized in such an arcane way deciphering."[3] Such listings were hardly the stuff of which laws made.

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* B.A., Stanford University, 1972; J.D., University of Kansas, 1977; Pres perdine University.

[1] N. WEBSTER, WEBSTER'S NEW UNIVERSAL UNABRIDGED DICTIONARY (2d ed

[2] Bode, *The College Catalogue as a Work of Art*, 26 CHRON. OF HIGHER ED 1983 at 64

Patents at Colleges and Universities

Guidelines
for the Development
of Policies

1985

COGR
COUNCIL ON
GOVERNMENTAL
RELATIONS

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Patents at Colleges and Universities

USE OF THE UNITED STATES patent system by colleges and universities has increased dramatically in recent years. The reasons are numerous, but much of the increased activity is due to the interest of industrial companies in commercializing inventions and discoveries emanating from the academic sector.

Patent rights are often necessary to the successful development of inventions. Those rights, which vary from country to country, are defined by the patent laws of each country.

In the United States, the patent system is based on the Constitution, and a complex legal specialty—patent law—has evolved over the years. This brochure is concerned primarily with United States patent law, and does not deal with the differences in various foreign patent systems. Nor does it deal with any more than the essential elements of the United States laws that affect the conduct of research at institutions of higher education.

An adequate policy statement and a level of understanding sufficient to handle patentable

discoveries in the proper manner can readily be established at any institution, regardless of size. The possession of this understanding can allow for the dissemination of important and valuable research findings by publication, by patenting, or by both, in a manner likely to produce the greatest benefit for the institution, the discoverer, and the public. This publication presents information about the administration of patentable discoveries; it does not deal with the question of rights in data or copyrights.

The guidelines in this document are intended to assist administrators in developing a policy and in determining the level of activity best suited to the invention and patent needs of their institutions. While inventions as assets may not result in substantial income to the institution, each institution should and can (and without excessive cost) acquire the capability of using the patent system to bring into public use any commercially valuable discovery made in its laboratories.

Patent Program Objectives

Colleges and universities establish patent programs and policies for a variety of reasons, usually to achieve one or more of the following objectives:

1. To facilitate the transfer of technology and the utilization of findings of scientific research in order to provide maximum benefit to the public therefrom.

2. To encourage research, scholarship, and a spirit of inquiry, thereby generating new knowledge.

3. To provide machinery by which the significance of discoveries may be determined so that the commercially meritorious may be brought to the point of public utilization.

4. To assist in an equitable disposition of interests in inventions among the inventor, the institution, and, when applicable, a sponsor.

5. To provide individual incentives to inventors in the form of personal development, professional recognition, and financial compensation.

6. To assist in the fulfillment of the terms of research grants and contracts.

7. To safeguard the intellectual property represented by worthwhile inventions.

8. To comply with applicable federal laws and regulations when the institution accepts federal funds for research.

9. To facilitate the development of collaborative research agreements and contracts with industrial sponsors.

Nature and Scope of Patents

A patent is a property right granted by a sovereign nation, which gives the holder the exclusive right to exclude others from the manufacture, use, and sale of an invention in that country for a period of years. As property, it may be sold or assigned, pledged, mortgaged, leased (licensed), willed, or donated, and be the subject of contracts and other agreements. Commercialization may be accomplished by the owner exercising the exclusive rights referred to above or by permitting others to exercise rights under the terms of one or more licenses.

Each country has its own requirements on patenting, including standards as to what is patentable, formalities for establishing a patent, the effective date and duration of the patent grant, requirements relating to the use of a patent, and annual taxes to maintain it in force.

Under United States standards of patentability, all patent applications are examined for novelty, utility, and nonobviousness. It is the applicant's responsibility to establish these elements to the satisfaction of the U.S. Patent and Trademark Office before the patent is allowed to issue. Novelty means that the invention is new; that is, it has not

been previously publicly used, sold, or described in printed form. Utility means that the invention has a use and is not just a subject for additional research. In regard to the third requirement, the invention must be nonobvious at the time of invention to a person having ordinary skill in the art to which it pertains.

