SES DRAFT
December 20, 1977

GOVERNMENT PATENT POLICY

Inventions resulting from research funded by the government constitutes a valuable national resource. The present amount of federal funds going into research dictates the necessity of examining the structural framework of the government's patent policy in order to maximize the delivery of inventive results to the public and protect the equities of all parties involved. A fair and productive government patent policy should avoid unjustified windfalls accruing either to the Government or the contractor. The unique position of the college and university community in patent development, warrants a detailed exploration as to where the equities lie with regard to ownership of patent rights developed on campus under Federal contracts.

The process of education in many colleges and universities embraces the conduct of basic research which may or may not develop a patentable item. In this respect, the resources of the institutions are devoted to ultimate objectives substantially different from those of private industry, whose purpose is to manufacture and market goods and processes for a profit in order to compete in the economy.

The Federal Government through its sponsorship of research conducted in universities has the objective of expanding the boundaries of existing knowledge in areas or on problems deemed in the public interest or related to national goals. The university is free to publish its research results and thus they are generally made available to all. This right is normally preserved in the negotiation of grants and contracts, as is the sponsoring agency's right to receive agree-upon reports. The occurrence of an invention during the course of the research is virtually always above and beyond the main objectives of the research agreement; in short, it is an incidental "by-product" and not a purpose of the research activity, largely attributable to serendipity and/or personal creativity of the investigator.

backed by his years of professional training and experience, and to the scholarly environment and research resources provided by the university. When patentable discoveries do occur, the equities to be recognized include those of the inventor, the university, and, very properly, the sponsors providing financial support for the particular research project most closely related to the discovery.

Inventions resulting from research sponsored by Federal agencies involve equities of the Government, the contractor and the inventor. Many factors must be considered in the decision of vesting the primary rights in such inventions. One factor is the extent to which the patentable discovery is (1) an integral part of the goals of the research or (2) a plus value or byproduct of the research derived from the creative abilities of the inventor and stimulated by the university environment.

When a patentable invention is made by an investigator in an academic institution with the help of Federal funds, rarely, if ever, are the Federal funds the sole or even the major factor contributing to the invention. The insight of the investigator, derived from a career working in a given field, is generally critical. The university itself virtually always helps to finance the laboratories, equipment and personnel contributing to an invention, and it provides a scholarly atmostphere. Accordingly, each of the parties has a claim in equity, and the problem is to decide who is equitably entitled to what, and what the most urgent social objectives are.

[redacted], a Government "take all" policy on the basis of its contribution eliminates the universities' ability to recognize the equities of other sponsors who contributed to the discovery of the invention as well as the contributions of the institutions themselves.

The results of the relationship between the Federal Government and its industrial contractors with respect to ownership of patent rights arising out of a contractual relationship is different from that between the Federal Government and colleges and universities. This difference arises primarily because educational institutions are not themselves organizaed either to manufacture or produce and market a patentable invention. Accordingly, if university inventions are to be used, institutions must seek to interest those in the industrial world who have the commercial capability the university lacks. This is often a difficult task, since few inventions coming out of university research offer prospects of a large market or a high return or investment. In addition, university based inventions are almost always in the early stages of development and require the investment of private risk capital to introduce the product to the market. Without the ability of the universities to furnish an exclusive license to the developers, and thereby induce the investment of the necessary capital by such developers, inventions resulting from Government contracts would not be developed to the point of marketability and thus the public would never receive the benefits of such invention.

In an industrial environment, the contractor's motivation for exploiting an invention may be conditioned by its possible interference with the contractor's existing products and/or a reluctance to issue licenses to competitors. Neither of these conditions exists in university research. The institution can objectively seek the best qualified source of development and monitor the diligence of the developmental efforts.

When the right to seek patents is reserved to the universities, patent applications may be filed promptly and negotiations immediately commenced with prospective licensees, with the active assistance of the inventor. When such right is not determined by prearrangement at the time of contracting, but

must await determination after the invention is made, substantial time is usually required to prepare documentation and apply to the sponsoring agency for determination. While awaiting the outcome of the administrative process, the invention lies dormant, and the inventor's interest in assisting in the development becomes attenuated and, therefore, more difficult to reestablish.

Deadlines for domestic and foreign applications are affected by " publication of patentable ideas in scientific journals. Delays in determining the disposition of rights to an invention result either in delay of publication of research results or risk of expiration of the time limit for patent application. Neither choice is beneficial to the public interest.

