DRAFT LJacobs/joc 3/4/77

### THOUGHTS RESPONSIVE TO "TWO CULTURES IN THE LABORATORY"

and the second second

PATENT BRANCH, OGC DHEW

MAR 2 4 1977

I will start off agreeing with the last paragraph of "Two Cultures." Under no circumstances should an academic scientist be subjected to pressure from administrators to select product-oriented problems. We can help avoid such situations by stipulating in institutional patent agreements that the institution's patent office must be removed administratively from the scientist and must have no connection with promotion committees or other committees that deal with a scientist's career.

On the other hand, awareness of the potential of patents on the part of the scientist who is described by Hans as spending a morning in ". . . developing an instrument or method so that he can apply it to a research problem in the afternoon . . . " may be helpful to the university and to him. A notable example occurred here when Sid Udenfriend developed the fluorospectrophotometer. I don't know if the instrument would have been developed by a commercial firm without an exclusive license. I do think that it benefited investigators in that field by having the instrument become available to them.

There are many crossovers between science and technology. As Hans points out, people in academe do both. Also, many of the projects that NIH supports are not basic research, but applied. Indeed, we are currently engaged in an exercise to try to classify "basic" and "applied" by asking executive secretaries and study section members to put the projects they review into various classes, clinical vs. non-clinical, mechanism-oriented or treatment-oriented. We are trying to classify contractual projects similarly, including development.

Publications and patents are not antithetical. A paper can be submitted to a journal and a patent application can be filed at the same time. There is not much lost by doing both, except a little time. The patent advocates say that the patent is another method of disclosure of the results of research, and they claim that the patent, if properly administered, assures further effort in the development of an invention to practical use.

I am not so much interested in seeing that individual scientists are rewarded for inventions through patents as I am in providing additional funding for their institutions and, even more important, that the products of research are exploited for the benefit of the general public, who after all pay for the support of research.

The advocates of the patent system state that failure to patent inventions results in failure to have useful products or methods developed to the point of application, because investment capital is not available for development when there is no assurance that there will be a return on the investment. Private capital flows where there is some protection of the investment by a patent or a license. Otherwise, when there is no such protection, competitors may come in and exploit the development when it is achieved. This type of situation, it is claimed, results in potentially useful inventions sitting on the shelves. When asked to give examples of inventions that were not exploited because they were not patented and fell into the public domain, the advocates of patents say that they cannot prove the negative. They would rather give examples of the development that followed the issuance of patents under the Federal patent policy that went into effect in the Kennedy era. A list of patents that led to development is attached. Here again, it is a judgmental appraisal of costs of development and market potential when we try to decide if the work would have been done without a license.

The perception that I have is that antipathy to patents is a phenomenon of the biomedical research community. Certainly chemists and physicists in universities have been alert to patents for years, particularly the chemists. It is a matter of the way the biomedical research culture regards itself. However, I see no harm in making biomedical research investigators aware of the patent route to development.

As I stated at the outset, the principal danger, that investigators may be pressed into an orientation towards patents, can be averted by various means. I am not so sure, either, that the better investigators can be pushed that way. They are the better investigators because of their curiosity and their intuition. When, either as a result of an intuitive approach or a serendipitous observation, they make a discovery that can lead to a beneficial product if it is developed, they can benefit their instituions and society as a whole.

2

\_\_\_\_\_

D R A F T - 2/28/77DStetten/nh

#### TWO CULTURES IN THE LABORATORY

The public at-large has shown increasing interest in what goes on in the laboratories dedicated to research and development in our nation, and this is fostered by an increasing attention to these matters in the public press and on television. The public, however, is sometimes confused about what actually transpires, and particularly about the purposes and intents of the people responsible for the action. This confusion, it appears to me, is in part due to the ill-advised use of certain terms, and sometimes it is the scientist himself who is responsible for the confusing usage. It is my purpose in what follows to try to find some useful order in what currently approaches chaos.