The duration of U.S. patents (other than those covering designs) is 17 years from the date of issue; they are not renewable. The life of drug patents may be extended a few years under certain limited conditions. The duration of most foreign patents is 20 years from the filing date. Maintenance fees in the United States on a patent issuing on an application filed on or after December 12, 1980, are now due 3½, 7½, and 11½ years after such patent issues, while maintenance fees in foreign countries are usually due on an annual basis and may be due while the patent application is pending.

Many of the statutory fees imposed by the Patent and Trademark Office may be reduced by half in the case of applications and patents assigned to "small entities," i.e., small businesses and nonprofit organizations such as colleges and universities. In order to establish small entity status, it is necessary for the assignee of the invention to file a statement in the Patent and Trademark Office. Statement forms are available from that office or from the patent attorney or agent filing the application.

It is the responsibility of a patent owner to police the patent against infringers. If a patent owner intends to keep a patent in force, he or she is obliged to defend the validity of the patent if it is attacked. Every patent granted by the Patent and Trademark Office is only prima facie evidence of the exclusive right it purports to establish. The presumption of validity that attaches to a patent may be subsequently invalidated in a federal court proceeding by third parties formally charged with infringement if they present satisfactory proof that the patent should not have been issued. Also, the

patent statutes provide for a procedure wherein a third party can cause the reexamination of an issued patent based on prior art not considered in the original examination of the patent application if the Commissioner of Patents and Trademarks rules that a substantial new question of patentability exists.

The patent laws set forth those classes of inventions eligible for patenting. Those statutes provide that any inventor who "invents or discovers a new or useful process, machine, manufacture, or composition-of-matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of the law."

The scope of statutorily patentable classes of inventions has been expanded to include life forms resulting from genetic engineering. When a U.S. patent application claiming a life form is filed in the Patent and Trademark Office, it is necessary that a sample of the biological material be made available to third parties only when and if the U.S. patent issues.

The U.S. law also allows the patenting of new varieties of asexually produced plants, other than tuber-propagated plants or plants found in an uncultivated state.

Design patents, which relate to the ornamental appearance of useful articles, are also provided for in the United States, but are seldom encountered in an academic setting.

Things that cannot be patented in the United States include:

1. Theories
2. Ideas
3. Plans of action
4. Results
5. Methods of doing business
6. Discoveries of laws of nature or scientific principles

7. Things immoral or injurious to health and the good of society
8. Works eligible for protection under the copyright laws

Patents and Publication

Patents and publications are closely related; publications can prohibit patenting under some circumstances. A patent is a specialized form of publication which describes an invention to the world at large in return for a limited period during which others can be excluded from using the invention. However, care must be taken against premature disclosure of an invention (by publication in a scientific or technical journal or by public use) in order to avoid placing the invention in the public domain and thus losing the right to obtain a patent.

In the United States a patent may be obtained if a patent application is filed within one year after the invention is disclosed through publication, sale, or public use. In many foreign countries a patent cannot be obtained if there has been any disclosure, even oral, of the invention to the public prior to the filing of a patent application. However, under an international convention, a patent application in the United States generally will preserve for one year the right to file patent applications abroad even though there has been publication of the invention after the filing of the U.S. patent application but before the foreign patent application is filed.

Dealing With Patentable Discoveries

In order to deal with discoveries that may have patentable significance, an institution should have the following:

1. A formal patent policy approved by the governing board, which defines the rights and obligations of the institution, the inventor, and, when applicable, a sponsor.

2. Administrative procedures, often spelled out in the patent policy itself, and a designated person responsible for patent matters to provide a focal point for patent information, to serve as a collection point for invention disclosures, and to assure their evaluation and appropriate processing.