Universities are unique instruments for transmitting inventions into the economy, for the public benefit, since private industry is more receptive to inventions or ideas generated by the academic community than those originating from any other source except their own in-house resources.

The university's motivation in prosecuting applications for patents is not based primarily upon production of income for the institution but upon the timely promotion of actual availability of the new products or processes to the general public. When the Government retains title, the patent may be made available to all comers on a nonexclusive or even royalty-free basis. This is tantamount to "dedication" of the invention to the public. In these cases, no one source is likely to have sufficient incentive to invest in the necessary development effort to make the product or process available to the public. Indeed, the tremendous investment required to bring a product or process to a marketable condition is sometimes far greater than the investment in original research from which the invention results.

Mere exclusivity in patent rights does not ipso facto create artifically high prices for related products. Royalties generally represent only a very small fraction of the retail price of marketed goods. Moreover, one must face the inescapable conclusion that the development of inventions under a liberal Government patent policy will benefit the public by making available products that would otherwi se not have been available at any price.

The university capability of transferring inventions to the beneficial use of the general public is an important national resource. The public obtains the benefit of this valuable resource through the efforts of those sponsoring agencies which offer adequate inducement to those who can bring the fruits of basic research into a form useful to the consuming public. Thus, economic stimuli afforded by a realistic licensing policy results in a public benefit, rather than causing an increase in the cost of the consumer products.

Under present government patent policy, in the absence of an "Institutional Patent Agreement," the Government normally asserts ownership of patent rights in any invention springing from government-sponsored reserach and requires a determination by the appropriate governmental department or agency of what use is to be made of such rights, in accordance with promulgated regulations. If an institution wishes to take title to an invention, it must request a waiver and a finding must be made by the Government that the invention would be more adequately and quickly developed for widest use, and the public interest will be best served, if the Government waives its claim of title to the invention in favor of the institutional sponsor of the research.

Where it is determined that it is in the public interest that expeditious development of the invention be undertaken, and that such development would be best accomplished by allowing the institution to have title to the invention, the granting of the waiver is subject to conditions specified by the Government.

An alternative to the "waiver" approach is the "Institutional Patent Agreement" approach, available since 1968.[1] This approach, endorsed by a 1968 GAO Report[2], permits the grantee institution to retain title and to administer the principal ownership rights in inventions made under department grants and awards, clearly defines the rights of the parties with respect to such inventions and sets forth general guidelines governing the licensing of inventions. It may include limitations on the duration of exclusive licenses to be granted. It also includes the reservation of a royalty-free license to the Government for governmental use and may include other appropriate safeguards to protect the public interest. These latter safeguards include a reservation to the Government of the right to require the granting of additional licenses on royalty-free basis or on other terms that are reasonable under the circumstances, where such licenses are necessary to fulfill public health, welfare or safety requirements.

In order that the usefulness of an invention may be manifested to the public, further development or engineering is usually required. Indeed, a normal prerequisite to further development or engineering, is testing or "screening" of a prototype of the product, process or machine which has been invented. Before the efforts and expenses incident to testing or screening are undertaken, those who are to invest in the promotion of the invention need to know who has the title to or ownership of the invention (i.e., the right secured to inventors and their assignees or licensees, for limited times as

---

[1] "Institutions Patent Agreement Governing Grants and Awards from the Department of Health, Education and Welfare" HEW Standard Form Rev. 8/26/68.

[2] Report to the Congress-Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry - Comptroller General of the United States - B 1640 31(2), 1968.

~~The leap [illegible] of fund~~

The difficulty in ~~expediting~~ nurturing the enormous leap of fundamental ideas from such laboratories to industrial development has been clearly recognized by the operating agencies of this Department ~~this Department~~ as will ~~become~~ appear ~~ent~~ from review of this report ~~and~~ and ~~contrary to~~ the assertations ~~of~~ throughout the ~~the~~ Dec. 22 report on "Health Technology Management" ~~are~~ to the contrary are deemed to be ~~[illegible]~~ in error as are the report's ~~recommendations~~ recommendations to solve what it perceives to be a problem

provided in the Counstitution).

There have been instances where prospective licensees have refused to undertake the testing, screening or development of inventions unless the licensor would grant an exclusive license for commercial sale or use. In some cases, no viable alternative has been available and, in the absence of an exclusive license, the public has not been able to obtain the use of the product, process or mahcine.