There are two quite distinct cultures in this country. One of these is housed largely in the laboratories of our universities and medical schools. The other is the predominant activity of the laboratories of the industrial sector. In the academic environment there is opportunity for science to prosper. "Science" derives from the Latin word for knowledge. It treats [largely] of ideas and stands in contrast to technology, which is emphasized in many industrial laboratories. "Technology" stems from a Greek root meaning art or craft. It deals largely with things-materials, instruments, machines, and sometimes methods. Science and technology are both among the creative activities of the human mind and the human hand. They are extraordinarily valuable activities. They are interdependent and they interdigitate very closely, but they are not the same. The frequent linkage of the two words by the conjunction "and" does not in any sense imply identity, any more than it does for "bacon and eggs." It is generally relatively easy to tell the bacon from the eggs. It is also relatively easy usually to distinguish the science from the technology. Science progresses through the performance of research, while technology proceeds by the conduct of development. Again, as with bacon and eggs, although research and development (R & D) are often spoken of in one breath and often appear as a single budgetary item, they are not identical. In almost every instance, the person working in the laboratory will know perfectly well whether he is doing research or doing development. It should be noted that the very same person may alternate his activities between research and development. Thus, he may spend the morning developing an instrument or a method in order that he can apply it to a research problem in the afternoon devoted to an understanding of a fundamental mechanism.

The goals of the two activities are also distinct. Research, if successful, leads to discovery; and discovery, in turn, leads to publication. Development, on the other hand, leads to invention; and invention, if deemed meritorious, leads to patents. The rewards of publication are manifold and include ego-gratification, a possibility of academic promotion, and an increase in likelihood of success in the competition for research support. In the rare instance it may also lead to the capture of a prize. Whereas the acquisition of pants may also have many gratifications, the one which clearly predominates is money. These matters are summarized in Table 1.

2

Whereas these two cultures are distinct and different in their origins and in their purposes, they relate to each other in many ways. The advance of science is critically dependent upon many technological developments, such as the invention of a novel analytical instrument or the development of a useful chemical synthesis. Conversely, the development of technology is critically dependent upon the knowledge which is generated by scientific research. Certainly practically every major technological development in the past can trace its origins back to scientific research which was fundamental to the developmental process.

It should, of course, not be supposed that research is the peculiar domain of academia, and development the exclusive pasture of industry. This line has frequently been crossed and in both directions. The stress, however, is perfectly clear. Whereas publication is the highly respected product--indeed, the currency--of academic research, patents are an important expectation of industrial development.

It is my belief that this dichotomy has proven valuable and is, in general, a good thing. Both channels must proceed if the totality of purposes is to be achieved. A quenching of scientific research could soon lead to the exhaustion of undeveloped knowledge, while a failure of technological development would certainly markedly slow down the progress of science.

Whereas science and scientists may have a slightly tarnished image at this time and in this country, the United States continues to have a love affair with rechnology. We love our automobiles, our airplanes, our

3

calculators, and our kitchen appliances. It is notable that as our children progress through the school system and are repeatedly exposed to courses in American history, they learn a good deal about Thomas Alva Edison, Samuel F. B. Morse, Alexander Graham Bell, and Eli Whitney. But do they ever hear of Joseph Henry, Josiah Willard Gibbs, A. A. Michelson, or Robert A. Millikan? In most general history courses, science as such receives short shrift despite the enormous contribution which scientific research has made to our present way of life. Recently, technology has come into prominence in such widely used phrases as "technology transfer" and "technology assessment." Curiously, we do not hear much about either the assessment or the transfer of science. Even in the field of medicine, it would appear that it is technology rather than science which must be transferred from the laboratory centers to the physicians in the hustings. This suggests that we are expected to treat our patients with new pills and new procedures but not with new knowledge.

The stress on technology in the absence of an offsetting stress on science is not without hazard. Technology leading to patents is certainly fiscally more immediately rewarding than is scientific research. During the affluent period when scientific research has been very generously supported and academic centers were not in financial distress, scientific research has of course flourished. As academic centers find it increasingly difficult to balance their budgets, as universities and medical schools are forced to cut programs, as Federal and other support of scientific research fails to keep pace with inflation, a new pressure will surely