3. A licensing capability to transfer patented technology to qualified manufacturers for development and marketing. This may be accomplished by an in-house patent management staff, by an institution-affiliated foundation, or by arrangements with invention management agencies. None of these three requirements need be expensive to maintain.

Elements of an Institutional Patent Policy

An institution seeking to establish or clarify its position regarding rights to and disposition of patentable inventions should develop a statement of patent policy. The statement should be broad enough to encompass all foreseeable patent situations, yet specific enough to allow administration of the policy without frequent recourse to policy deliberations by an advisory committee. The statement should briefly define the administrative structure for processing a patentable discovery and it should be directly and succinctly presented for clear understanding by lay persons. The basic purpose of a patent policy is to define the rights and obligations of both the inventor and the institution regarding patent matters. To the extent that policies on consulting deal with patents, it is advisable to take them into account when formulating a patent policy.

Some institutional patent policies are incorporated into patent manuals that provide the reader with a brief orientation on patent matters. These publications can be helpful to neophyte inventors, but they should be prepared so that the institutional policy is clearly distinguishable from general instructional materials.

The following topics typically are found in institutional patent policies:

1. Preamble
2. Applicability of the policy
3. Establishment of the inventor commitment
4. Rights of the parties
5. Income-sharing arrangement
6. Administrative arrangements

Preamble. Although optional, this section is recommended. It should relate the basic purposes of the institution, its obligations to the public, and the scholarly aims of its faculty to the institution's interest in patents and ways in which patents serve these ends. The preamble should be kept short and to the point and establish a sound foundation for what is to follow.

Applicability of the Policy. This section defines research situations, sources of funds, all categories of persons who may invent (that is, faculty, staff, and students), activities in which such persons are engaged, and any combinations of these elements that would bring an inventor into the scope of, or exempt him or her from, provisions of the policy. Educational institutions do not usually lay claim to all inventive concepts generated by their employees or students. Rather, they limit themselves to those that arise as a result of employment relationships or use by the researcher of institutional resources, facilities, or funds.

Establishment of the Inventor Commitment. Once an institution determines the criteria for applying the policy to individuals, its personnel may be required to dispose of inventions as determined by the institution in one of several ways (listed in generally decreasing order of enforceability):

1. By a formal written inventor agreement to assign. This is a legally enforceable contractual commitment by a person to dispose of inventions as determined by the institution.

2. By a state statute stipulating that inventions made in state institutions or by state employees be disposed of in a predetermined manner.

3. By a person giving his or her written assent to the stated patent policies of the institution, which policies set forth an obligation by the individual with respect to inventions.

4. By a stated patent policy containing a patent commitment that is established by the governing board and brought to the attention of individuals, but to which such persons are not required to give their personal formal assent.

5. By the presence of a policy allowing the individual to dispose of inventions as determined by the institution or to retain title, at his or her option.

To allow an institution conducting federally sponsored research to fulfill its contractual obligations, it is essential that every person engaged in such research, or using federal funds, execute a valid, written, binding commitment to assign inventions to the institution or the government.

Rights of the Parties. The policy should specify the rights that the institution, the inventor, and sometimes outside sponsors have in an invention. The institution usually receives an irrevocable assignment of title to the patent application together with a commitment by the inventor to cooperate in executing legal documents, reviewing patent prosecution papers, and, in some cases, assisting in the development or marketing of the patent. The inventor is entitled to receive from the institution a clear statement of his or her rights and share of income and the institution's plans for bringing the invention into public use. Sponsors' interests in these situations are usually represented by the institution based on the terms of the research agreement. Sponsor equities in patents must be scrupulously observed by the institution to permit it to perform and maintain its contractual obligations.

Income-Sharing Arrangement. Educational institutions that accept assignment of inventions and

patents from inventors customarily share royalty income with them. The inventors' share generally ranges from 15% to 50% of net income, although there are a few policies that authorize income outside this range. Some institutions use sliding scales of income-sharing, with a greater percentage going to the inventor from the early receipts and the rate of sharing declining as the amount of royalties increases.

