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UNIVERSITY OF WASHINGTON
SEATTLE, WASHINGTON 98195
Government Fiscal Relations and Patent Office
275 Administration Building AG-70

April 13, 1982

Mr. Donald E. Sowle
Administrator
Office of Federal Procurement Policy
Office of Management and Budget
Washington, D.C. 20503

Dear Mr. Sowle:

We wish to acknowledge with thanks your consideration in sending us the details describing the way in which your office developed the final regulations implementing PL 96-517. This is the first instance, to our knowledge, where those who contributed comments on the proposed regulations have been provided with detailed feedback on the disposition of those comments. In our opinion, this is a worthwhile procedure which we hope other units of government will follow.

It appears to us that your agency has achieved a fair balance between the government and the university/non-profit sectors. Naturally, we are most concerned about the provisions affecting universities, and we are pleased to note that the final regulations took into account the most significant objections raised by the university community after the first draft regulations were published.

Sincerely yours,

Wallace C. Treibel
Government Fiscal Relations
and Patent Officer

cc: Mr. Milton Goldberg, COGR
Mr. J. F. Ryan/Mr. H. R. Cottrell
Dean William C. Richardson

'Rules' Drawn For Marketing Gene Research

By Philip J. Hilts
Washington Post Staff Writer

At an unusual summit meeting yesterday, the leading universities and corporations in gene engineering work agreed to a set of tentative ethical principles for commercializing scientific research.

The session was sparked by the growing concern that the rush to market gene engineering techniques is creating conflicts between universities and businesses.

Some scientists believe that research has become more secretive because of the intrusion of corporations and their need to keep trade secrets, and with the new emphasis on products, scientists are being pushed into research that literally pays off instead of into traditional basic research.

The agreement adopted is voluntary, and critics, who were closed out of the conference, said it was only a weak and equivocal effort to take a stand on the issues.

The meeting near Monterey, Calif., was called by Donald Kennedy, president of Stanford University, to try to outline rules that would protect the integrity of academic research while allowing some of its products to be marketed commercially.

Kennedy said in a telephone interview yesterday that the 11-page agreement produced by the conference "doesn't make policy, but outlines the problem" so that universities and businesses can establish their own guidelines from it.

The group of five university presidents and 11 corporate executives reached a consensus on several important points, Kennedy said:

• There was a "strong presumption" against allowing businesses, under normal circumstances, to gain exclusive licenses to research work.

• Universities should establish explicit conflict-of-interest codes to govern the conduct of their professors.

• Universities generally should not own or have substantial equity in companies staffed by their own professors.

• Associations between businesses and universities should not impair "openness and communication" among researchers, and if that openness is limited for commercial reasons, the period of secrecy should be brief.

• The direction of research in universities should not be governed by commercial interests, but by the intellectual demands of the research itself.

Kennedy said no vote was taken at the two-day meeting, and that those attending are free to disassociate themselves from any part of the agreement. He said the group did not meet "to set up proscriptions or carve up territory," but to make a beginning toward establishing a national consensus on research guidelines.

The agreement was immediately challenged yesterday by a coalition of labor, environmental and consumer groups.

"A lot of this document is window dressing," said Al Meyerhoff, a leader of the coalition. "I was surprised that men of this stature could meet for two days and not address directly the questions of exclusive patent rights, what kind of conflict-of-interest rules we should have, and what kind of public disclosure of researchers' corporate connections we should have."

The coalition objected that the public and many organizations critical of the rushed commercialization were not invited to the meeting.

"I am hopeful but dubious," Meyerhoff said, "that this meeting will open up an avenue of communication."

Kennedy said other meetings will be scheduled to continue to develop research guidelines.

Over the past several years, the lines between commercial and academic research have blurred as virtually all top university researchers in gene engineering have become paid consultants to the more than 100 companies now racing to get gene engineering products on the market.

'Rules' Drawn for Marketing Gene Research

GENES, From A1

At the same time, many corporations have made special arrangements with universities in which the corporations have given millions of dollars to the universities in return for the right to exclusive commercial use of gene research.

One of the key points in the agreement is the discussion of whether universities should grant such an exclusive license.

The agreement said, "some people fear allowing a single firm the sole right to develop a patent will necessarily remove competition, slow the development of the patent, or even prevent development altogether."

