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They concede that the biggest hurdle to overcome is the weight of conventional wisdom. It goes something like this. Such a bill would permit the founding of monopolies that can charge high prices for the fruits of tax-aided research. It's a free lunch, say the critics, and it's not fair. One Senate aide who was skeptical of the bill put it this way. "At the stroke of a pen," he said, "you are creating billions of dollars of property that did not exist before, property that is created with taxpayer support. We are not about to jump on the bandwagon. We have an obligation to the public and to other patent holders. We want to make sure this is good public policy before we start touting its wonders."

For more than 30 years, the government has operated on the assumption that the economic rewards from federally funded R & D should be captured by the government, or shared only grudgingly with others, since public funds were used. Hence, the government's collection of 30,000 patents. That policy, however, has not produced an astounding record of economic returns, and the conventional wisdom on public money and private gain may be change. The innovation over, is becoming pop denced not only by the A domestic policy review coverage such as the 4 J cover story on innova "Has America lost its ed of opinion are shifting. It take a leap of logic to see lic policy might include private gain, especially w tive is patent portfolios on government shelves.

—WIL

Whistle Blower Reinstated at HEW

For more than a decade, Norman J. Latker, while working as patent counsel for HEW, urged the department to give the patents derived from HEW-funded research back to the universities that originally did the work. During this time, HEW patent policy became a model for many federal agencies. Then, last December, Latker was bounced out of government service after denouncing an attempt by his superiors to put a lid on patent transfers. He has now, however, been reinstated.

Latker returned to his post as HEW patent counsel at the end of July. The action was called for by a civil service review board that overturned Latker's firing on procedural grounds. HEW, which hedged for 1 month before commenting on the action of the review board, has decided not to appeal the ruling.

The reinstatement is timely. Support is now building for the Bayh-Dole patent bill, and Latker's return to HEW is seen by many university researchers and patent-transfer fans, to whom Latker is something of a hero, as a shot in the arm for their cause.

Latker is anything but a revolutionary. A 22-year veteran of government service, with 15 of them in HEW's patent office, he is credited with helping develop such mild-mannered innovations as Institutional Patent Agreements (IPA), which aid the flow of patent rights from government to universities. The story of their rise at HEW is simple. In 1968, the Government Accounting Office (GAO) investigated the pharmaceutical programs at the National Institutes of Health (NIH) and found no evidence that drugs developed with NIH support ever reached the public. GAO blamed the lack of technology transfer on HEW's practice of retaining all rights to inventions.

After a departmental shake-up in 1969, Latker helped develop a system whereby HEW automatically gave patent rights to the university where a discovery was made and allowed it to license the patent to a private company, which could then develop and market the product. Such IPA's were issued only to universities with a good track record of technology transfer. Latker, however, also urged the transfer of patent rights to universities without such an IPA, eventually releasing 30 to 40 patents a year on such a case-

send all requests for patent waivers up to the H counsel's office. And there they sat. Up unt Latker had final say on patent transfers. But n public position of HEW was that all patent n "under study," and that no one in the gene office was quite sure just when the review w ished.

By the fall of 1978, more than 30 requests f patents and three requests for IPA's were gath the general counsel's office. Universities go complained to Congress. So did Latker.

In September 1978, Senator Dole accus "pulling the plug" on biomedical research. To charge, he quoted an internal memorandum fr general counsel's office. "Recent experience v cost of proliferating health care technology," i gests that there may be circumstances in which ment would wish to restrict or regulate the ava cost of inventions made with HEW support." tary Califano and his advisers had decided to "runaway medical technology." One way to d parently to deny universities the transfer of from government-funded research. On 13 Sep Dole and Bayh held a press conference and a bill that would cut through the backlog. HEW quickly. The next day Califano ordered his sta the patents back to the universities. Within w released 20 of the 30 patents. Soon afterward leased Latker.

Departmental spokesmen now insist that La given the boot for blowing the whistle on H was dismissed, they say, because his super Beattie said Latker did not meet "professional and because of "specific instances" of mis cluding "forms of lobbying flat out forbidden ernment's codes of conduct."

Latker recently told *Science*, however, charges were never brought against him. He fired. But now that the civil service has reinsta HEW has decided not to appeal the ruling, La is simply glad to be back. "It's been a difficult

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE

Surgeon General, PHS

AUG 14 1964

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.

As a further thought in regard to this matter, I would like to point out that, 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.

1/3/66

COPY

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.

Kenneth M. Endicott, M. D.

KME:REL:egm

+ Legal 2-4

Manuel B. Hiller
Department Patents Officer

August 21, 1964

Deputy Surgeon General (SGD) DAVID E. PRICE

Need for Changes in Department Patent Policy--Transmittal of Dr. Shannon's Memorandum dated August 14, 1964

I am attaching a memorandum from the Director, National Institutes of Health, elaborating on the problem of collaboration with industry both by our grantees and by our own intramural investigators. We have recognized this problem for a considerable period of time and believe we cannot afford to let it go unresolved much longer.

When we first began to discuss it, the problem was more theoretical than real because experience had not clearly identified cases where our patent policy prevented a type of industrial collaboration necessary to the successful development of an invention to the point of public availability.

In addition to specific cases cited in Dr. Shannon's memorandum, we have the Jefferson Medical College-Rohm and Haas-Baxter negotiations that we discussed in my office on August 20. These tend to emphasize that our policy does not facilitate arrangements for bringing to bear the risk capital and technological know-how of the private sector. As you know, I concur in the point of view that it is preferable to create conditions that will attract private initiative rather than to undertake complete government financing of the cost of research and development of all inventions that grow out of the government's programs.

I should like to offer whatever assistance the staff of the Public Health Service can give toward an earlier resolution of this perplexing problem.

Attachment

8-26-64
cc: Dr. Meder
Dr. Sessons — initialed
Dr. Sherman
Mr. Latka
cc Dr Endroth per Dr Sessons 9/1/64