Most royalty-sharing arrangements are predetermined, that is, the inventor cannot negotiate a higher rate of sharing than stipulated in the institutional policy. Predetermined sharing rates have the advantage that it is unnecessary to pass judgment on the relative worth of each invention. They are easier to administer and usually reward the inventor equitably because a valuable invention's true merit is reflected in the greater total royalty revenues it generates, a portion of which inures to the benefit of the inventor. Where several individuals collaborate on a patentable invention, the inventors' income share is divided among them.

Administration and Licensing of Inventions

The provisions of the institutional patent policy usually determine the make-up of the policy board and the administrative organization for patents.

Patent policies usually specify that patent activities be placed under the administrative cognizance of an institutional patent committee appointed by the governing board, the president, or the faculty senate, with a majority of the individuals on the committee representing scientific or technical disciplines. It is not uncommon for a dean, a vice president, or even the president to serve as chairman. This committee often has the responsibility for recommending or establishing patent policy, adjudicating disputes, determining which inventions shall be the subject of patent applications, and overseeing the administration of patent matters in the institution.

In a large institution, it is advisable to have at least a full-time patent administrator. In a smaller institution, this individual may come from one of the science or engineering departments and spend only a few hours a month on duties related to patents. Regardless of the size of the patent operation, there should be at least one person who understands the essential requirements for handling inventions and serves as a campus focal point for all patent-related activities.

The licensing of patentable inventions typically occurs in one of three ways: in-house, by an institution-affiliated foundation, or by a patent management organization.

In-house. In this case, the institution controls and performs the invention evaluation that precedes the decision to seek a patent, to file a patent application, and to license. This option is initially more costly because it requires an early outlay for patent application costs and the overhead costs of patent administrative services. However, if sizable royalties are earned, this approach may be the most advantageous overall.

Institution-affiliated foundation. This option can have the advantages of better availability of funds to carry on the development of inventions (a speculative activity) and greater freedom to employ commercial methods to develop and promote the uses of inventions. Assuming equal capabilities to develop inventions, the presence of a foundation may result in less income for the institution because of the foundation's expectation of sharing income. If the foundation's board consists primarily of representatives from the institution, then no less income will flow eventually to the inventor.

Both the in-house management and the institution-affiliated foundation management of patents allow the inventor to work closely with the unit promoting the invention. The inventor's ready assistance and background often are crucial to getting the invention covered by a patent and "off the ground" as a commercial success.

A patent management organization. Patent development and marketing by one of these organizations has some distinct advantages: use of a patent development organization permits an institution to be active in patenting and licensing patent inventions through an agent with minimum financial outlay and may allow considerable legal, marketing, and patent management expertise to be tapped at no immediate cost to the institution. The chief disadvantage in this arrangement is, of course, that a substantial portion of any royalties earned is retained by the patent management group as compensation for services.

These three routes of invention development need not be mutually exclusive. Many institutions use more than one, depending on the type of invention reported and the location of the various capabilities needed to develop it.

It is essential for an institution (or anyone) involved with patents to have available the services of a patent attorney or agent. Because of the diversity of complex inventions generated in colleges and universities, it is important that the patent attorney prosecuting the patent application be competent in the area of technology to which the invention relates.

Patents and Sponsored Research

The patent policy of the institution may be an important consideration at the time a research proposal is submitted to a potential sponsor. It is important for administrators and the faculty performing such research to be aware of any sponsor patent policies that may conflict with the institution's patent policy. If this information is known in advance, the faculty member will be able to determine the institution's position with regard to the submission of proposals that are likely to produce policy conflicts. When there is a conflict it may be possible to negotiate the differences, thereby asssuring the availability of research funds. If the faculty is made fully aware of the situation and the reason for a particular institutional policy, the chances are improved that they will support the administration's efforts to negotiate acceptable arrangements.

