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Memorandum

TO : Chief, Division of Research Grants DATE: July 6, 1962

THRU : Chief, Research Grants Review Branch, DRG

FROM : Executive Secretary,
Medicinal Chemistry Study Section

SUBJECT: Procedures Relating to Patent Policy

Transmitted herewith is a statement on the "Impact of New Procedures Relating to Patent Policy on the Public Health Service Extramural Programs" submitted on behalf of this Study Section.

The members hope that this report will be widely circulated and given careful administrative consideration.

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IMPACT OF NEW PROCEDURES RELATING TO PATENT POLICY ON THE PUBLIC HEALTH SERVICE EXTRAMURAL PROGRAMS

The sharp increase during the past five years in governmental spending in support of research and development, directed largely toward the development of a space-age technology, has resulted in the expression of concern, especially by members of the U. S. Congress, that unless adequate safeguards are provided, some individuals or corporations may turn some of the fruits of this effort to selfish financial profit. The preventive measure most often proposed is a restatement of patent policy and changes in patent procedures relating to Federally-supported research and development.

It should be recognized at the outset that the majority of commercially exploitable products or discoveries are much more likely to be encountered in developmental research than in fundamental scientific studies. In general, Federal research and development expenditure is through the contract instrument for attaining developmental goals. A contract is essentially a purchase order for delivery of a specified item, be it a necessary new component or system for a satellite or missile, a material of defined properties, or the application of specified criteria for selecting materials to meet a defined goal. Contract-supported developmental research constitutes a small fraction (less than four percent) of the current dollar value of the extramural programs of the Public Health Service.

One of the principal goals of these Public Health Service programs is the support of fundamental research in the health sciences through the grant mechanism, which in sharp contrast to the contract instrument, is an assistance program for a scientist. Other Public Health Service extramural programs deal with training of research scientists at the pre- and postdoctoral levels, support of established investigators, and partial support of construction of new research facilities.

The aim of fundamental research is the discovery of new knowledge, without concern as to whether it can be applied to solution of practical problems. It is generally agreed that we must maintain an adequate reservoir of new knowledge, in order to provide, among other benefits, a well-spring of information necessary to the solution of practical problems of importance to society. In recent years, many expert scientific advisors have warned that the accentuated demands of World War II for application of extant knowledge dangerously lowered the reserve of unapplied fundamental information, and have recommended that immediate restitutive steps be taken.

It is to be hoped, in the interest of maintaining the vigor of our national scientific effort in both fundamental research and developmental (applied)

research, that those who finally set patent policies and procedures relating to government-sponsored research and development understand clearly the different circumstances under which these two activities are conducted. Tempting though it may be to evolve a single blanket policy, the differences in the endeavors may be so great that this will be impossible to accomplish. Irreparable harm can be done to fundamental research by application of a set of policies that might be quite workable, on the other hand, in the developmental research area. Congressional review and directive may eventually be necessary, both to assist the various governmental disbursing agencies in arriving at satisfactory policies, and to protect the agencies against criticism.

Beginning not later than 1955, it is clear from the regulations under which the Public Health Service operates that public benefits and rights are to be recognized in the fruits of scientific research or development supported by Public Health Service funds; this was later extended to include activities assisted by Public Health Service awards. Prompt publication of new knowledge is understandably encouraged as being in the best interests of the public and of science. The situation regarding inventions arising in the sponsored work is less clear. No definition of the term "invention" is offered; presumably, the term "patentable discovery" could be substituted. In order to be patentable currently in the U. S., a discovery must involve a novel material, process, or use. In addition, the discovery must have an unexpected quality, not predictable from past knowledge. It is evident that recognition of whether an invention has been made requires knowledge, not only of the general scientific literature in the field of the invention, but also of the specialized information contained in the patent literature. Finally, the drawing up of a successful patent application almost invariably requires the collection of a substantial amount of supporting data to defend the claims of invention.

The Surgeon General is authorized by current regulations to determine disposition of inventions growing out of Public Health Service financial sponsorship, and to see that public use of such inventions is not unduly restricted or denied. Alternately, this disposition may be determined by the nonprofit grantee institution if there is in effect a separate formal institutional patent agreement with the Surgeon General. It is recognized that patent protection of the invention may be advisable, in order to foster an adequate commercial development to make a new invention widely available. The policy is also expressed that in the case of inventions arising from work only partly supported by Federal funds, the public use of the fruits of the research will not be unduly restricted or denied. It has not yet been determined how small the Federal contribution need be before this equity is inoperative.

