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CURRENT GOVERNMENT PATENT POLICY AS APPLICABLE TO UNIVERSITIES AND NONPROFIT ORGANIZATIONS

To: Pat Hoyle
From: Norm LATKER

A few days ago, by happenstance, and coincidental to the remarks of the luncheon speaker, Mr. Baker, I came across and read for the first time the famous 1939 letter from Dr. Einstein to President Roosevelt pointing out to the President the imminence of the first controlled nuclear chain-reaction and the advent of the Atomic Age. In the letter Einstein made the following recommendations with a view toward expediting the work:

> "In view of this situation you may think it desirable to have some permanent contact maintained between the Administration and the group of physicists working on chain reactions in America. One possible way of achieving this might be for you to entrust with this task a person who has your confidence and who could perhaps serve in an unofficial capacity. His task might comprise the following:
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> a) to approach Government Departments, keep them informed of the further development, and put forward recommendations for Government action, giving particular attention to the problem of securing a supply of uranium ore for the United States;

b) to speed up the experimental work, which is at present being carried on within the limits of the budgets of University laboratories, by providing funds, if such funds be required, through his contacts with private persons, who are willing to make contributions for this cause, and perhaps also obtaining the co-operation of industrial laboratories, which have the necessary equipment. (emphasis added)

In these few words Einstein seems to have properly identified and assigned to each element of the collaborative team he deemed necessary to the completion of development, the duty which each would perform best. Thus, he suggests that the universities be aided in completing their experimental or fundamental research, that industrial laboratories be tapped for their ability to bring such fundamental findings into practical application through the use of their equipment and the Government act as the catalyst or impresario in bringing these factors together.

As simple as Einstein's formula for delivery of the results of fundamental research into practical use appears the Departments and Agencies of the Executive have done little to formulize it until recent years. The closing of the enormous gap between the fundamental findings of universities in new fields of knowledge as dramatically innovative as radar, computer memory cores, lasers, antibiotics etc., and their practical implementation by industry with the exception of the few cases

where the Government has determined to provide the continued funding to industry for development of such findings has been left to random and haphazard execution.

From the viewpoint of the Government and the public, the stake in closing this gap is very high. The sheer magnitude of Government support of research and development at universities demands evidence of useful results if it is to be continued in the prevailing competition for the Federal dollar. In fiscal year 1972, approximately $3.1 billion of the $12 billion; or over one quarter spent by the Government on research and development outside its own laboratories went in the form of grants and contracts to universities. Of the $3.1 billion the Department of Health, Education, and Welfare was responsible for administering $1.2 billion.

On September 23, 1975, the Federal Council on Science and Technology's Committee on Government Patent Policy recommended that all agencies of the Executive Branch provide to universities a first option to substantially all future inventions generated with Federal support, provided that the inventing organization is found to have an identified technology transfer function and subject to strengthened march-in provisions. 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.

These long sought positive developments were based on the June 1975 findings of the University Subcommittee on Patent Policy, an interagency group responsible to the Committee on Government Policy.

At the outset of its study, this subcommittee identified some general premises from which it would be necessary to proceed. As you will note all of these premises were intuitively understood by Einstein in 1939.

First, a sympathetic and encouraging Federal climate is very important to technological progress. Thus, in cases where the requirement for university/industry relations is not met in a satisfactory manner, Government can have an important role to play as a catalyst or "impresario" in creating the framework within which regular contacts take place between university and industry.

Second, the University community and industry, left to their own initiatives, will probably be unable to generate this atmosphere. Private business, even though concerned with institutional barriers that preclude systems innovations, can't do much about it. They are responsible for outputs of their businesses, and must ordinarily work within the narrow confines of the companies' responsibilities to maximize profits and minimize risks for the firm.

Third, there appears to be an absolute need for industrial collaboration with universities if the results of Government-sponsored university research are to reach the marketplace. This is true, since

much of the work performed under Government-sponsored grants and contracts at universities is basic, as opposed to applied research. Inventions arising out of basic research involve at most compositions of matter with no clear utility, prototype devices, or processes which usually require much additional development. Universities themselves do not undertake the complete development of such inchoate inventions as development leading to commercial marketing is not ordinarily within the scope of their missions or physical capability. Further, financing of that type of development work needed is not generally available from Government sources. Consequently, development of such inventions will generally be accomplished only where industry has knowledge of them and has an incentive to utilize its risk capital to bring them to the marketplace.

