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TO: Surgeon General, PHS
Through: Director, NIH

OD/NCI
April 18, 1962

FROM: Director, NCI

SUBJECT: Patent Policy

I am deeply concerned over our present patent policy and over operating trends which appear to be developing within the Department of the Public Health Service in implementing the policy. I think our policies need examination by an external study group selected so as to provide broad competence in economics, finance, industry and law, as well as science and medicine. I urge that you seek support from the Secretary for the appointment of such a body.

BACKGROUND

Our present patent policy for employees and grantees has not created many problems for us and has found some approbation in the Congress. On the surface, the policy appears to protect the public interest without imposing a serious administrative burden. In general, we advocate publication in lieu of patents and in those situations where patents appear desirable we dedicate the patents so as to make the inventions freely available. We rely on individual scientists and their institutions to determine when an invention has occurred and to inform us so that appropriate action may be taken.

But even the most casual examination of our file of invention reports discloses a general lack of awareness of the nature of inventions on the part of scientists and institutions. I suspect that many inventions go unreported. It is unlikely that the information in many of the published papers constitute invention disclosures sufficient to estop others from acquiring patents.

Growing awareness of gaps in our operations has led to a recent flurry of actions designed to tighten up the reporting procedure and thus give real substance to our patent policy. The steps taken thus far are superficial and will probably not change things much but there is increasing pressure to put real teeth in the procedure and to recruit a staff to handle the anticipated workload. The total impact of such a change is difficult to assess but there is much to suggest that by processing thousands of stimulated invention reports the Department could probably create a patent portfolio which would come to dominate the entire field of drugs and medical technical equipment. I am

uncertain what this would accomplish but it would surely impede scientific communication and might have profound effect on our domestic and foreign commerce.

To focus down on specifics may I offer the following comments on the regular patent policy which has three main elements:

(a) It emphasizes dedication of inventions to the public through publications;

(b) the grantees and employees are required to report inventions to the Surgeon General; and

(c) final determination of the right to patent is solely the responsibility of the Surgeon General.

Each of the above components of the patent policy presents problems -- some obvious, some obscure.

PUBLICATION

The publication policy presents a number of difficulties. The original supporters of this policy assumed that publication results in inventions becoming open to the public. Furthermore, it was assumed that placing an invention in the public domain would almost always serve the public interest. There are grounds for doubting that either of these two surmises are true.

Publications of scientific data by employees and grantees, like those by scientists generally, are not specifically designed to disclose inventions. Consequently one can expect that many published scientific findings will remain available to patent by others since the patent law requirements of full disclosure will not have been met. The pharmaceutical houses can be expected to capitalize on such an opportunity and they often employ university scientists as consultants who can help them do so.

Publication of new process or new use patents, relating to an already patented material, merely give added benefits to holders of product patents so the concept of free availability of such inventions is meaningless.

Where publication does result in an open invention it is not clear that the public interest is served. The drug industry in the United States is to a great extent built on patent rights. If a compound is open,

attempts will be made to develop a related compound, not necessarily better, which can be patented. Thus, publication tends to stimulate the marketing of patentable substitutes rather than the original and, perhaps, even better drug.

There is a considerable time and dollar span between a conceived and a marketable product. Applied research, development, production, engineering, testing, securing a new drug application, and marketing take much effort and substantial investment. There are reasons to believe that a no-patent concept delays the marketing of inventions because there is no protection for the investment of the developer. We know from experience that we have trouble getting manufacturers to produce new drugs with limited markets and which are not protected by patents. The situation regarding exploitation of unpatentable drugs of greater value is not clear but there are good grounds for believing that the delays in getting such an open compound to market is substantial unless the company can acquire other means of protecting its investment.

REPORTING OF INVENTIONS

Neither the HEW policy statement nor implementing instructions describe what an invention is, or at what point in the process between conception and demonstration of utility an invention is made.1/

Inventions simply are not being reported in anything like the volume one would expect in such a massive research program. Discussion of this phenomenon with scientists reveals both ignorance and apathy or even antagonism to patents and to invention reports.

Few of the scientists know the essential elements of a patentable invention and most of them are unaware that they are inventors. Those who do know prefer publication and see little point in filing an invention report since any patent which might result would probably be dedicated to the public anyway. They see no advantage to themselves, their institution, the government, or the public. Others are openly antagonistic on the grounds that the procedure delays publication, wastes their own time and tends to relegate them to the category of inventor rather than scientist. If their research is supported by more than one sponsor, they are reluctant to be caught in the middle between the conflicting policies of the several sponsors.

1/ It has been our observation that reporting of inventions, and decision-making on patents, requires closely knit organization, strongly motivated to the need for patenting, elaborate procedures and records for establishing priority of discovery and high-paid staff, including

In the area of pharmaceutical patents there is the additional difficulty in knowing who the inventors are. One man conceives the idea, another synthesizes the chemical, another proves its structure, another tests it in animals and still others prove its utility in the clinic. The total process usually involves non-grantees as well as grantees and not infrequently involves a pharmaceutical company as well as several independent institutions. We have given no guidance as to who reports, or when.

DETERMINATION OF PATENT RIGHTS

The third portion of the patent policy provides that the Surgeon General has the sole right of determination as to whether an invention should be patented. When an invention report is filed, the Surgeon General and his staff are immediately confronted with making the decision whether patenting is worthwhile. Considerable staff time has been taken on the very few invention reports that have come in. Unlike the drug industry, the Public Health Service does not have the skills and the environment to make judgments as to whether a patent should be pursued or abandoned since the major considerations may be economic and commercial and not scientific.

The claimed right of the Surgeon General to make binding unilateral decisions concerning patents presents major problems as we have become involved in multiple-support operations. Under the existing policy and practice, the Surgeon General is expected to claim all rights even though PHS support is negligible.

Of at least equal importance from the standpoint of stimulating collaboration with industry, the policy does not now permit an agreement in advance on the disposition of patent rights in a collaborative research program involving support from PHS and other agencies and organizations. Instead, the policy requires that, if any funds from PHS are involved, the Surgeon General must reserve sole right to dispose of the invention after the fact.

In conclusion, I believe that our current patent policy requires a major reexamination. In so doing we need to be clear as to what we are trying to accomplish and what must be done to accomplish it.

1/ Cont'd. patent attorneys and market experts in the drug field. Secrecy is essential. One finds these conditions in pharmaceutical houses but it is far removed from the situation one finds in the scientific environment we find in universities and nonprofit medical research organizations.

Furthermore, we need to understand and define public interest, and measure rights reserved to government in terms of practical improvement of the public health. Knowledge of the interplay of patent law, the dynamics of industry, grantee institutions and the behavior of scientists are all essential to the resolution of this complex subject. I suggest that arrangements be made by contract, or otherwise, to have this whole matter subjected to a thoughtful and imaginative study by a distinguished group of experts outside government who can bring a fresh view and broad experience to bear on our problems.

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