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ABSTRACT

The relationship between university research and public need is discussed from both a historical and contemporary perspective. Examples are cited of European experiences in which there has been obvious industrial motivation for research performed by the universities. The author notes that there are no difficulties with the level of government support going to universities for basic research if efforts at technology transfer are made, but that there is growing concern in Congress to better account for research funding. Such concern, he suggests, evidences a misunderstanding that universities can generally solve public problems without the further collaborative aid of industry, or at least have the means to determine whether the practical results of their research have been adopted and applied by industry. Several barriers to effective cooperative efforts are described. The conclusion is drawn that in order to afford the correct property exchange from the fundamental innovator to the industrial developer at the right time, the innovating university must identify the establish rights in more intellectual property than it will exchange through the timely management of intellectual property policies. Investigators must be taught to think ahead, since the patent laws are written against those who delay protection. (Author/LBH)

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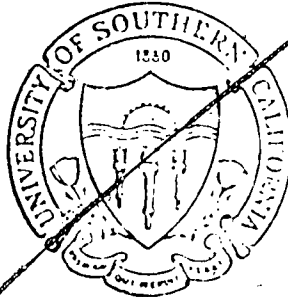
UNIVERSITY PATENT POLICY

by

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U.S. DEPARTMENT OF HEALTH
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"Ethical and Economic Issues - University Policies for
Consulting, Overload Instructional Activities and Intellectual Property"

University Patent Policy

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The social institution that is science has grown dramatically in the last 180 years. During this period the relationship of science to education, Government and industry has by necessity been significantly altered. Yet, I would suggest that in recent years the relevance of research performed at our universities to modern industrial society has become less apparent than it has been in years past and must be positively rearticulated.

Probably the most important impetus for change in the scientific scene during this long period was the industrial revolution and the demands of the new industries for greater scientific input. This was explicitly recognized in the creation of the Ecole Polytechnique in 1794 by a group of noted scientists led by the chemist Fourcroy. Fourcroy saw that "a sound training in the geometrical and physical sciences was all the basis industry needed for aiding the country in its defense during war".

The Ecole Polytechnique experience can be identified in the support which German industries, particularly the chemical industry, gave to the Technisches Hochschulen which sprouted in many German cities. History leaves little doubt of the industrial motivation behind the founding of the Royal College of Chemistry and the Royal School of Mines in England.

It was at research institutions like this that important 19th century generalizations in science emerged, such as: the theory of conservation of energy, the atomic theory of matter, the germ theory of disease, the field theory of forces, and the cell theory of the organism. It then appeared that nature would inevitably be mastered by man.

But even as we look at these representative theories, we note that this was also a period of scientific specialization, during which there was much effort directed to reducing such complex theories into innovations which fed the industrial revolution.

Thus, the synthetic organic chemical industry and the electrical industry could not have existed except for the scientific discoveries made in laboratories of the emerging research institutions. Further, then as now, the translation of new scientific discoveries into successful industrial tools depended, moreover, on the development of scientific and technical education and training furnished by such institutions.

The synthetic dye industry was born in the year 1856, when William Henry Perkin, an eighteen-year-old student at the Royal College of Chemistry in London, synthesized a strong mauve dye from coal tar. The process was not patented. Within a year, Perkin launched a new industry with the aid of his father. The synthesis was made in a laboratory at a technical college

and the ability to put the new science to work depended upon the fact that there were a large number of trained chemists, graduates of the Royal College of Chemistry and of the Technische Hochschulen in Germany - - people who knew how to manipulate and control the many processes involved in the making of organic dyes. By 1862, five years after Perkin began manufacturing, five important industrial colors were being synthetically produced. Synthetic mauve, fuchsia, aniline blue, yellow and imperial purple which were previously made from their natural analogues, changed the economy of several nations.

Yet, notwithstanding the British preliminary discovery, within a short time Germany had outstripped England as a producer of organic dyes, and by the end of the 19th century Germany was exporting synthetic dyes to England.