The universities, obviously, do not usually possess the critical facilities necessary to bring drug products (for example) from the clinical testing stages to marketability. Thus, it is imperative that the universities be in a position to grant either exclusive or nonexclusive licenses to those organizations which already have those critical facilities.

Qualified universities that have developed a transfer capability in government-supported inventions should be granted a first option to the title on that campus developed process. However, one must recognize that rights must still be reserved to the government in order to prevent abuse of patent rights retained by the institution and to minimize any anti-competitive effects that may be generated by such a policy. In addition, government personnel, since they are not as intimately familiar with the process that has been developed, would be in a much less favorable position to ascertain the commercial marketability of a given porcess. It is, therefore, feared that the ultimate result of a government title policy coupled with a licensing approach could well be the drying up of inventions disclosures from university researchers, and the failure to adequately bring possible useful processes to market. Institutions with technology transfer capabilities should be given the option of ownership of inventions made in the course of any contract, grant or other arrangement.

make a profit in the short and medium ~~and~~ term by spending on advertizing, and improving manufacturing processes.

This appears to be the reason why innovation ~~do~~ is not ~~get~~ championed effectively in large corporations such as the smokestack industries except in rare cases. ~~Explains of~~ ~~Probably the best expl~~

The Life Sciences

(Attachment — diagrams the route from genesis to use of a new drug)

While the innovative process in general is complex for the reasons stated above, ~~its co~~ ~~the addition of~~ ~~the~~ Government regulation of many life science innovations adds ~~a formidable barri~~ an additional barrier of ~~enorm~~ enormous proportions that must be overcome by the innovating ~~[illegible]~~ entity. This additional barrier ~~becomes~~ is even more formidable ~~if~~ to the innovator ~~is~~ employed by Government, a non-profit organization or a university ~~who are all of which are isolated~~ ~~isolated~~ ~~from the resources~~ ~~for resources of the industrial concerns~~ ~~necessary to~~ ~~none of which~~ who can not unilaterally command ~~[illegible]~~ the resources that ~~are~~ must be forthcoming from industrial ~~concerns~~ sector in order bring their innovations to fruition with ~~over approximately~~ over 3 billion dollars being utilized by Government non-profit and university laboratories for research in the life sciences the need for ~~[illegible]~~ policies that enhance collaboration between ~~those~~ such laboratories and industrial developers seems apparent.

Many institutions have been able to license inventions made by their faculty members, students, and employees, to the ultimate benefit of the public. The public will suffer if an inflexible Government "Title" policy is adopted with respect to Federally funded research conducted by institutions of higher learning and other non-profit institutions or organizations. The motivation of institutions of higher learning in obtaining and promoting the utilization of patents is primarily based on their desire to make the products or processes actually and promptly available to the public. The monetary benefits received by the institutions and inventors are secondary. With the active assistance of the inventors, the institutions are in a better position than the Federal Government to transfer the technology to the public through the economy. A Government "Title" policy, however, precludes the university from recognizing the equities of others, including inventors and non-governmental sponsors, and fails to acknowledge an important national resource which more than compensates the tax-paying public for its contribution to the institutions' research efforts.

Innovation and the Life Sciences

to difficult social problems

In General

Before any recommendations can be formulated on how innovation in the life sciences should be managed, it is important to have a basic understanding of innovation.

~~First~~, It is important to recognize that inventions are not generally "flashes of genius" which provide instant solutions but more likely a system of costly incremental developments taking anywhere from 15 to 50 years before understood, accepted and widely adopted. Few great inventions emerge under ~~the pressure of~~ time constraints no matter what resources are brought to bear in ~~resolving a problem~~ bringing them forth. ~~Because of~~

Failure to address the fact that technological solutions take long periods of time to evolve have generated in many situations intervention attempts on the part of ~~well meaning~~ lay people that in most instances complicate rather than expedite ~~technolo~~ innovation development.

Because of these long periods of ~~time~~ ~~necessary to bring innovation to fruitition, it becomes axiomatic~~ ~~a diligent~~ the presence of a highly trained diligent enthusiastic, nearly obsessive, individual who will advocate the innovation is axiomatic. Since resources are a fundamental part of successful innovation ~~in the life sciences~~ such individuals are ordinarily ~~usually~~ found in organizations ~~corporations~~ willing to devote such resources to accomplish the innovator's desires. While large corporations have all the resources necessary to satisfy the innovator's needs, generally their resources are not utilized in this manner since it is alternatively easier for such a corporation to

often confronted by social hostility that views change as disruptive of the status quo.

and financial technical and social hostility