When a research sponsor finds the institutional patent policy acceptable, there is normally little delay in accepting funding. Where there is a policy conflict, months of negotiation may be required. Since changes take place in government regulations and in the policies of private sponsors, staff members in the office of research administration should monitor the incoming grants and contracts to insure that no changes have been made in the patent requirements and other terms and conditions. If there are changes, the office responsible for patent matters should be alerted to interpret these alterations with regard to the institution's own policy and, if necessary, assist research administrators in preparing and presenting the necessary arguments to the sponsor to effect a modification of the terms of the contract.

Federal policy. There was a major change in federal patent law with the enactment of P.L. 96-517 in 1980. This change was designed to enable institutions and small businesses to more easily retain title to inventions made under a federal grant or contract. The law took precedence over approximately 26 different agency policies.

Testimony in the Congressional Record showed that less than four percent of federally owned and managed inventions were commercialized. Data obtained after enactment and implementation of P.L. 96-517 indicated that about one-third of inventions in which institutions elected to retain title were commercialized.

P.L. 96-517, enacted by Congress and signed by President Carter on December 12, 1980, came into effect on July 1, 1981. Implemented by OMB Circular A-124, it provides for title retention by nonprofit institutions and small businesses for inventions arising under funding agreements with any federal agency except the Tennessee Valley

Authority. Institutions are required to have written agreements with their employees (except clerical and nontechnical employees) to assure compliance with their obligations to the federal government pursuant to P.L. 96-517. Many of the provisions of P.L. 96-517 are similar to those previously used in Institutional Patent Agreements with federal agencies. Some licensing restrictions and conditions are specified.

An institution must report inventions made under federal grants and contracts to the applicable federal agency within 60 days. The contractor or grantee then has a stipulated time within which to elect to take title to a reported invention. The government retains certain march-in rights to inventions not brought to commercialization after several years. For example, under P.L. 96-517, a university could grant an exclusive license to a large business under U.S. patent rights for only a limited period of time.

P.L. 98-620, signed into law on November 9, 1984, removed a number of constraints present in P.L. 96-517. Most notably, P.L. 98-620 (a) removed the limitation on the period of exclusivity that can be granted to large business firms under a license for U.S. patent rights; (b) granted nonprofit operators of government-owned contractor-operated facilities (GOCOs) the right to elect title to inventions made while operating such facilities; (c) expanded the definition of "invention" to include any novel variety of plant that is or may be protectable under the Plant Variety Protection Act; (d) assured that the reporting provisions of OMB Circular A-124 would be continued; and (e) assured that inventions arising under scholarships and other educational awards would be free of any federal government claim to title.

Regulations implementing P.L. 98-620 have been issued as 37 CFR Chapter IV, Part 401, and these regulations replace OMB Circular A-124 for inventions arising after November 8, 1984.

Both P.L. 96-517 and P.L. 98-620 are codified at 35 USC 200-212.

Patent License Agreements

A patent owner, having the right to exclude others from practicing the patented invention, may also give permission to others to infringe. This is normally done by a contract, usually referred to as a license. (While a license may also arise from the conduct of the patentee, this publication is concerned only with those licenses established by contract.) Licensing restrictions imposed on federally funded inventions are found at 35 USC 202.

A license agreement is the usual method by which a patented invention developed in an educational institution is put into public use. Such an agreement sets forth the understanding of the parties and covers the following points, among others:

1. The term of the license, which is often until the end of the life of the patent, but may be shorter.

2. The territory of the license, which may vary from a single country (typically the United States) to worldwide, depending on the extent of patent coverage.

3. A license grant, which may be either exclusive, nonexclusive, limited by field of use, limited in time, or in some other way. It is usually necessary to grant an exclusive license where large expenditures of time and money must be made by the licensee in order to get the invention into the market, such as in the case of a new drug.

4. An exclusive license typically requires payment of a license issue fee or some other initial consideration by the licensee. The amount of the fee will vary, depending on the value of the invention being licensed.