But Harvard University President Derek Bok said there must be some reward for businesses that support research, and if exclusive licenses are not allowed, then "some research won't get done."

The paper said as a general principle, "it is important for universities and industry to maintain basic academic values in their research agreements. Agreements should be constructed, for example, in ways that do not promote a secrecy that will harm the progress of science, impair th ucation of students, interfere with the choi faculty members of the scientific question o of inquiry they pursue, or divert the energ faculty members from their primary obligatio teaching and research.

"One way of accomplishing this result," it "is to make public the relevant provisions search contracts with industry. Another m may be to allow a faculty committee or other competent body to examine all research tracts with industry and assure that their are consistent with the central academic valu

Yesterday's meeting was called "Asilom after a 1975 conference at Asilomar, Calif. meeting codified the first gene research guid

The presidents of three other universi Massachusetts Institute of Technology, Cali Institute of Technology and the University o ifornia at Berkley—attended yesterday's me as well as executives of 11 corporations, inc Dupont, Eli Lilly and Genentech.

'Kennedy Paper'

Preamble

Research of the past several decades, through enlightened public support, has profoundly advanced the understanding of life processes. A new biotechnology of extraordinary promise has emerged. While much of great importance remains to be learned at the most fundamental level about living organisms, applications of present knowledge can be foreseen that are likely to be of far-reaching benefit to people everywhere. These useful applications may well improve health, enhance food and energy supplies, improve the quality of the environment, and reduce the cost of many industrial processes and products.

With such beneficial possibilities at least dimly foreseeable, it becomes a matter of urgent concern to take constructive steps toward their fulfillment. Most of the basic research which made these applications possible has been done in universities in the United States, mainly with federal government funding. The development of these findings into useful processes and products is already vigorously underway in American industry. The chain of progress from basic research to useful applications necessarily involves universities and industry. For the promise to be fulfilled, all links in the chain must be strong.

The translation from opportunity to reality is not simple or easy. Serious problems are involved. These problems center on the preservation of the independence and integrity of the university and its faculty, both faced with unprecedented financial

pressures and complex commercial relationships. Universities are a repository of public trust, and, in many cases, of public funds as well, and they have an obligation to the public as well as to their students and faculty to ensure that they remain devoted to their primary goals of education and research, and that their resources be properly used in their pursuit of these goals.

Therefore, leaders from five of the universities that have engaged heavily over many years in research in the life sciences met to explore problems and clarify the considerations essential to wise policy-making in this area. Each university invited members of its own faculty and people from the business community to attend as discussants and resources. These considerations must be viewed from the perspective of individual scientists, universities as institutions, industry large and small, and the general well-being of people everywhere who can someday benefit from the uses of biotechnology. The social consequences of the technologies are an integral part of research in this field.

There are several strong motivations for academic institutions and their faculties to seek industry support for research. First, there is a genuine interest in facilitating the transfer of technology -- from discovery to use -- to contribute to the health and productivity of society; second, there is interest in ongoing dialogue between academia and industry which could improve the level of applied science by close association with industry applications; and, third, academic institutions and

their faculty members are feeling particularly hard-pressed financially and see such cooperation with industry as a way of compensating for a small but important part of the support lost from federal sources.

Although biotechnology is at the center of today's news, we have considered it appropriate to discuss a broader range of university-industry relationships without regard to subject area.

From industry's point of view, a competitive position is critical. Each high-technology company seeks to develop the "best technology" and to use it productively. The development by a business of a cooperative research relationship with a university is likely to be based on the presumption that "best technology" can most readily be created by "best people," access to whom is one objective for the business which finances the program. As long as the conditions which surround access to a university's "best people" are not too onerous, business will continue to make new agreements with universities to enhance their opportunities to achieve competitive advantages.

But the appropriate development of new opportunities in academic-industrial relations presents universities with a host of problems. The most important of these is the potential distortion such relationships may cause to academic objectives. While this issue may vary in degree from one academic institution to another, it is shared by most research-based universities and institutes. If not carefully managed, these patterns of

affiliations among university faculty, universities and industrial firms, beneficial though they may be to the transfer of technology, may lead to serious difficulties.

