FEDERAL PATENT POLICY AND H.R. 8596

ISSUE

There is ample reason to believe that the present legislative framework and administrative policies governing the disposition of Government-funded inventions may be inhibiting their commercial development. Given the fact that the Government is responsible for more than half of the total United States investment in R&D, it is essential that these dollars be made to produce more than defense and space benefits. On the international side, policies that discourage investment by U. S. industry in Government-sponsored inventions meant to resolve social problems leaves the door open for foreign industry, especially if state-controlled or subsidized, to capitalize on these inventions to the detriment of American jobs and industry.

Representative Thornton, joined by 13 Congressmen, including the Chairman of the Committee on Science and Technology, has introduced H.R. 8596, which would establish a comprehensive Government-wide policy regulating the allocation of rights to inventions made by Government grantees, contractors, and employees, having as one of its main objectives maximizing utilization of such inventions. The bill also provides legal authority, now lacking in a number of Federal agencies, for the licensing of Government-owned patents.

Summary of H.R. 8596

Briefly, the major provisions of H.R. 8596 are:

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Title I, which contains a statement of findings and purposes.

Title II, which provides an institutional framework through OSTP and its subcommittees to assure uniform implementation of the Act's provisions.

Title III, Chapter 1, which would allow grantees and contractors the right to retain title to inventions subject to various limitations and conditions, including a case-by-case right of deviation in individual agencies where, for example, the Government is fully funding the development of a product or process to the point of commercial application.

Title III, Chapter 2, which is an effort to codify the criteria of Executive Order 10096 initially issued by President Truman allocating rights in inventions made by Federal employees in performance of official duties, and which also includes authority for such an incentive awards program covering inventions made by such employees.

Title IV, which provides all Federal agencies authority to license Federally-owned inventions. It also provides the Department of Commerce with certain additional authorities, so that a centralized Government licensing program could be undertaken, although participation in the Commerce program is left to agency discretion, and

Title V, which contains definitions, amendments and repealers of existing statutes.

In my opinion, the bill, except for Title III, Chapter 1, should not prove controversial, since most of its provisions embody precedents and conclusions that have been to some degree uniformly agreed upon.

Controversy over Title III, Chapter 1, seems inevitable, since it would supplant approximately 22 different statutory and administrative policies and procedures covering allocation of contractor and grantee inventions.

Genesis of H.R. 8596

H.R. 8596 is the culmination of years of discussion and agency operating experiences starting from the increased influx of Government

research and development funds after World War II to the present 22 billion dollar annual investment. The bill in part is an adaptation of a draft bill that was prepared in 1976 by an Interagency Committee on Government Patent Policy who appear to have been partially inspired by the 1972 Report on the Commission on Government Procurement. The Commission, composed of public and private sector members, recommended that Government patent policy continue to be guided by the President's memorandum on Government Patent Policy. However, the Commission also recommended legislation similar to the H.R. 8596 in the event of unsatisfactory experience under the President's Memorandum.

More obvious problems under the President's Memorandum became apparent soon after issuance of the Commission report. First a Justice Department memorandum maintaining that disposition by the Executive Department of future inventions at the time of contracting constitutes disposition of property requiring statutory authority, and lawsuits filed by Public Citizens, Inc., based on that thesis, directly challenged the constitutionality of parts of the President's Memorandum. In addition, the Congress has since instituted a number of new research and development programs through statutes having patent policy provisions inconsistent with the President's Memorandum. Notwithstanding the withdrawal of the Justice memorandum and dismissal of the Public Citizens's suits on procedural grounds, the probability and actuality of additional suits based on the same thesis and additional piecemeal legislation prompted the Committee on Government Patent Policy to develop the 1976 draft bill.

Patent Policy Alternatives

The most basic aspect of Government patent policy involving grantees and contractors is the type of patent clause that is included in any given grant or contract. Basically there are three types of clauses that might be used in any given situation:

(a) A provision giving the Government title to all contractor inventions.

(b) A provision providing for contractor retention of title, subject to whatever licenses and other rights it is agreed that the Government will obtain, or

(c) A provision that the Government will have the right to determine the disposition of rights in any inventions after they are identified (the "deferred determination" approach).

Debate over Government patent policy has centered on which and under what circumstances these types of clauses should be used in Government contracts and grants.

For the most part Government agencies now use only the last two types of clauses, since even most so-called "Title in the Government" clauses provide to the contractor the right to request greater rights than a nonexclusive license after an invention has been made (unless otherwise precluded by statute).

Notwithstanding the number of outstanding statutes, most agencies, including major research and development agencies such as DOD and HEW, have no statutory provisions regulating their policies and have been guided by the Presidential Memorandum. In fact, many of the agencies with statutes have generally followed that policy to the extent that

it is not incompatible with their statutes. However, the President's Memorandum only establishes general guidelines as to when title in the Government, title in the Contractor, or deferred determination clauses should be used. It has not prevented the development of a maze of individual agency regulations and procedures, and has provided no guarantee that agencies would consider similar contracts as requiring similar clauses. H. R. 8596 has as one of its objectives the elimination of this current web of statutes and regulations.

Available Approaches for a Legislative Government Patent Policy

More important, H. R. 8596 has as its basic objective the development of a policy that will enhance economic growth by maximizing utilization of Government-supported inventions. The primary issue remains whether the approach taken in Title III, Chapter 1, of the bill will best accomplish that result.

It is anticipated that opponents of the bill will argue that allowing contractors to retain title is a "give-away," "anticompetitive," and provides contractors with a "windfall." Objective review of the subject has been difficult to achieve in the past, since opponents are wont to dispose of the issue through the catchwords cited above, and others such as "what the Government pays for it should own." Experience indicates that there are few situations in which the Government funds inventions resulting from its programs to the point of practical application outside of situations where the Government is the invention's primary purchaser. Notwithstanding, it is not possible at this time to

statistically conclude that the contractor's ultimate financial contribution to bringing an invention resulting from Government funding to the marketplace is in any given case significant in comparison to that of the Government. This leads to what is believed to be the most persuasive argument or approach available to opponents of the H.R.