Last the difficulty of collaboration is compounded when those who now perform essential parts of a function refuse to modify their operations to meet the needs of the whole system. (The Committee's recommendations make it evident that the Federal Government was not to be excluded as one of the principals who must modify its operations.) These vested interests constitute by far the most serious institutional barriers to socially important innovations. Ordinarily, the principals can't be ordered to collaborate. Nor will they do so unless they see something in it for themselves. The problem perceived was how to provide the means for inducing them to integrate voluntarily into a

system that performs a socially desirable function.

With these premises in mind, the University Subcommittee began its review of the university difficulty in transferring the results of its research to industry. The following were identified as the primary problems that needed to be overcome before optimum results in transferring technology could be achieved.

First, and thought to be the most important, was the conclusion that universities do not generally have an adequate management capability to facilitate the timely identification, protection and the transfer of their inventive results to industrial concerns that might make use of them. Even those organizations having the right to transfer a degree of patent protection desired by industry may well fail to succeed in encouraging utilization if an adequate, organized effort to identify, protect and communicate these results is not made.

It was preceived that the mere existence of a body of research publications and other technical information was not enough to result in significant industrial innovation.

Second, was the "not-invented-here" syndrome. Industrial organizations have commercial positions in most areas of their research. Accordingly, there is an in-house incentive for such organizations to further develop the results of their research in order to improve their commercial position. This incentive stems

from the organization's ability to continuously evaluate their research through all stages of its development. It follows that there will be a lesser incentive for industry to further develop the results of university research where such research will not be under its initial review or control. It was suggested that this bias toward investment in further development of its own ideas, rather than ideas from outside sources, might be lessened by early identification by industry of university investigators who may be working in their areas of interest.

Third, was the uncertainty over ownership of inventions made at universities that may be collaboratively developed or are generated through a collaborative relationship.

DHEW had noted situations of industry refusal to collaborate with universities in bringing DHEW-funded inventions to the marketplace unless provided some patent protection as quid pro quo for additional investment and development required.

This was substantiated by the Harbridge House Study and a 1968 GAO Report on the DHEW Medicinal Chemistry program. Both of these studies indicated an industry-wide reluctance by pharmaceutical firms to test compositions of matter synthesized or isolated by DHEW grant-supported investigators due to DHEW's patent policy, which industry felt failed to take into consideration the large private investment before such compositions could be marketed as drugs. Similar situations

had occurred in the area of medical hardware devices.

It was determined from the experiences noted in university dealings with the pharmaceutical industry and medical device manufacturers that there will be the same reluctance to collaborate with universities in bringing other high-risk inventions to the marketplace if some patent exclusivity is not first provided to the developer.

Fourth, is the problem of contamination. As used by industry and university investigators, "contamination" means the potential compromise of rights in proprietary research resulting from exposure of industry to ideas, compositions, and/or test results arising from Government-sponsored research. For example, an invention made at an university under a Government-funded research program is looked into by a company doing parallel research. If the company incorporates into its research program some of the research findings of the university and then develops a marketable product patentably distinct from the university's invention, the company fears that the Government is in a position to assert claims to their product.

These problems had the effect of persuading the Subcommittee that the Federal Government needed to act to create an atmosphere conductive to the transfer of inventive results from universities to industry.

To overcome these barriers to technology transfer, it was deemed essential to the Subcommittee that the Government persuade universities to provide a management capability within the institution that will

serve as a focal point for identification,receipt and prompt protection of the inventive results of university research for later dissemination by itself or other management organizations to those industrial concerns most likely to utilize such results. It was the conclusion of the Subcommittee that this might be accomplished by guaranteeing to universities at the time of funding, patent rights in Government-supported inventions in return for establishment of a management capability created to undertake such identification, protection and transfer of the inventive results of university research. I believe that the primary basis for the recommendation was the realization that a substantial majority of inventive ideas require "advocates" in order to reach the marketplace and that experience indicates that the inventing organization, if interested, is a more likely "advocate" then a distant, unmotivated Government staff. The guarantee of patent rights to the university carries with it the right to license commercial concerns, thus creating the incentive necessary for development in those situations where collaboration would not otherwise be accomplished and lessening or eliminating industry fear of contamination. Further, under such a policy collaborative arrangements could be made wherein industry's participation is protected before it is even clear whether or not inventions will be made. Such prior arrangements should minimize the problem of the "not-invented-here" syndrome, since a collaborator would not be viewed as an "outsider."

As noted previously, the Subcommittee identified the problem as finding the means to induce voluntary integration into a system that results in technology transfer. It is believed that the Committee's recommendations provides such an inducement for all three of the parties involved through recognition of their equities.