5. Earned royalty rates depend on a variety of factors such as the value of the invention, the degree of development of the invention, and whether the license is exclusive or nonexclusive.

Generally, they are based on sales of the patented item and fall within a range for a given type of product. There is no "normal" earned royalty rate, however; each situation requires its own negotiation.

6. As a means of assuring diligent development, an exclusive license should provide for payment of minimum annual royalties after a given period of time. Failure to meet a minimum annual royalty payment would give the licensor the right to convert the exclusive license to nonexclusive or to terminate the license altogether.

7. An exclusive license should contain diligence milestones to be met by the licensee for developing and marketing the invention. Failure of the licensee to meet the milestones should give the licensor the right to terminate the license.

8. In an exclusive license, the institution should always retain an irrevocable, royalty-free license to practice the invention for its own research purposes. If federal funding were involved, a license to the government should be recognized in the agreement, and the constraints of 37 CFR 401 included.

9. All license agreements should provide for the licensee to indemnify the institution, particularly for product liability. In the case of licensees with limited assets, there should be proof of adequate insurance, with the institution named as co-insured.

Transfer of Technology Outside the Patenting Process

It is normal for educational institutions to provide considerable public utilization of their faculty's scientific findings aside from patents. Typically, this is accomplished by the publication in appropriate journals of information describing advances which in themselves are not patentable, but which in the aggregate are important contributions to the advancement of a given technology.

More complete concepts and technologies are often developed that may or may not be patentable, and about which an institution is unsure of the commercial prospects. For example, in the case of genetically engineered life forms, it is sometimes possible for an investigator to publish freely, yet retain the genetically engineered life form per se as a trade secret. Thus the life form, even though unpatented, may itself be licensed to third parties having an obligation not to make it available to others.

In the course of evaluating an unpublished invention, it is often worthwhile to determine if the invention has commercial merit by disclosing it to prospective licensees. In order to protect the institution's rights in the invention as well as foreign patent rights, disclosure of such unpublished inventions to third parties should be made only after the third party has signed a suitable secrecy agreement. By determining whether or not there is commercial interest in an invention, the institution can make a decision as to whether or not the expense of filing a patent application can be justified. In fact, it is often the case that a commercial organization will be sufficiently interested in such an invention that it will underwrite patent expenses in return for the right to obtain a license to the invention.

Invention Disclosures

An invention disclosure in this context is a complete description of an invention written by the inventor to report an invention to the institution or a sponsor. Along with the original laboratory notebooks and records, it is one of the most important documents in an institutional patent program, and the original must be retained by the institution. The invention disclosure is based on the information contained in laboratory notebooks. (See Appendix A, "Guidelines for Keeping Laboratory Records.")

It is customary for the office responsible for patents to provide a disclosure form or set of guidelines for preparing disclosures. Whichever is used, completeness is more important than format. The invention disclosure should be couched in good

technical language rather than in legalistic style. If the invention becomes the basis for a patent application, a patent attorney describes the invention in language acceptable to the Patent and Trademark Office.

The invention disclosure is valuable in several ways. Writing the disclosure helps the inventor to mentally clarify the inventive concept and, if the concept has not yet been reduced to practice, to better organize his or her thoughts concerning it. A good disclosure is essential for the technical evaluation of the invention, for an accurate assessment of its commercial feasibility, for a determination of its patentability, and for reporting the invention to others.

The invention disclosure may later be used as the basis for preparation of the patent application. Well-prepared disclosures readily transmit the patentable idea to the patent attorney and aid in preparing an application that precisely describes the invention. The less attorney time required for this, the lower the cost to the institution. Finally, when witnessed laboratory records bearing earlier dates are not available, the invention disclosure can serve as proof of the date of conception, or at least of the earliest recording of the invention. It thus may be an important document in any controversy over which of two parties first made an invention.