. . . that disposition be made at the time of contracting on a case-by-case basis and/or deferred until identification of an invention.

Under such an approach it is contemplated that disposition, whether made at the time of contracting or after identifcation of the invention, will take into consideration the equities of the Government vis-a-vis the contractor in ultimately bringing the invention to the marketplace. However, since the equities of the parties at the time of contracting in a yet-to-be-made invention are virtually impossible to assess objectively, opponents of H. R. 8596 have indicated a clear predilection toward deferring determination of ownership until an invention has been made, so that deposition can be made on better facts. Accordingly, it is believed that if uniformity is to be one of the prerequisites of a legislative Government patent policy, the choice appears to be realistically limited to the H.R. 8596 and deferred determination approaches. (As already noted, a "title in the Government" approach which does not take into consideration requests for greater rights in the contractor after an invention has been made and has been virtually abandoned by the major R&D agencies, as it is not considered a means of maximizing utilization of Government-funded inventions, since it rejects the need

for the patent incentive in the contractor in all situations.) Accordingly, the remainder of the presentation is limited to comparing the H.R. 8596 and deferred determination approaches against the objectives sought by a legislative Government patent policy.

The Objectives of Government Patent Policy

There is general agreement that the primary objectives of Government patent policy should be to (1) promote further private development and utilization of Government-supported inventions, (2) ensure that the Government's interest in practicing inventions resulting from its support is protected, (3) ensure that patent rights in Government-owned inventions are not used for unfair, anticompetitive or suppressive purposes, (4) minimize the cost of administering patent policies through uniform principles, and (5) attract the best qualified contractors.

Comparison of the Deferred Determination and the "Title-in-the-Contractor" Approach Against the Objectives of Government Patent Policy

Objective (2) is satisfied equally by either approach, since the Government as a minimum will retain a royalty-free license, even if the contractor has title (Stated in other words, if the Government is the primary purchaser, it makes little difference who has title.)

The fourth objective (minimizing administrative costs) is best met by the H. R. 8596 approach, since agency experience indicates that a great amount of Government and contractor time is required to process requests for rights made under deferred determination clauses. Indeed, a great hardship would be involved in shifting to a Government-wide

deferred determination approach, unless this was accompanied by a significant increase in the patent and related support staffs of a number of agencies. For example, it is unlikely that DOD could expeditiously process each contractor requests for patent rights under a deferred determination procedure with present staffing.

The fifth objective (attracting the best qualified contractors) seems best satisfied by H.R. 8596, since there is evidence that many firms with established commercial positions and which are not primarily engaged in Government contracting would refuse to undertake or compete for Government research and development contracts (or subcontracts) in the area of their established positions if the Government insisted upon the use of a deferred determination clause. It is not realistic to believe that such firms will jeopardize a privately established commercial position on the chance of ownership of a major improvement of such position made with Government funding. Refusal to participate in this situation will probably necessitate that the Government contract with a less qualified contractor or not contract at all.

To avoid this problem the policy would have to leave open the negotiation of other terms in cases which demand deviation from a deferred determination clause. However, this would necessarily increase the administrative costs of a deferred determination approach, since negotiation of special patent clauses at the time of contracting is a time consuming process. More important is the fact that no definitive criteria has ever been developed, nor does it appear likely that it can be developed, which would establish when such a deviation was justified.

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This centers the debate on which approach best meets the objectives of promoting utilization of Government-funded inventions while guarding against abuse (objectives 1 and 3).

In general, opponents of H.R. 8596 argue that leaving first option to rights in inventions to contractors will not really ensure greater utilization and will lead to abuses, such as suppression, higher prices, and market concentration. Proponents argue that the H.R. 8596 will maximize utilization of Government-funded inventions, that the potential abuses are more theoretical than real, and that in any case, the bill's "march-in" provisions are available to rectify any abuses that might develop. They also argue that the issue of higher prices, to the extent it is true, assumes that the invention is commercialized, while under the deferred approach many fewer inventions will be commercialized. For those that are not, the issue of price is moot, and the public has been deprived of many new or improved products.

Factors Affecting Utilization

A decision by any firm to invest in the development and marketing of a patentable invention is dependent on numerous factors, only one of which may be patent ownership. Obviously, patent rights will not be a factor in such decisions unless a commercial market is envisioned. But all other things being equal, the ownership of patent rights is a positive incentive for investment in commercialization. Ownership may well be the deciding factor on commitment of private capital, since studies have shown that the cost of bringing an invention from its initial conception or reduction to practice (which is as far as most

Government inventions are funded by the Government) to the commercial market is approximately 10 times the cost expended in first inventing it under a Government grant or contract. In many situations this additional investment will not be made if it is perceived that a competitor can avoid this initial investment and undersell the original developer.

Further, as a general proposition, the inventing organization is more likely to be interested than will other organizations in commercializing an invention due to inherent ability to assess the merits of the invention from inception through early stages of development.

It is probably also better qualified, or at least as qualified as any other firm, to promote or undertake further technical development, since it may have know-how not necessarily available to other companies. It will also normally have an inventor and technical team willing to advocate that their idea be brought to fruition. Further, in the case of many commercial contractors a Government-funded invention may only be an improvement on extensive contractor-owned technology, and, therefore, will not alone form a basis for a major new commercial line.

Can the Deferred-Determination Approach Minimize Monopoly Profits Without Inhibiting Utilization

Because of the above circumstances, proponents of H.R. 8596 argue that there are strong reasons to permit the inventing contractor a first opportunity to retain title to its invention and commercialize it. Indeed, in the case of nonprofit organizations or smaller non-manufacturing firms, it is believed unreasonable to expect any effort on their part in transferring the invention to concerns capable of

marketing without the incentive of ownership. In fact, it is argued that there is little point in going through a deferred determination process if the Government's objective is to maximize utilization.

Deferred determination advocates would claim that the Government can make a better judgment after the invention is identified, denying where not necessary exclusivity and all the abuses it may engender. Implicit in this claim is the assumption that Government personnel will either be in a position (i) to determine if the existence of exclusive patent rights is needed as an incentive to further development, or (ii) to find a better qualified firm to commercialize the invention through a Government licensing effort after taking title to the invention.