develop in the academic laboratories. One can imagine that the university officer whose responsibility it is to balance the budget may feel constrained to put pressure upon the scientists who are conducting research in the university laboratories to urge upon them to select product-oriented problems which may lead to remunerative patents. Thus, the financial officer of the university will behave very much as the director of development in an industrial situation must behave. Such pressure could, in fact, upset the present apparently satisfactory balance between the two cultures which we have described. The occasional development of a patentable discovery in the course of a research program has of course occurred and will continue to occur. Notable examples are the oft-quoted discoveries made by scientists at the University of Wisconsin, leading to the establishment and subsequent success of the Wisconsin Alumni Research Foundation. This, however, is quite another matter from the exertion of administrative pressure upon academic scientists to dedicate themselves toward patentable invention. Technological development will always continue to take place in the cellar of the individual inventor, in our great industrial laboratories, and from time to time in academic institutions. Scientific research, however, is so heavily concentrated in these academic institutions that if they should become inhospitable to this activity it would find no other place to go.

# Table 1

## The Two Cultures

Academia Industry Science.....(and)...Technology Research.....(and)...Development Discovery Invention Publication Patents Gratifications\* Money

\*See text

DRAFT LJacobs/joc 3/4/77

#### THOUGHTS RESPONSIVE TO "TWO CULTURES IN THE LABORATORY"

## -----

PATENT BRANCH, OGC

DHEW

MAR 2 4 1977

I will start off agreeing with the last paragraph of "Two Cultures." Under no circumstances should an academic scientist be subjected to pressure from administrators to select product-oriented problems. We can help avoid such situations by stipulating in institutional patent agreements that the institution's patent office must be removed administratively from the scientist and must have no connection with promotion committees or other committees that deal with a scientist's career.

On the other hand, awareness of the potential of patents on the part of the scientist who is described by Hans as spending a morning in ". . . developing an instrument or method so that he can apply it to a research problem in the afternoon . . . " may be helpful to the university and to him. A notable example occurred here when Sid Udenfriend developed the fluorospectrophotometer. I don't know if the instrument would have been developed by a commercial firm without an exclusive license. I do think that it benefited investigators in that field by having the instrument become available to them.

There are many prossovers between science and technology. As Hans points out, people in academe do both. Also, many of the projects that NIH supports are not basic research, but applied. Indeed, we are currently engaged in an exercise to try to classify "basic" and "applied" by asking executive secretaries and study section members to put the projects they review into various classes, clinical vs. non-clinical, mechanism-oriented or treatment-oriented. We are trying to classify contractual projects similarly, including development.

Publications and patents are not antithetical. A paper can be submitted to a journal and a patent application can be filed at the same time. There is not much lost by doing both, except a little time. The patent advocates say that the patent is another method of disclosure of the results of research, and they claim that the patent, if properly administered, assures further effort in the development of an invention to practical use.

I am not so much interested in seeing that individual scientists are rewarded for inventions through patents as I am in providing additional funding for their institutions and, even more important, that the products of research are exploited for the benefit of the general public, who after all pay for the support of research.

The advocates of the patent system state that failure to patent inventions results in failure to have useful products or methods developed to the point of application, because investment capital is not available for development when there is no assurance that there will be a return on the investment. Private capital flows where there is some protection of the investment by a patent or a license. Otherwise, when there is no such protection, competitors may come in and exploit the development when it is achieved. This type of situation, it is claimed, results in potentially useful inventions sitting on the shelves. When asked to give examples of inventions that were not exploited because they were not patented and fell into the public domain, the advocates of patents say that they cannot prove the negative. They would rather give examples of the development that followed the issuance of patents under the Federal patent policy that went into effect in the Kennedy era. A list of patents that led to development is attached. Here again, it is a judgmental appraisal of costs of development and market potential when we try to decide if the work would have been done without a license.

The perception that I have is that antipathy to patents is a phenomenon of the biomedical research community. Certainly chemists and physicists in universities have been alert to patents for years, particularly the chemists. It is a matter of the way the biomedical research culture regards itself. However, I see no harm in making biomedical research investigators aware of the patent route to development.

As I stated at the outset, the principal danger, that investigators may be pressed into an orientation towards patents, can be averted by various means. I am not so sure, either, that the better investigators can be pushed that way. They are the better investigators because of their curiosity and their intuition. When, either as a result of an intuitive approach or a serendipitous observation, they make a discovery that can lead to a beneficial product if it is developed, they can benefit their instituions and society as a whole.

3