Disclosures of inventions are required under the terms of federal research agreements and must be sufficiently complete and of a quality that will allow the federal agency to evaluate and prepare a patent application in the event that the institution does not elect to retain title. A complete and accurate invention disclosure is extremely important to outside patent management organizations because they often are not located in close proximity to the inventor. These organizations must, therefore, rely heavily on the inventor's written description to assess the worth of the invention and to determine any interest in accepting it and in carrying it forward to patenting and commercial development. (A typical set of instructions for preparing invention disclosures appears as Appendix B.)

References

BNA's Patent, Trademark & Copyright Journal, William A. Beltz (editor-in-chief), The Bureau of National Affairs, Inc., Washington, D.C. (current review, by subscription).

Goldscheider, Robert, *Eckstrom's Licensing in Foreign and Domestic Operations: Forms,* Clark Boardman Company, Ltd., New York, 1978–79 (revised annually).

Goldscheider, Robert and Tom Arnold (eds.), *The Law and Business of Licensing: Licensing in the 1980s,* Clark Boardman Company, Ltd., New York, 1981 (supplemented annually).

Kintner, Earl W., and Jack Lahr, *An Intellectual Property Law Primer,* 2d ed., Clark Boardman Company, Ltd., New York, 1982.

Les Nouvelles—Journal of the Licensing Executives Society, Jack Stuart Ott (editor-in-chief), LES, Inc., Cleveland, Ohio.

Mayers, Harry R., and Brian G. Brunvold, *Drafting Patent License Agreements,* 2d ed., The Bureau of National Affairs, Inc., Washington, D.C., 1984.

Massachusetts Institute of Technology and National Council of University Research Administrators, *Intellectual Property Series,* NCURA, Washington, D.C., 1984.

Nordhaus, Raymond C., *Patent License Agreements—Law and Terms,* Jural Publishing Company, Chicago, Illinois, 1967 (supplemented semiannually).

Rosenberg, Peter D., *Patent Law Fundamentals,* Clark Boardman Company, Ltd., New York, 2d ed. 1980 (revised annually).

Samuels, Jeffrey M., (ed.), *Patent, Trademark, and Copyright Laws,* The Bureau of National Affairs, Inc., Washington, D.C., 1984.

Sperber, Philip, *Intellectual Property Management: Law—Business—Strategy,* Clark

Boardman Company, Ltd., New York, 1974 (revised annually).

U.S. Department of Commerce—Patent and Trademark Office, *General Information Concerning Patents,* U.S. Government Printing Office, Washington, D.C., revised June 1978.

U.S. Department of Commerce—Patent and Trademark Office, *Official Gazette of the United States Patent and Trademark Office,* Government Printing Office, Washington, D.C.

U.S. Department of Commerce—Patent and Trademark Office, *Patents & Inventions: an Information Aid for Inventors,* U.S. Government Printing Office, Washington, D.C., reprinted June 1980.

U.S. Department of Commerce—Patent and Trademark Office, *Q&A About Patents,* U.S. Government Printing Office, Washington, D.C., revised May 1982.

U.S. Small Business Administration, Staff Member of the, *Introduction to Patents,* Small Business Administration, Management Aids Number 6.005, U.S. Government Printing Office, Washington, D.C., 1963.

Appendix A

Guidelines for Keeping Laboratory Records

1. Legibly enter in ink concurrent with your daily work a complete and accurate record of your research activities and sign and date each page.

2. Whenever possible, preface each series of pages with a brief heading of the most generic nature of the work performed (that is, statement of problem) rather than what you expect or hope will be the results achieved. Avoid gratuitous conclusions.

3. Similarly, when an experiment or run is completed and it represents the reduction to practice of only one or more species, include a paragraph setting forth still other species and parameters of variables stating the reasons you expect them to be effective in order to later provide a valid basis for a generic claim. This is conveniently included under a "Modifications and Extensions" heading and need not include complete data at that time.