As to whether exclusivity is needed as an incentive for private investment in an identified invention, it should be recognized that if the Government determines that exclusivity is not needed but is wrong, no further development may take place. On the other hand, if the Government was right, consumers may save the hypothetical difference in price that would be charged by someone holding exclusive rights, as opposed to someone who developed the product without exclusive rights. In any case, the public will presumably get an improved product or process which they find more beneficial than its previous alternative.

Moreover, for the Government to be right more often than not when making a deferred determination would require extensive technical, marketing, and economic studies of the firms, technology, industries

and market involved. The cost to taxpayers of such programs could be more than any savings they would produce for consumers. This appears to be the present situation, since in most deferred determination cases exclusivity has been deemed necessary, and the costly determination process has been engaged in simply to confirm this fact. This has been substantiated by NASA, HEW and NSF (the three agencies who have historically made the largest number of deferred determinations) by the grant of over 90 percent of the requests for "greater rights" over a period spanning 10 years.

Similarly, the ability of Government personnel to decide after an invention is identified that utilization will best be promoted by the Government's taking title and offering the invention for licensing, assumes that commercial developers, other than the inventing contractor, can be found (presumably but not necessarily on a nonexclusive basis). There is really no effective means for Government personnel to ensure that other firms, whether licensed exclusively or nonexclusively, would do a better job of developing the invention than a willing contractor or a licensee of the contractor. One can be sure that in most cases the inventing organization will have little interest or incentive to transfer its know-how to another firm, possibly a competitor. Moreover, the very process of attempting to find alternative developers will simply serve to delay private investment and cool the interest of the inventing contractor. It will also force the Government into the expense

of filing patent applications in order to assure that a patent is available if exclusive licensing is ultimately deemed necessary.

It is important also to emphasize that a deferred determination that is truly geared to resolve the questions that trouble opponents of H. R. 8596 approach would be so costly, complex, and time consuming as to discourage many contractors from requesting rights in the first instance, especially small businesses and universities. They may even neglect to report the invention under such circumstances. In all likelihood, without a request for rights to trigger the deferred determination process, most agencies will have little incentive to do anything with the disclosure and, in most cases, the invention will be practiced by no one, as seems to be the case with a very substantial portion of the 28,000 patented inventions now in the Government's patent portfolio. Indeed, under a deferred determination approach the agencies could be devoting so many resources to those cases where rights were requested that they would have insufficient personnel or interest to study inventions and encourage development and marketing where rights were not requested. Thus, it appears that H.R. 8596 is more likely than alternate approaches to maximize the commercialization of Government-funded inventions.

Other Concerns of Deferred Determination Advocates

In addition to the concern over higher profits, advocates of the deferred determination approach have generally voiced two other concerns. First, they express the fear that some contractors will take advantage

of patent rights to suppress the utilization of an invention. Such fears have been expressed throughout the years, but no case of such suppression has ever been documented, despite the thousands of instances in which Government contractors have retained title to inventions. Further, H. R. 8596 includes so-called "march-in" provisions that would remedy any such abuse.

Finally, proponents of deferred determinations argue title-in-the-contractor may lead to concentration of an industry by a contractor. Studies indicate that contractors normally license their patent technologies and that, in any event, alternative technologies are generally available. No example of such concentration has ever been given. It is also questionable whether the Government could identify the possibility of such concentration during the deferred determination process.

A strong argument can be made that allowing contractors to retain patent rights will tend to promote competition in an industry, whereas a deferred determination approach where the Government normally retained title and either dedicated the invention to the public or licensed the invention on a nonexclusive basis approach would do otherwise. The proposition that title-in-the-contractor can lead to concentration is very much dependent on the assumption of a competitive marketplace in which all concerns start with equal capacities. In fact, many industries are currently oligarchial in structure and do not fit the model of pure competition. When this is the case, the

retention of rights in the Government and a policy of nonexclusive dedication or licensing tends to serve the interests of the dominant firms for whom patent rights are not normally a major factor in maintaining dominance. Rather, control of resources, extensive marketing and distribution systems, and superior financial resources are more important factors in maintaining dominance and preventing entry of new firms. It is important to note that such firms may well be foreign-based and dominant through subsidization by their governments, making the inadequacies of a policy of the Government's normally acquiring title even more pronounced. Certainly the Government should not be conducting research and development and permitting the results to emure to the benefit of foreign countries to the detriment of our own economy.

On the other hand, smaller firms in an industry must of necessity rely on a proprietary position in new innovations and products in order to protect their investment in foreign and domestic markets. Thus, patent rights tend to be a much more significant factor affecting their investment decisions. They may need the exclusivity of patent rights to offset the probability that a successful innovation will lead to copying by a dominant firm which would soon undercut their market through marketing, financial, and other commercial techniques. Accordingly, the deferred determination approach in which title normally is retained by the Government may, in fact, be anti-competitive, since it encourages the status quo by discouraging innovation.

Congressman Thornton has provided an unprecedented forum for resolution of one of the country's least understood but important problems. While giving the patent bar the opportunity to educate the public on the essential part the patent system plays in the economic life of a country pledged to individual freedom and the right of individuals to contribute to its society - this is an opportunity we cannot afford to lose to parochial interests.

The social institution that is science has grown dramatically in the last 180 years. During this period the relationship of science to education, government and industry has by necessity been significantly altered. Yet I would suggest that in recent years the relevance of research performed at our universities to modern industrial society has become less apparent than it has been in years past and needs to be positively rearticulated.

Probably the most important impetus for change in the scientific scene during the period was the industrial revolution and the demands of the new industries for greater scientific participation. This was explicitly recognized in the creation of the Ecole Polytechnique in ~~1974~~ 1794 by a group of noted scientists led by the chemist Fourcroy. Fourcroy saw that "a sound training in the geometrical and physical sciences" was all the basis industry needed for aiding the country in its defense during war.