To a large extent the September 23rd recommendations of the Committee on Government Policy are a ratification of the policies implemented by DHEW since 1969 and the National Science Foundation since 1974. The DHEW policies in turn, were initiated in part, through the impetus created by the critical remarks from the 1968 GAO study mentioned previously on the lack of timeliness in processing petitions for greater rights in identified inventions and the need to clarify the use of Institutional Patent Agreements guaranteeing future invention rights to universities with technology transfer capabilities.

Now, in practice, what has happened at DHEW since the 1968 GAO Report? In October, 1974 we collected some statistics which can be considered to be only approximate in that they were accumulated very rapidly through our files and with conversations with the parties in interest. The statistics are on the low side, as not all the interested parties could provide information to us within the time frame necessary, and most that gave use statistics were conservative when they felt figures could not be readily verified.

First, in regard to the GAO comments on Department performance, I would note, that since January 1, 1969, the Department has executed 62 new Institutional Patent Agreements (list available). Second, in regard to requests for greater rights in identified inventions under our deferred determination policy which is applicable to all universities not having institutional agreements and to all DHEW industrial contractors average processing time is running between 15 and 20 weeks from time of receipt of a petition to final determination. This compares to a situation in 1968 to which GAO aimed its recommendation for "timely determination of rights" when petitions basically were not processed.

Now, in regard to rights dispositions as of October 1974, our study indicates that 167 patent applications were filed since 1969 by institutions who chose to exercise their first option to invention rights under their Institutional Patent Agreement. Under the 167 patent applications filed, the universities have negotiated 29 non-exclusive licenses and 43 exclusive licenses. In addition, seven options to license have been negotiated. Seventeen joint-funding arrangements with commercial organizations, involving only the possibility of rights to future inventions, have been made. This is an important statistic since it indicates a willingness to make arrangements prior to the time that inventions have been made on the basis that the institution has the flexibility of providing to the

concern some invention rights if an invention should evolve from the jointly funded effort. The institution gains this ability to negotiate by virtue of its Institutional Patent Agreement. We were advised that on the basis of all the agreements noted, approximately 24 million dollars of risk capital was committed to the development or making of inventions evolving with DHEW support.

Under our deferred determination policy, it was determined that since July 1, 1968, 178 petitions have been reviewed as of October, 1974. Of these 178, 162 petitions were granted. Under the 162 petitions granted, the institutions involved and responding have to October 1974 granted 15 nonexclusive licenses and 35 exclusive licenses. These licenses have generated a commitment of risk capital of approximately 53 million dollars. One of the petitions granted involved a burn ointment discovered at an university, which was patented for the university by Research Corporation, licensed to a pharmaceutical company, clinically tested under the direction of the company, and cleared by the Food and Drug Administration on the company's initiative. The drug is now commercially available.

To my knowledge, this is the only drug outside the Cancer Chemotherapy Program which was initially discovered with Department support and has reached the marketplace through the investment of risk capital from the drug industry. We are aware of at least five other drugs outside Cancer Chemotherapy at various states of development

which were discovered with Department support and are now being developed with private support under licenses made possible under our deferred determination policy some of which are very close to market clearance. (I cannot at this time advise whether the licenses granted under inventions retained under IPA's involve any drug development situations, but it is presumed they do.) These numbers compare to zero situations at the time of the GAO Report.

The approximately 75 million dollars committed to development of Department initiated inventions, although on the face appearing to be insignificant in comparison to the $1.8 billion dollars yearly devoted to research and development at DHEW, is in fact substantial when compared to the 100 million dollars devoted to directed research with profit-making organizations in 1973 and to lesser amounts in preceding years. The comparison to the 100 million dollars is deemed more realistic, since the 75 million dollars of risk capital committed is substantially all for development purposes as is our the $100 million dollars committed to contracts with commercial concerns.

Much more significant than the figures involved (which I believe have greatly increased since October, 1974) is information provided by the University Community indicating that the last four years industrial organizations have been actively pursuing university research. I believe this to be clearly the result of the University Community's active solicitation of collaborative arrangements, which, in turn, was partly

motivated by the flexibility provided by our patent policy. Thus, while the GAO Report indicated that in many instances investigators formerly could not reach the point of conclusive failure with their innovations, that pathway appears to be open, along with the hope of successful utilization.

It is hoped that the growing success of the DHEW experience will be expanded to the rest of the Executive through the Committee on Government Patent Policy recommendations of September 23rd. DHEW recognizes that the tax funds available for the funding of R&D have been primarily generated by a free economy dependent on the private ownership and advocacy of inventive ideas as fostered by the patent system. Our intention is continued support of that system.