4. Faithfully have your work corroborated by having your notebooks witnessed by dated signature of an associate (not a coworker or one who collaborates in your research area and who could be or is a joint inventor). Notation of witness should appear after the last line of your experiment and not necessarily only at the bottom of every page. If necessary or desirable, explain in detail the work performed.

5. Prior to destroying any samples, run sheets, or records of any kind, check with the director to make certain they are of no value to any project member.

6. Clear all proposed publications (including abstracts) with the director in order to most fully protect and preserve property rights in research.

7. Record your observation of physical results even if not fully appreciated or understood at that time.

8. Use the last four to five pages for an index, as desired.

9. Start a new page for each new experiment and draw a continuous diagonal line through unused portions of pages remaining at the close of an experiment.

10. Avoid erasures, but where necessary cross out with a single line.

Appendix B

Guidelines for Preparing an Invention Disclosure

The following guidelines illustrate the preferred layout and content for invention disclosures. A disclosure is a description of the invention. Completeness is very important in preparing the disclosure so that it can serve as a basis for a worthwhile patent search and for preparing the patent application. To be complete, the disclosure should include all the pertinent experimental data available, both pro and con, which has a bearing on the inventive concept. (The data, if voluminous, may be attached as an appendix.) It is also important that the inventor have considered the various alternative ways of constructing (in the case of apparatus) or performing (in the case of a process) the invention. This is something a potential infringer would do, and having the alternative embodiments on hand permits the preparation of a patent application that is broad in scope. The inventor should, however, specify which embodiment is preferred.

The Disclosure

The disclosure should contain the following elements:

A. *A Title.* The ideal title is brief but comprehensive, technically accurate, and descriptive.

B. *An Abstract of the Invention to Be Disclosed.* (of about 100 words).

C. *Statement of the Background of the Invention.* The disclosure should state the field of art to which the invention pertains. The basis for this requirement is that an accurate description will permit a future patent application to be properly classified in the Patent and Trademark Office, and therefore it is helpful if the inventor can accurately categorize the invention within the field of his or her endeavor.

D. *Description of the Prior Art.* A statement of the prior art known to the applicant should be set forth. This will include a description of the various existing devices or processes and their shortcomings that are remedied by the present invention. If published material such as scientific papers, patents, or commercial literature relating to or describing the prior art is known to exist, it should be cited (or supplied, if available).

E. *Summary of the Invention.* In this section describe in detail:

1. How the invention is designed. Where alternative designs are available, describe these and select the preferred embodiment. To clarify, attach and refer to descriptive drawings, flow charts, circuit diagrams, etc.

2. Ranges of operating conditions, such as time, temperature, or pressure, where these are relevant to the invention. Preferably these should be in terms of broad ranges of conditions and narrower optimum or preferred ranges. Where materials may be varied, sufficient specific materials should be enumerated to illustrate the range of usable materials. A sufficient number of specific working examples should be set forth to illustrate the variations in conditions and materials.

3. How the invention operates to produce a result or results not achieved in the prior art.

4. The new concept that has been invented: describe succinctly.

5. All advantages such as efficiencies, cost benefits, etc. produced by these new results.

F. *Utility of the Invention.* Indicate briefly and in general terms, particularly for chemical cases.

Where the utility is evident from the earlier sections, this section may be omitted.

G. *Publication of the Invention.* List (and append, if possible) all publications in which the invention was described or occasions on which it was described orally to others; for example, at symposiums.

H. *Budget Numbers Used to Defray Research Costs.* List all budget numbers, including federal grant or contract, Hatch Act, McIntyre-Stennis, Animal Health and Disease Act, or Colleges of 1890 and Tuskegee Institute Act, all administered by USDA, used to defray any research costs that are invention-related.

I. *Signatures, Witnesses, and Dating.* Each inventor should sign the disclosure before a witness who understands the invention. The witness should also sign. Each set of signatures (inventor and witness) should be dated.