The Ecole Polytechnique experience can be identified in the support which German industries, particularly the chemical industry, gave to the Technisches Hochschulen which sprouted in many German cities. There is little doubt of the industrial motivation behind the founding of the Royal College of Chemistry and the Royal School of Mines in England.

It was at research institutions like this that important 19th century generalizations in science such as; the theory of conservation of energy, the atomic theory of matter, the germ theory of disease, the field theory of forces, and cell theory of the organism, emerged and made it appear that nature would enivability be mastered by man.

But even as we look at these representative theories, we note that this was also a period of scientific specialization, during which there was much effort directed to reducing complex theories into simpler and more understandable parts.

Thus, the synthetic organic chemical industry and the electrical industry

could not have existed except for the scientific discoveries made in laboratories of the emerging research institutions. Further, then as now, the translation of new scientific discoveries into successful industrial tools depended, moreover, on the development of scientific and technical education and training furnished by such institutions.

The synthetic dye industry was born in the year 1856, when William Henry Penkin, an eighteen-year-old student at the Royal College of Chemistry in London, synthesized a strong mauve dye from coal tar. Within a year, Penkin launched a new industry with the aid of his father. The synthesis was made in a laboratory at a technical college, and the ability to put the new science to work depended upon the fact that there were a large number of trained chemists, graduates of the Royal College of Chemistry and of the Techisches Hochscholen in Germany, who knew how to manipulate and control the many processes involved in the making of organic dyes. By 1862, five years after Penkin began manufacturing, five important industrial colors were being synthetically produced. Synthetic mauve, fuchsia, aniline blue, yellow and imperial purple which were previously made from their natural analogues, changed the economy of several nations.

Yet, notwithstanding the British preliminary discovery, within a short time, Germany had outstripped England as a producer of organic dyes, and by the end of the 19th century, Germany was exporting synthetic dyes to England.

It is suggested by some that the reasons for England's loss of market were greater opportunities for wide scientific and technical training offered by Germany while England lagged behind depending on a few great men of science.

This English loss of ability to participate in the practical returns of a great industry it made possible, was even more dramatically duplicated years later when the United States seized on the findings of Drs. Alexander Fleming and Howard Florey of St. Mary's Hospital of London and Oxford University some eleven years after their initial report on penicillin and created the antibiotic industry.

One may well conjecture that these major economic losses to the United Kingdom may not have occurred or would have been ameloriated if the investigators involved and their supporting management had taken greater note of the world's patent systems and their practical implications. I will say more on this later, though I would note that the United Kingdom is said to have taken these losses into consideration during its deliberation to establish the National Research and Development Corporation after the 2nd World War.

The 19th century then can be understood as a century of applied science when we recognize that its achievements depended not alone upon the basic scientific discoveries made by the great men of science, but required the development of the institutional underpinnings - the educational facilities, the research laboratories, the instrumentation and the equipment which permitted the application of new discoveries.

But then even as now, science and government leaders could not agree on the balance of support between basic and applied research, or in other words, the search for detailed specificity or theoretical broadness. Thus, Joseph Henry, the first secretary of the Smithsonian Institution noted in the Institution's Annual Report of 1853 that:

> "As soon as any branch of science can be brought to bear on the necessities, conveniences, or luxuries of life, it meets with encouragement and reward. Not so with the discovery of the incipient principles of science; the investigations which lead to those receive no fostering care from the government and are considered trifles unworthy of the attention of those who place the supreme good in that which immediately administers to the physical needs . . . . But he who loves truth for its own sake, feels that its higher aims are lowered and its moral influence manned by being continually summoned to the bar of immediate and pulpable utility"

(Dr. Henry no doubt had his own Senator Proxmire to contend with.)

As if in response, Henry Roscoe in an eulogy of Louis Pastuer in 1889 stated:

> "For although it is foolish and short-sighted to decry the pursuit of any form of scientific study because it may be as yet for removed from practical application to the wants of men, and although such studies may be of great value as an incentive to intellectual activity, yet . . . discoveries which give us the power of rescuing a population from starvation, on which tend to diminish the ills that flesh, whether of man or beast, is heir to, must deservedly attract more attention and create a more general interest than others having so far no direct bearing on the welfare of the race" (emphasis added)

(It does not seem that Senator Proxmire would have made out very well with Dr. Roscoe either.)

Pasteur, himself a great pragmatist, stated:

> "There is no greater charm for the investigator than to make new discoveries; but his pleasure is heightened when he sees that they have a direct application to practical life"

The Pasteur statement in addition to supporting applied research carries with it an implication that their is an inherent desire in every investigator to apply his fundamental findings which should be satisfied.

It is my perception that the balance of research being conducted at universities with Government support to day is substantially in the nature of that espoused by Dr. Henry rather than Dr. Roscoe. I find no fault in this itself if it is coupled with an increased and identified effort on the

part of universities accepting support to transfer fundamental findings whenever possible to those in industry who could make best use of them or at least establish means to document the flow of research funds into practical results.

While I may have no difficulties with the level of Government support going to Universities for basic research since this is not inconsistent with Dr. Roscoe's view if efforts at technology transfer are made, there is some growing concern in Congress to better account for research funding. Thus, the Mansfield Amendment which permits DOD to support only mission related research (though I understand that its is honored more in its breach), and the recently defeated Baumann Amendment which proposed Congressional review of NSF grants a concern that funds not be utilized to satisfy "idle curiousity" but for projects which evidence some prospect of solving immediate public problems.

Further questions posed by the Congressional Subcommittees responsible for HEW and NASA appropriations have clearly indicated an interest in determining whether the funding of basic research at universities was generating solutions to public problems.

These inquiries to some extent evidence a misunderstanding that universities can generally solve public problems without the further collaborative aid of industry or at very least have the means of determining whether the practical results of their research have been adopted and applied by industry. In regard to the former it appears necessary that we all make better efforts in the future to explain that Government support of research at universities is in the main to serve the purpose of generating fundamental bases of scientific information upon which industry builds useful results. However, in regard to the latter as I have previously suggested, I believe

universities could be doing more to interface and obtain the cooperative aid of sophisticated industrial developers in delivering fundamental innovations to the marketplace. This effort seems to be needed more now than years past due to a number of barriers that did not exist in the 19th century, such as industry's preoccupation with its own in-house efforts, the huge proliferation of basic findings, organization barrings generated by size, government regulation and many more barriers which have impeded meaningful interface and communication.