The inability of the British to participate in the practical returns of a great industry which they made possible, was even more dramatically duplicated years later. The United States, capitalizing on the findings of Drs. Alexander Fleming and Howard Florey of St. Mary's Hospital of London and Oxford University some eleven years after the initial report on penicillin, created the antibiotic industry.

One may well conjecture that these major economic losses to the United Kingdom may not have occurred or would have been ameliorated if the investigators involved and their supporting management had taken greater note of the world's patent systems and their practical implications. I will say more on this later, though I would note that the United Kingdom is said to have taken these losses into consideration during its deliberation to establish the National Research and Development Corporation after the second World War.

The 19th century then can be understood as a century of applied science when we recognize that its achievements depended not alone upon the basic scientific discoveries made by the great men of science, but required the development of the institutional underpinnings - the educational facilities, the research laboratories, the instrumentation, equipment and chemistry which permitted the application of new discoveries.

But then, even as now, science and Government leaders could not agree on the balance of support between basic and applied research. Thus, Joseph Henry, the first Secretary of the Smithsonian Institution, noted in the Institution's Annual Report of 1853 that:

"As soon as any branch of science can be brought to bear on the necessities, conveniences, or luxuries of life; it meets with encouragement and reward. Not so with the discovery of the incipient principles of science; the investigations which lead to those receive

no fostering care from the Government and are considered trifles unworthy of the attention of those who place the sum of their sin that which immediately administers to the physical needs ... But he who loves truth for its own sake, feels that its higher aims are lowered and its moral influence marred by being continually summoned to the bar of immediate and culpable utility."

As if in rebuttal, Dr. Henry Roscoe in his eulogy of Louis Pasteur in 1889 stated:

"For although it is foolish and short-sighted to decry the pursuit of any form of scientific study because it may be as yet far removed from practical application to the wants of men, and although such studies may be of great value as an incentive to intellectual activity, yet ... discoveries which give us the power of rescuing a population from starvation, or which tend to diminish the ills that flesh, whether of man or beast, is heir to, must deservedly attract more attention and create a more general interest than others having so far no direct bearing on the welfare of the race." (Emphasis added.)

Pasteur, himself a great pragmatist, once stated:

"There is no greater charm for the investigator than to make new discoveries; but his pleasure is heightened when he sees that they have a direct application to practical life."

The Pasteur statement, in addition to supporting applied research, carries with it an implication that there is an inherent desire in every investigator, which should be satisfied, to apply his fundamental findings.

It is my perception that the balance of research being conducted at universities with Government support today is substantially in the nature of that espoused by Dr. Henry, that is, basic rather than applied. I support this balance on

the grounds that sooner or later some important application of this research would find its way into our market economy. Furthermore, absent basic research, we would sooner or later reach the point where applications trailed off into insignificance. However, I believe this balance can better be defended if it is coupled with an increased and identified effort on the part of universities accepting support to transfer fundamental findings whenever possible to those in industry who could make best use of them or at least establish means to document the flow of research funds into practical results.

While I note no difficulties with the level of Government support going to universities for basic research if efforts at technology transfer are made, there is growing concern in Congress to better account for research funding. Thus, the Mansfield Amendment which permits DOD to support only mission-related research, and the recently defeated Baumann Amendment which proposed Congressional review of NSF grants, to assure use of funds for projects which evidence some prospect of solving immediate public problems.

Further, questions posed by the Congressional Subcommittees responsible for HEW and NASA appropriations have clearly indicated an interest in determining whether the funding of basic research at universities was generating solutions to public problems.