The purpose of the meeting was to contribute usefully to a more fruitful process of policy-making -- but not to make policy. This responsibility rests with the individual institutions. The focus of the conference was to define the areas of difficulty or potential conflict and to develop suggestions for guiding the growth of industry-university cooperation in research. It has long been felt that university administrators, faculty and industry leaders have not been communicating enough about the problems arising within the universities in connection with the commercialization of basic research. Equally important, the problems and objectives of industry have been often ignored. As a result, different institutions have been engaged in ad hoc policy formulation, without the benefit of sharing their experience and discussing their common problems.

The overriding concern of the participants was to explore effective ways to satisfy the university community and the public that research agreements and other arrangements with industry be so constructed as not to promote a secrecy that will harm the progress of science; impair the educational experience of students and postdoctoral fellows; diminish the role of the university as a credible and impartial resource; interfere with the choice by faculty members of the scientific questions they

pursue, or divert the energies of faculty members and the resources of the university from primary educational and research missions.

Relationships Between Universities and Industry

Research Agreements

It is important that universities and industries maintain basic academic values in their research agreements. Agreements should be constructed, for example, in ways that do not promote a secrecy that will harm the progress of science, impair the education of students, interfere with the choice by faculty members of the scientific questions or lines of inquiry they pursue, or divert the energies of faculty members from their primary obligations to teaching and research.

Universities have a responsiblility not only to maintain these values but also to satisfy faculty, students and the general public that they are being maintained. One way of accomplishing this result might be to make public the relevant provisions of research contracts with industry. Another method may be to allow a faculty committee or some other competent body to examine all research contracts with industry and assure that their terms are consistent with essential academic values. Reasonable people may differ on the choice of methods to be used,

and we propose no single solution. What is essential is that each university establish some effective method.

The traditions of open research and prompt transmission of research results should govern all university research, including research sponsored by industry. Those traditions require that universities encourage open communication about research in progress and research results. However, as discussed below, it is appropriate for institutions to file for patent coverage for inventions and discoveries that result from university research. This action may require brief delays in publication or other public disclosure.

Receipt of proprietary information from a sponsor may occasionally be desirable to facilitate the research. Such situations must be handled on a case-by-case basis in a manner which neither violates the principle stated above nor interferes with the educational process. Any other restrictions on control of information disclosure by institutions are not appropriate as general policy.

Patent Licensing

Patents and patent licensing provide valuable incentives to facilitate the process of translating scientific discoveries into useful processes and products. By protecting the rights of the inventor, patents also encourage inventors and institutions to

make public their discoveries, thus promoting the progress of science and technology. These advantages are fully applicable to universities, which need an incentive to identify potentially useful discoveries and to seek companies that have the resources and capabilities to bring these ideas to the marketplace. The federal government has recognized these advantages by amending the law to allow universities to own and license patents on discoveries made in the course of research financed by government grants and contracts.

Universities are now developing more effective programs to identify and patent potentially useful discoveries and to license them to interested firms. With few exceptions, such programs have not resulted in significant financial gains to universities though greater gains may come in the future. However, regardless of the uncertainty of the economic return, as recipients of public funds, universities have a responsibility to initiate and maintain effective patent and patent-licensing programs to encourage technology transfer.

It is important that universities administer patent programs in a manner that conforms to the public interest and to the universities' primary commitment to teaching and research. One important question is whether universities should grant exclusive or non-exclusive licenses. Some people fear that allowing a single firm the sole right to develop a patent will necessarily remove competition, slow the development of the patent or even

prevent development altogether. This fear is exaggerated. Although, in some cases, multiple licenses will undoubtedly speed development, in other cases, exclusive rights are essential if development is to take place since no firm will expend large sums for development that will primarily benefit others.

Thus, universities should be able to negotiate exclusive licenses provided that exclusivity seems important to allow prompt, vigorous development of the patent to occur. The desirability of exclusivity in certain cases is recognized under current federal law. When exlusivity is allowed, however, it should be permitted for only the interval necessary to encourage the desired development. In addition, the university should insist upon a requirement of due diligence on the part of the licensee in developing and using the patent. In exercising these responsibilities, universities should seek to insure that their patents are vigorously developed -- not only to promote the public interest but also to further the universities' rights to royalty income.