A new procedure was initiated by the Public Health Service in February, 1962. The obligation was restated for prompt reporting of all inventions arising from activities assisted by Public Health Service grants and awards. In addition, the responsible individual involved in a research grant, training grant,

or career or fellowship award, and the institutional official responsible for patent matters are required to co-sign an Annual Invention Statement listing inventions conceived, reduced to practice, or made the subject of patent application. If none of these items were involved in the supported program, it must be so stated. Continued support of the program is contingent on filing of the Statement. There is no difficulty in dealing with the latter two categories of information, as it is quite clear to the investigator and his institution whether work is in progress on filing of patent applications. To decide, however, whether inventions have been conceived in the research or training program may be extremely difficult or impossible for the investigator, within the resources available to him. Obviously, both he and his institution run the risk of perjury in this connection, and it is grossly illogical and unfair to require that a positive statement be made in the face of such uncertainties. For example: None of the material* supplied to the Study Section defines the term "invention". Thus neither the principal investigator nor the "official of the University responsible for patent matters" knows exactly what he is signing.

It would behoove each principal investigator and the individual responsible for patents not to sign the Annual Invention Statement until some definition of "invention" is supplied by the U. S. Public Health Service. It is suggested that an invention should be defined as " a novel idea, product, compound or device or any 'new use' which may have monetary value if patented by the discoverer, or potential monetary value to others if published."

Grants are made on the premise that the grantee will make a contribution to knowledge--a discovery, thus an invention. Strictly interpreted, if the principal investigator signs the Annual Invention Statement indicating that no discovery or invention has been made, it signifies that the expectations of the Study Section and Council which recommended the grant have not been fulfilled.

The main theme of the items on the Federal Register dated September 14, 1955 is the early recognition of patentable inventions or discoveries. The adjective "patentable" is however omitted in subsequent items in the Federal Register. Most of the ambiguity in the present Annual Invention Statement would be resolved if "patentable" were inserted to make the rulings apply not to basic discoveries but patentable inventions.

An alternate plan of dealing with this situation would involve submission by the investigator of all laboratory notes and records to a properly qualified body of experts for determination of whether a patentable dis-

*Reprints from the Federal Register dated September 14, 1955, December 4, 1957, February 27, 1958, memo of January 22, 1958, face sheet of UEPH research grant application, procedure sheet from PHS 3945 1-62, and Annual Invention Statement, PHS 3945.

covery had been encountered, and a decision of what additional steps, if any, should be taken. There is no quarrel with the concept of review of the result of contract-supported research of a developmental character, where patentable discoveries are likely to occur, and where the contractual relationship regularly provides for the presentation of reports and data to the contracting officer of the sponsoring agency for this purpose. To apply the same operational principle in the area of research grants and awards, where such discoveries are relatively quite rare, would result in a large, unjustifiable financial burden to the U. S. tax payer. The public interest would not be best served by other consequences of such a policy. Traditional academic freedom of the investigator, so necessary in the pursuit of new knowledge through fundamental research, would be invaded or destroyed by the undue emphasis and preoccupation with pragmatic qualities of the work. The burdensome collection of information required for reduction to practice of an invention and defense of patent applications, which would not add to the body of fundamental knowledge, would further distract the investigator from his primary responsibility. Wide and prompt publication of research findings would be delayed, impeding scientific progress.

The following recommendations are offered:

(1) The Annual Invention Statement on Public Health Service Grants and Awards should be modified promptly in the introductory phraseology so as to exclude consideration of conception of invention, leaving intact the questions regarding inventions reduced to practice or which were the subject of patent application.

(2) The entire matter of patent policies for the total ramification of Federally-sponsored research and development should be examined at high level(s). In such a review, the intrinsic differences between contract-supported developmental research and grant- or award-supported fundamental research must be recognized. Hopefully, a framework of policies and procedures might be evolved which will better serve the public interest than those in current operation. This framework should foster a wholesome environment for discovery and dissemination of fundamental new knowledge, and yet provide an effective operational plan for developing and making available to the public the pragmatic applications of this knowledge, using extant industrial resources of our nation with supplementation, when necessary, by Federal subsidy. Realistic policies must be evolved for licensing the commercial development of useful inventions growing out of Federally-sponsored development programs, such that the public will not be denied their benefits. When both governmental and

and nongovernmental funds are involved with the development, a fair determination of equities of the various parties must be recognized. The specialized problems of the various disbursing agencies of the U. S. Government in operation of research and development programs must be considered, in order that the final policies and procedures offer reasonable protection to the agencies against criticism, and avoid the need for intra-agency interpretations and regulations.

Respectfully submitted by the
undersigned members of the
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