We believe from experience that mere publication of results will not necessarily guarantee utilization of fundamental findings. This is evident when it is understood that inherent to the transfer process is a decision on the part of the industrial entrepeneur on whether the intellectual property rights in the innovation being offered for development are sufficient to protect its interests. While we know that not all transfers include an exchange of intellectual property rights, it is unpredictable as to which transfers the entrepreneur will consider to require such an exchange. We do know, however, that where substantial risk capital is involved, there is a likelihood that transfer will not occur if the entrepreneur isn't afforded some property protection.

Now, this leads to the obvious, but not yet substantially implemented, conclusion that in order to afford the correct property exchange from the fundamental innovator to the industrial developer at the right time, the innovating university must identify, and establish rights in more intellectual property than it will exchange through the timely management and intelligent intellectual property policies. Because of this necessary property protection,

investigators must be taught to think ahead, since the patent laws are written against those who delay protection. This type of management can only be afforded by universities willing to acquaint themselves with the basic principles of intellectual property protection and the ability to communicate to investigators its importance in the transfer mechanism.

Let me suggest that if this policy had been implemented by the United Kingdom as early as 1850, the British may well have shared in the economic reward of the synthetic dye industry for many more years than they were permitted by German competition. More important, the antibiotic industry may well be British rather than American and penicillin might well have been brought to the public ten years earlier with the resultant preservation of hundreds of thousand lives. As I noted previously, the British have attempted to avoid further loss of its economic position in British inventions by establishing NRDC, a central Government licensing organization. Although we believe the NRDC type organization not be be an adequate substitute for an effective university patent management organization, it has successfully managed the licensing and development by a British pharmaceutical concern of cephalbsporin,one of the major second generation antibiotics generated by Oxford University with Government support.

It now seems clear that the continual stream of technological development, which forms an important basis for economic growth, cannot be obtained through the simple expedient of nurturing scientific and technical ideas in the hope that their commercial relevance will be apparent to the industrial sector. University and investigator advocacy of such ideas is nearly always imperative in order to create a likelihood of their commercial use.

On September 23, 1975, the Committee on Government Patent Policy acting for the Federal Council for Science and Technology in an effort to create an incentive in universities to advocate their inventive ideas and to eliminate one serious barrier to transfer,recommended that all the agencies of the Executive provide to universities a first option to substantially all inventions generated with federal support if they are found to have an identified technology transfer function. In addition, the Committee also directed that an interagency committee be formed for the purpose of joint agency identification of universities having a satisfactory technology transfer function.

Notwithstanding, these long sought positive developments, it should be noted that implementation of the recommendations by agencies that do not presently have such policies has been left to each agency's own discretion. Accordingly, the opinions of each university on these matters will significantly effect the direction that individual agencies may take.

As I previously suggested with well over 3 billion dollars of federal support going to support of research at universities, questions on accountability can hardly be avoided and may well be easier to respond to if technology transfer functions capable of tracking results exist at all universities who are substantially involved in research. In other words, support of non-specific and non-measured objectives may well be in the public interest as suggested by Joseph Henry but its justification will be much more difficult in this era of capital shortage.

PRESENTATION BY

NORMAN J. LATKER

PATENT COUNSEL

BEFORE THE SECOND ANNUAL ACADEMIC PLANNING CONFERENCE

"Ethical and Economic Issues: University Policies for Consulting, Overload Instructional Activities and Intellectual Property"

University of Southern California

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The social institution that is science has grown dramatically in the last 180 years. During this period the relationship of science to education, Government and industry has by necessity been significantly altered. Yet, I would suggest that in recent years the relevance of research performed at our universities to modern industrial society has become less apparent than it has been in years past, and must be positively rearticulated.

Probably the most important impetus for change in the scientific scene during this long period was the industrial revolution and the demands of the new industries for greater scientific input. This was explicitly recognized in the creation of the École Polytechnique in 1794 by a group of noted scientists led by the chemist Fourcroy. Fourcroy saw that "a sound training in the geometrical and physical sciences was all the basis industry needed for aiding the country in its defense during war".

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But even as we look at these representative theories, we note that this was also a period of scientific specialization, during which there was much effort directed to reducing such complex theories into innovations which fed the industrial revolution.

Thus, the synthetic organic chemical industry and the electrical industry could not have existed except for the scientific discoveries made in laboratories of the emerging research institutions. Further, then as now, the translation of new scientific discoveries into successful industrial tools depended, moreover, on the development of scientific and technical education and training furnished by such institutions.

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Yet, notwithstanding the British preliminary discovery, within a short time Germany had outstripped England as a producer of organic dyes, and by the end of the 19th century Germany was exporting synthetic dyes to England.

The inability of the British to participate in the practical returns of a great industry which they made possible, was even more dramatically duplicated years later. The United States, capitalizing on the findings of Drs. Alexander Fleming and Howard Florey of St. Mary's Hospital of London and Oxford University some eleven years after the initial report on penicillin, created the antibiotic industry.

One may well conjecture that these major economic losses to the United Kingdom may not have occurred or would have been ameliorated if the investigators involved and their supporting management had taken greater note of the world's patent systems and their practical implications. I will say more on this later, though I would note that the United Kingdom is said to have taken these losses into consideration during its deliberation to establish the National Research and Development Corporation after the second World War.

The 19th century then can be understood as a century of applied science when we recognize that its achievements depended not alone upon the basic scientific discoveries made by the great men of science, but required the development of the institutional underpinnings - the educational facilities, the research laboratories, the instrumentation, equipment and chemistry which permitted the application of new discoveries.

