DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE

Surgeon General, PHS

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Director, NIH

Need for Changes in Department Patent Policy to Permit Effective Collaboration with Industry

The general problem

As you know, the Department's patent policy has been a controversial subject for a number of years. Dr. Endicott was so concerned about the area that he wrote to you on April 18, 1962, suggesting a thorough review. Since that time our problems in the area have increased to the point where it appears to be imperative that the Department policy be subjected to a prompt review. Many of our most pressing problems occur at the point where our scientific investigators feel that it is essential to collaborate with a commercial organization in order to complete their work. As Dr. Endicott stated, drug manufacturers are unwilling to develop drugs with limited markets without some degree of patent protection.

As you know, the DHEW Patent Regulations provide for reporting of all inventions generated in the performance of a PHS funded grant to you for disposition. Officially, paragraph 8.2(b) of the regulations permits the disposition of patent rights to a grantee institution if there is evidence that this will result in faster development of the invention for public use. In practice, this paragraph has not been used in approximately five years and proposals which have been advanced for Department approval have invariably resulted in decisions to keep title in all reported inventions with the Federal Government.

The Department has determined that when compounds are synthesized by grantees with NIH funds and the grantee's suggested therapeutic utility is confirmed by an independent screener, the resulting invention, as above, will be reported to you for disposition. Title to the invention, as above, accrues to the Government whether the screening is done gratuitously or for hire.

NIH does under some circumstances, e.g. CCNSC, aid its intramural and extramural organic chemists in bringing a compound which suggests therapeutic use to the point of commercial use by financing the development

of clinical data needed to support an approved new drug application (N.D.A). Further, NIH is supporting a number of investigators who are developing clinical data on industry owned compounds. These data ultimately form a portion of the data accumulated by industry in supporting their N.D.A.'s. But in a number of situations NIH's ability to aid its intramural and extramural organic chemists is limited to the funding of the actual synthesis of the compound, and providing or aiding in obtaining screens designed to distinguish possible useful from non-useful drugs, and possibly a portion of the clinical data needed for an N.D.A. But an N.D.A. requires (1) extensive clinical data along with (2) toxicity data and (3) any data showing adverse side effects that develop in the course of clinical use. Thus, the NIH supported scientist who possesses a compound with a suggested utility or with a utility confirmed by an independent screener and would like to have it brought to the point of commercial use finds that the drug industry is best able to accumulate all the data necessary for licensure of a new drug because of organizational structure and continuing familiarity with various requirements essential to their objectives.

Attitude of the drug industry

But the drug industry has refused through the Pharmaceutical Manufacturer's Association (PMA) and in some instances individually to collaborate with our scientists in bringing their drugs to the point of practical application without some guarantee of exclusive patent rights as compensation for and protection of their possible investment. Since an investment ultimately may amount to between $200,000 and $400,000 for an N.D.A., PMA feels the requested exclusivity is needed because the risks of ultimate non-marketability, due to uncertainty as to ultimate safety and effectiveness, continual obsolescence of drugs, as well as the ever present competitive factors. Under present Departmental policy, it is clear the above guarantee cannot be given. As you can see, this situation results in a serious loss of incentive to invest in the perfection and marketing of PHS supported inventions.

Pending cases

We have some of these cases pending now in both the intramural and extramural areas, and it appears that positive resolution may not result without some change in our policy.

As an example of a situation existing in our intramural program, Dr. Sjoerdsma of our Heart Institute has devised a new test for pheochromocytoma based on pressor responsiveness to tyramine. The use of tyramine in testing for pheochromocytoma has resulted in no morbidity as is associated with the commonly used test for this condition. This test is certainly of medical importance but could not be considered financially important to a commercial organization.

Since this invention involves the treatment of the human body, an N.D.A. would have to be obtained before the invention could be placed in the hands of the public. NIH has no program which would provide the toxicity and clinical testing data necessary for such an N.D.A.

Merck Company, a leader in the hypertension field, has indicated to Dr. Sjoerdsma that they would be willing to compile the necessary data for an N.D.A. but has requested that they be granted a 5 year exclusive license in order to recoup their investment. Presently, the Bureau of Medical Services is investigating their capability in accumulating the clinical data necessary for an approved N.D.A. for Dr. Sjoerdsma's test. It is not clear at this time whether they will be able to proceed.

In the extramural area we have a similar problem with a Dr. Rose of McGill University who has found that Schering Company, a leader in the field of antihistamines, is willing to compile the necessary toxicity and clinical data for a drug synthesized in performance of a PHS grant for use as an antihistamine. In return for this service Schering asks for exclusive patent rights.

President's 1963 memorandum

Perusal of the President's October 10, 1963, memorandum on patents indicates that the Government has a responsibility to foster the fullest exploitation of its inventions for the public benefit. The memorandum further provides that the public interest might be served by according exclusive commercial rights to a contractor in situations where a contractor has an established non-governmental commercial position and where there is a greater likelihood that the invention would be worked and put into public use than would be the case if the invention was made more freely available. If such rights are accorded a contractor, the memorandum requires safeguards against repressive practices and insures that the public will be adequately protected by a clause similar to the "march-in" clause of our Cancer Chemotherapy Research Program.

It would appear from these provisos that it is the obligation of the Department to see that drug inventions synthesized at its expense are brought to the point of practical application by any means at its disposal, one of which may be the granting, under proper safeguards, of exclusive rights to private industry as an incentive for further development.

NIH recommendation

I personally am in favor of granting short periods (in relation to the usual 17 year patent monopoly) of patent exclusivity in a situation as discussed above, since compounds which show some promise in early stages of investigation are of no benefit to the public and do not serve the public interest unless clinical testing for an effective N.D.A. is undertaken and the resulting drug marketed. Further, since the risks of ultimate non-marketability of such compounds are very great, it seems to me that the Government should encourage industry to take the risks of development in the public interest, provided, of course, this is done under the safeguards set forth in the President's memorandum.

I would point out that, in lieu of granting such exclusive rights, we could enter into contracts to develop NIH inventions and pay the full cost, including a reasonable profit margin. It would seem obvious, however, that it is infinitely to the Government's advantage to encourage industry to finance the cost and take the risk through the granting of exclusive rights under the provisions of the President's memorandum.

's a further thought in regard to this matter, I would like to point out hat, as the Department patent policy reads now, CCNSC could enter into a contract with a drug manufacturer for drug development and leave patent rights with the manufacturer through the alternate patent rights clause. But if this same drug was synthesized by one of our grantees or employees, we could do nothing to give exclusive patent rights to the same manufacturer in order to bring the drug to the point of practical application. This seems to be inconsistent and should be rectified.

Anything you can do to bring these problems to the attention of the Department for positive resolution would be greatly appreciated. If I can provide you with further information on this matter, please let me know.

(Sgd) James A. Shannon

James A. Shannon, M. D.