These inquiries to some extent evidence a misunderstanding that universities can generally solve public problems without the further collaborative aid of industry, or at the very least have the means of determining whether the practical results of their research have been adopted and applied by industry. In regard to the former, it appears necessary that we all make better efforts in the future to explain that Government support of research at universities is in the main to serve the purpose of generating fundamental bases of scientific information upon which industry builds useful results. However, in regard to the latter as I have previously suggested, I believe universities could be doing more to interface and obtain the cooperative aid of sophisticated industrial developers in delivering fundamental innovations to the marketplace. This effort seems to be needed more now than years past due to a number of barriers impeding meaningful interface and communication which did not exist in the 19th century. Some of these barriers might be considered; industry's preoccupation with its own in-house research efforts, the huge proliferation of basic findings, organizational barriers generated by size, Government pre-market clearance of drugs and medical devices and other regulation and the difficulty of establishing and transferring intellectual property rights.

Because of these existing barriers, it is perceived that mere publication of results will not necessarily guarantee utilization of fundamental findings. It is evident that intellectual property rights, including patents, are important to the accomplishment of utilization when it is understood that inherent to the transfer process is a decision on the part of the industrial entrepreneur on whether the intellectual property rights in the innovation being offered for development are sufficient to protect its interests. While we know that not all transfers include an exchange of intellectual property rights, it is unpredictable as to which transfers the entrepreneur will consider to require such an exchange. We do know, however, that where substantial risk capital is involved, there is a likelihood that transfer will not occur if the entrepreneur isn't afforded some property protection.

Now, this leads to the obvious, but not yet substantially implemented, conclusion that in order to afford the correct property exchange from the fundamental innovator to the industrial developer at the right time, the innovating university must identify and establish rights in more intellectual property than it will exchange through the timely management and intelligent intellectual property policies. Because of this necessary property protection, investigators must be taught to

think ahead, since the patent laws are written against those who delay protection. This management can only be afforded by universities willing to acquaint themselves with the basic principles of intellectual property protection and the ability to communicate to investigators its importance in the transfer mechanism.

Let me suggest that if this policy had been implemented by the United Kingdom as early as 1850, the British may well have shared in the economic reward of the synthetic dye industry for many more years than they were permitted by German competition. More important, the antibiotic industry may well be British rather than American, and penicillin might well have been brought to the public ten years earlier with the resultant preservation of hundreds of thousands of lives. As I noted previously, the British have attempted to avoid further loss of its economic position in British inventions by establishing NRDC, a central Government licensing organization. Although we believe the NRDC type organization not an adequate substitute for an effective university patent management organization, it has successfully managed the licensing and development by a British pharmaceutical concern of cephalosporin, one of the major second generation antibiotics generated by Oxford University with Government support.

It now seems clear that the continual stream of technological development, which forms an important basis for economic growth, cannot be obtained through the simple expedient of publishing scientific and technical ideas in the hope that their commercial relevance will be apparent to the industrial sector. University and investigator advocacy of such ideas is nearly always imperative in order to create a likelihood of their commercial use.

On September 23, 1975, the Committee on Government Patent Policy, acting for the Federal Council for Science and Technology in an effort to create an incentive in universities to advocate their inventive ideas and to eliminate one serious barrier to transfer, recommended that all the agencies of the Executive provide to universities a first option to substantially all inventions generated with Federal support, if they are found to have an identified technology transfer function. In addition, the Committee also directed that an interagency committee be formed for the purpose of joint agency identification of universities having a satisfactory technology transfer function. This recommendation is near final implementation through a Federal Procurement Regulation.

Notwithstanding these long sought positive developments, it should be noted that implementation of the recommendations by agencies that do not presently have such policies has been

left to each agency's own discretion. Accordingly, the opinions of each university on these matters will significantly affect the direction that individual agencies may take.

As I previously suggested, with well over 3 billion dollars of Federal support going to support of research at universities, questions on accountability can hardly be avoided and may well be easier to respond to if technology transfer functions capable of tracking results exist at all universities which are substantially involved in research. In other words, support of non-specific and non-measured objectives may well be in the public interest as suggested by Joseph Henry, but its justification will be much more difficult in this era of capital shortage.