But then, even as now, science and Government leaders could not agree on the balance of support between basic and applied research. Thus, Joseph Henry, the first Secretary of the Smithsonian Institution, noted in the Institution's Annual Report of 1853 that:

> "As soon as any branch of science can be brought to bear on the necessities, conveniences, or luxuries of life, it meets with encouragement and reward. Not so with the discovery of the incipient principles of science; the investigations which lead to those receive

> no fostering care from the Government and are considered trifles unworthy of the attention of those who place the supreme good in that which immediately administers to the physical needs ... But he who loves truth for its own sake, feels that its higher aims are lowered and its moral influence marred by being continually summoned to the bar of immediate and culpable utility."

As if in rebuttal, Dr. Henry Roscoe in his eulogy of Louis Pasteur in 1889 stated:

> "For although it is foolish and short-sighted to decry the pursuit of any form of scientific study because it may be as yet far removed from practical application to the wants of men, and although such studies may be of great value as an incentive to intellectual activity, yet ... discoveries which give us the power of rescuing a population from starvation, or which tend to diminish the ills that flesh, whether of man or beast, is heir to, must deservedly attract more attention and create a more general interest than others having so far no direct bearing on the welfare of the race." (Emphasis added.)

Pasteur, himself a great pragmatist, once stated:

> "There is no greater charm for the investigator than to make new discoveries; but his pleasure is heightened when he sees that they have a direct application to practical life."

The Pasteur statement, in addition to supporting applied research, carries with it an implication that there is an inherent desire in every investigator to apply his fundamental findings which should be satisfied.

It is my perception that the balance of research being conducted at universities with Government support today is substantially in the nature of that espoused by Dr. Henry, that is, basic rather than applied. I support this balance on

the grounds that sooner or later some important application of this research would find their way into our market economy. Furthermore, absent basic research, we would sooner or later reach the point where applications trailed off into insignificance. However, I believe this balance can better be defended if it is coupled with an increased and identified effort on the part of universities accepting support to transfer fundamental findings whenever possible to those in industry who could make best use of them or at least establish means to document the flow of research funds into practical results.

While I note no difficulties with the level of Government support going to universities for basic research if efforts at technology transfer are made, there is growing concern in Congress to better account for research funding. Thus, the Mansfield Amendment which permits DOD to support only mission-related research, and the recently defeated Baumann Amendment which proposed Congressional review of NSF grants, to assure use of funds for projects which evidence some prospect of solving immediate public problems.

Further, questions posed by the Congressional Subcommittees responsible for HEW and NASA appropriations have clearly indicated an interest in determining whether the funding of basic research at universities was generating solutions to public problems.

These inquiries to some extent evidence a misunderstanding that universities can generally solve public problems without the further collaborative aid of industry, or at the very least have the means of determining whether the practical results of their research have been adopted and applied by industry. In regard to the former, it appears necessary that we all make better efforts in the future to explain that Government support of research at universities is in the main to serve the purpose of generating fundamental bases of scientific information upon which industry builds useful results. However, in regard to the latter as I have previously suggested, I believe universities could be doing more to interface and obtain the cooperative aid of sophisticated industrial developers in delivering fundamental innovations to the marketplace. This effort seems to be needed more now than years past due to a number of barriers impeding meaningful interface and communication which did not eixst in the 19th century. Some of these barriers might be considered; industry's preoccupation with its own in-house research efforts, the huge proliferation of basic findings, organizational barriers generated by size, Government pre-market clearance of drugs and medical devices and other regulation, and the difficulty of establishing and transferring intellectual property rights.

Because of these existing barriers, it is perceived that mere publication of results will not necessarily guarantee utilization of fundamental findings. It is evident that intellectual property rights, including patents, is important to the accomplishment of utilization when it is understood that inherent to the transfer process is a decision on the part of the industrial entrepreneur on whether the intellectual property rights in the innovation being offered for development are sufficient to protect its interests. While we know that not all transfers include an exchange of intellectual property rights, it is unpredictable as to which transfers the entrepreneur will consider to require such an exchange. We do know, however, that where substantial risk capital is involved, there is a likelihood that transfer will not occur if the entrepreneur isn't afforded some property protection.

Now, this leads to the obvious, but not yet substantially implemented, conclusion that in order to afford the correct property exchange from the fundamental innovator to the industrial developer at the right time, the innovating university must identify and establish rights in more intellectual property than it will exchange through the timely management and intelligent intellectual property policies. Because of this necessary property protection, investigators must be taught to

think ahead, since the patent laws are written against those who delay protection. This management can only be afforded by universities willing to acquaint themselves with the basic principles of intellectual property protection and the ability to communicate to investigators its importance in the transfer mechanism.

Let me suggest that if this policy had been implemented by the United Kingdom as early as 1850, the British may well have shared in the economic reward of the synthetic dye industry for many more years than they were permitted by German competition. More important, the antibiotic industry may well be British rather than American, and penicillin might well have been brought to the public ten years earlier with the resultant preservation of hundreds of thousands of lives. As I noted previously, the British have attempted to avoid further loss of its economic position in British inventions by establishing NRDC, a central Government licensing organization. Although we believe the NRDC type organization not an adequate substitute for an effective university patent management organization, it has successfully managed the licensing and development by a British pharmaceutical concern of cephalosporin, one of the major second generation antibiotics generated by Oxford University with Government support.

It now seems clear that the continual stream of technological development, which forms an important basis for economic growth, cannot be obtained through the simple expedient of publishing scientific and technical ideas in the hope that their commercial relevance will be apparent to the industrial sector. University and investigator advocacy of such ideas is nearly always imperative in order to create a likelihood of their commercial use.

On September 23, 1975, the Committee on Government Patent Policy, acting for the Federal Council for Science and Technology in an effort to create an incentive in universities to advocate their inventive ideas and to eliminate one serious barrier to transfer, recommended that all the agencies of the Executive provide to universities a first option to substantially all inventions generated with Federal support, if they are found to have an identified technology transfer function. In addition, the Committee also directed that an interagency committee be formed for the purpose of joint agency identification of universities having a satisfactory technology transfer function. This recommendation is near final implementation through a Federal Procurement Regulation.

Notwithstanding these long sought positive developments, it should be noted that implementation of the recommendations by agencies that do not presently have such policies has been

left to each agency's own discretion. Accordingly, the opinions of each university on these matters will significantly affect the direction that individual agencies may take.