While the foregoing policies seem acceptable for licensing patents on discoveries already made, greater difficulties arise in corporate research agreements where the sponsor requests the right to exclusive licenses on all discoveries made as a result of the research funded by the company. Some of us believe that such exclusive rights are an appropriate <u>quid pro quo</u> for the funds provided for research. Others believe that the university

should be willing to agree to provide instead non-exclusive royalty-free licences to the sponsor, but should not give up its right to examine the appropriateness of exclusivity for each invention on a case-by-case basis. This question needs to be addressed by universities on a continuing basis in light of their experience.

It is important that universities not influence the nature of the research proposed by professors, postdoctoral fellows, or students by pressing them to do work of potential commercial importance or to become involved in other commercial activities. Professors may choose to delay publication of research findings for a brief period to permit the timely filing of patent applications, but, absent a contractual obligation, universities should not try to prevent faculty members from publishing or disclosing their research findings to preserve the universities' patent rights.

Universities should not be improperly influenced in choosing a licensee by the fact that a faculty member, or the university itself, is a substantial stockholder or has other significant ties with a particular company.

Licensing agreements between a university and a company are intended to accomplish the transfer of technology in an effective way. In those rare instances where a faculty member or the university has a major financial interest in a company seeking such an agreement, and where the technology to be licensed has

been, in whole or in part, developed by the faculty member, licensing should ordinarily be on a non-exclusive basis. Exceptions might arise if the transfer of technology is best accomplished through an exclusive arrangement for a limited period, as, for example, in the case of companies possessing unique skills necessary to such transfer on a timely basis.

The University and Its Faculty

University professors have long associated with companies through consulting and other types of relationships. Such interaction can have significant advantages to the university, to the faculty member, to the company, and to the public. In many fields, faculty involvement with the commercial world provides valuable material for teaching and research, career opportunities for students and support for institutional activities.

Notwithstanding these benefits, professors' relationships with commercial firms should not be allowed to interfere with their overriding obligation to the university to fulfill their primary responsibilities of teaching and research.

In recent years, the problems of achieving this goal have assumed greater urgency by virtue of the growing tendency, especially in the biotechnology field, for professors to own significant blocks of stock in commercial enterprises, to assist

in the formation of such enterprises, or even to assume substantial executive responsibilities. Conflicts of interest may arise through combinations of public funding, private consulting, and equity holding in companies engaged in activities in a faculty member's area of research. These developments underscore the need for universities to consider the rules and procedures needed to insure that faculty members fulfill their responsibilities to teaching and research, and to avoid conflicts of interest.

At times, the research or entrepreneurial efforts of a faculty member may have the potential materially to affect the economic condition of a company. (In such cases, the faculty member is often a substantial stockholder in the firm.) Under these conditions, investment by the professor's own university in the firm gives the institution a financial stake in the activities of its faculty member. This situation may cause others to believe that the university encourages entrepreneurial activities by its faculty. Moreover, it may cause, or appear to cause, the university to extend preferential treatment to the professor, for example, in such matters as promotion, space, or teaching loads and thus undermine the morale and academic integrity of the institution. Hence, it is not advisable for universities to make such investments unless they are convinced that there are sufficient safeguards to avoid adverse effects on the morale of the institution or on the academic relationships between the university, its faculty, and its students.

Many approaches have been used by different universities to address these problems. We make no effort to specify the proper rules and procedures to be used for this purpose. The development of these rules is a matter internal to each university and extends to all faculty members -- scientists and non-scientists alike. Hence, this conference does not provide a proper forum in which to resolve such issues. Different rules and procedures may well be appropriate to suit the special circumstances and traditions of different institutions.

Although we see no single "right" policy, we do believe that each university should address the problem vigorously and make efforts to publicize widely and effectively the rules and procedures it adopts to avoid compromising the quality of its teaching and research. Our institutions are committed to such an undertaking.

We also feel that faculty members have an obligation not only to abide by the prevailing rules but to make these restrictions known to the companies with which they have a relationship.

Finally, we suggest that firms ask for copies of applicable rules in hiring university consultants and act in conformity with these regulation.

We do not view this summary statement as the end of the process of deliberation on these important issues. Rather, we

offer it as a contribution to further consideration in meetings of other groups and in many individual institutions. We emphasize again that what we have produced is not policy, but an agenda of issues that may be a useful framework for the development of policy.