As I previously suggested, with well over 3 billion dollars of Federal support going to support of research at universities, questions on accountability can hardly be avoided and may well be easier to respond to if technology transfer functions capable of tracking results exist at all universities which are substantially involved in research. In other words, support of non-specific and non-measured objectives may well be in the public interest as suggested by Joseph Henry, but its justification will be much more difficult in this era of capital shortage.

CLEVELAND SPEECH - APRIL 16, 1977

I VERY MUCH APPRECIATE YOUR INVITATION, SINCE I BELIEVE YOU ARE WORKING IN AN AREA OF TECHNOLOGY OF GREAT IMPORTANCE TO THE PUBLIC, AND THIS IS AN OPPORTUNITY TO EXPLAIN THE IMPORTANCE OF PATENT PROTECTION IN BRINGING THAT TECHNOLOGY TO FRUITION, ESPECIALLY IN LIGHT OF THE PREMARKET CLEARANCE REQUIRED BY THE NEW MEDICAL DEVICE ACT.

THE ALLOCATION OF INVENTIONS ARISING FROM GOVERNMENT-SPONSORED RESEARCH AT UNIVERSITIES AND NONPROFIT ORGANIZATIONS IS AN AREA OF VITAL INTEREST TO HEW. THE DEPARTMENT IS BY FAR THE LARGEST SINGLE SOURCE OF FUNDING FOR SUCH RESEARCH IN THE UNITED STATES, AND PROBABLY THE WORLD.

IT IS A FUNDAMENTAL PREMISE OF HEW PATENT POLICY THAT A GUARANTEE OF SOME PATENT PROTECTION MAY BE NECESSARY TO AN INDUSTRIAL DEVELOPER IN ORDER TO ASSURE TRANSFER OF HEW-FUNDED UNIVERSITY GENERATED INVENTIONS TO SUCH DEVELOPER. THIS PREMISE SEEMS OBVIOUS, GIVEN THE FACT THAT COMMERCIALIZATION OF UNIVERSITY INVENTIONS MUST ULTIMATELY BE ACCOMPLISHED BY INDUSTRY, AND INHERENT TO THE COMMITMENT OF RISK CAPITAL IS A DECISION ON THE PART OF THE INDUSTRIAL DEVELOPER ON WHETHER THE INTELLECTUAL PROPERTY RIGHTS IN THE INNOVATION BEING CONSIDERED FOR DEVELOPMENT ARE SUFFICIENT TO PROTECT ITS INTERESTS. CONVERSELY, FAILURE TO PROVIDE SUCH GUARANTEE IN CASES WHERE IT IS NECESSARY MAY FATALLY AFFECT UTILIZATION OR TRANSFER OF A MAJOR UNIVERSITY INNOVATION.

THE CONTROVERSY OVER GOVERNMENT PATENT POLICY THAT SOME OF YOU MAY HAVE HEARD OF, AT LEAST IN THE RESEARCH AND DEVELOPMENT AGENCIES, SEEMS TO ME TO BE NOT, AS COMMONLY STATED, WHETHER THESE AGENCIES SHOULD TAKE "TITLE" OR "LICENSE" TO INVENTIVE RESULTS IT HAS FUNDED, BUT WHEN AND TO WHAT EXTENT A GUARANTEE OF PATENT PROTECTION SHOULD BE MADE. EVERY MAJOR RESEARCH AND DEVELOPMENT AGENCY SUPPORTING RESEARCH IN THE UNIVERSITY SECTOR BELIEVES IT SHOULD HAVE THE DISCRETION TO WAIVE OR LICENSE PATENT RIGHTS WHEN IT IS DEEMED APPROPRIATE TO ACHIEVE COMMERCIAL UTILIZATION.

THE MORE MEANINGFUL PROBLEM IS SIMPLY THAT THE AGENCIES HAVE NOT UTILIZED THIS DISCRETION ON A UNIFORM BASIS IN SIMILAR FACT SITUATIONS.

IN A 1939 LETTER DR. EINSTEIN ADVISED PRESIDENT ROOSEVELT OF THE COMING OF THE ATOMIC AGE, AND SUGGESTED THAT THE GOVERNMENT AID UNIVERSITIES AND INDUSTRY TO COLLABORATIVELY BRING ABOUT A CHAIN REACTION. IN A FEW WORDS, DR. EINSTEIN IDENTIFIED AND ASSIGNED TO EACH ELEMENT OF THE COLLABORATIVE TEAM HE DEEMED NECESSARY TO THE COMPLETION OF THE DEVELOPMENT, THE DUTY WHICH EACH WOULD PERFORM BEST. THUS, HE SUGGESTED THAT THE UNIVERSITIES BE AIDED IN COMPLETING THEIR EXPERIMENTAL OR FUNDAMENTAL RESEARCH, THAT INDUSTRIAL LABORATORIES BE TAPPED FOR THEIR ABILITY TO BRING SUCH FUNDAMENTAL FINDINGS INTO PRACTICAL APPLICATION THROUGH THE USE OF THEIR EQUIPMENT, AND THE GOVERNMENT ACT AS THE CATALYST OR IMPRESARIO IN BRINGING THESE FACTORS TOGETHER.

AS SIMPLE AS DR. EINSTEIN'S FORMULA FOR DELIVERY OF THE RESULTS OF FUNDAMENTAL RESEARCH INTO PRACTICAL USE APPEARS, THE CLOSING OF THE ENORMOUS GAP BETWEEN NEW FIELDS OF KNOWLEDGE AS DRAMATIC AS RADAR, COMPUTER MEMORY CORES, LASERS, ANTIBIOTICS, ETC., AND THEIR PRACTICAL IMPLEMENTATION BY INDUSTRY, WITH THE EXCEPTION OF THE FEW CASES WHERE THE GOVERNMENT HAS DETERMINED TO PROVIDE THE CONTINUED FUNDING TO INDUSTRY FOR DEVELOPMENT OF SUCH FINDINGS, HAS BEEN LEFT TO RANDOM AND HAPHAZARD EXECUTION.

THE STAKE IN CLOSING THIS GAP IS VERY HIGH. IN 1975 APPROXIMATELY 3.2 OF THE 13 BILLION DOLLARS, OR ONE-QUARTER SPENT BY THE GOVERNMENT ON RESEARCH AND DEVELOPMENT OUTSIDE ITS OWN LABORATORIES, WENT IN THE FORM OF GRANTS AND CONTRACTS TO UNIVERSITIES.

ON SEPTEMBER 23, 1975, THE COMMITTEE ON GOVERNMENT PATENT POLICY RECOMMENDED, ON THE BASIS OF ITS UNIVERSITY SUBCOMMITTEE'S STUDY, THAT ALL AGENCIES OF THE EXECUTIVE BRANCH PROVIDE TO UNIVERSITIES A FIRST OPTION TO SUBSTANTIALLY ALL FUTURE INVENTIONS GENERATED WITH FEDERAL SUPPORT, SUBJECT TO STATUTORY PROHIBITION, AND PROVIDED THAT SUCH UNIVERSITY IS FOUND TO HAVE A TECHNOLOGY TRANSFER FUNCTION. THIS FIRST OPTION TO OWNERSHIP IS SUBJECT TO A NUMBER OF CONDITIONS, THE MOST IMPORTANT OF WHICH ARE THE STANDARD LICENSE TO THE GOVERNMENT, A LIMIT ON THE TERM OF

ANY EXCLUSIVE LICENSE GRANTED, AUTHORITY TO WITHDRAW SPECIFIED PROJECTS FROM THE OPTION, A REQUIREMENT THAT ROYALTY INCOME BE UTILIZED FOR EDUCATIONAL OR RESEARCH PURPOSES, WITH THE EXCEPTION OF A REASONABLE SHARE TO THE INVENTOR, AND THE RIGHT OF THE AGENCY TO REGAIN OWNERSHIP DUE TO PUBLIC INTEREST CONSIDERATIONS OR THE UNIVERSITIES' FAILURE TO TAKE EFFECTIVE STEPS TO COMMERCIALIZE THE INVENTION.

THE IMPLEMENTATION OF THE COMMITTEE'S RECOMMENDATION HAS BEEN CIRCULATED FOR PUBLIC COMMENT IN THE FORM OF A FEDERAL PROCUREMENT REGULATION AND IS NOW IN ITS FINAL STAGES OF REVIEW.

THE UNIVERSITY SUBCOMMITTEE REPORT IDENTIFIED SOME GENERAL PREMISES FROM WHICH IT PROCEEDED, ALL UNDERSTOOD BY DR. EINSTEIN IN 1939.

FIRST, A SYMPATHETIC AND ENCOURAGING FEDERAL CLIMATE IS VERY IMPORTANT TO TECHNOLOGICAL PROGRESS.

SECOND, THE UNIVERSITY COMMUNITY AND INDUSTRY, LEFT TO THEIR OWN INITIATIVES, WILL PROBABLY BE UNABLE TO GENERATE THIS ATMOSPHERE.

THIRD, THERE APPEARS TO BE AN ABSOLUTE NEED FOR INDUSTRIAL COLLABORATION WITH UNIVERSITIES IF THE RESULTS OF GOVERNMENT-SPONSORED UNIVERSITY RESEARCH ARE TO REACH THE PUBLIC. MUCH OF THE WORK PERFORMED UNDER GOVERNMENT-SPONSORED GRANTS AND CONTRACTS AT UNIVERSITIES IS BASIC, AS OPPOSED TO APPLIED RESEARCH.

INVENTIONS ARISING OUT OF BASIC RESEARCH INVOLVE AT MOST COMPOSITIONS OF MATTER WITH NO CLEAR UTILITY, PROTOTYPE DEVICES, OR PROCESSES WHICH USUALLY REQUIRE MUCH ADDITIONAL DEVELOPMENT. UNIVERSITIES DO NOT UNDERTAKE DEVELOPMENT OF SUCH INVENTIONS, AS DEVELOPMENT LEADING TO COMMERCIAL MARKETING IS NOT ORDINARILY WITHIN THE SCOPE OF THEIR MISSIONS OR CAPABILITY. FURTHER, FINANCING OF THAT TYPE OF DEVELOPMENT WORK NEEDED IS NOT GENERALLY AVAILABLE FROM GOVERNMENT SOURCES. THERE ARE MANY MORE INVENTIVE IDEAS THAN FEDERAL RESOURCES FOR DEVELOPMENT PURPOSES. CONSEQUENTLY, DEVELOPMENT OF SUCH INVENTIONS WILL GENERALLY BE ACCOMPLISHED ONLY WHERE INDUSTRY HAS KNOWLEDGE OF THEM AND HAS AN INCENTIVE TO UTILIZE ITS RISK CAPITAL TO BRING THEM TO THE MARKETPLACE.

LAST, THE DIFFICULTY OF COLLABORATION IS COMPOUNDED WHEN THOSE WHO NOW PERFORM ESSENTIAL PARTS OF A FUNCTION REFUSE TO MODIFY THEIR OPERATIONS TO MEET THE NEEDS OF THE WHOLE SYSTEM. ORDINARILY, THE PRINCIPALS CAN'T BE ORDERED TO COLLABORATE. THE PROBLEM PERCEIVED IS HOW TO PROVIDE THE MEANS FOR INDUCING THEM TO INTEGRATE VOLUNTARILY INTO A SYSTEM THAT PERFORMS A SOCIALLY DESIRABLE FUNCTION.

WITH THESE PREMISES IN MIND, THE UNIVERSITY SUBCOMMITTEE IDENTIFIED THE FOLLOWING AS THE PRIMARY PROBLEMS THAT NEEDED TO BE OVERCOME BEFORE OPTIMUM RESULTS IN TRANSFERRING TECHNOLOGY COULD BE ACHIEVED.

FIRST, AND THOUGHT TO BE THE MOST IMPORTANT, WAS THE CONCLUSION THAT UNIVERSITIES DO NOT GENERALLY HAVE AN ADEQUATE MANAGEMENT CAPABILITY TO FACILITATE THE TIMELY IDENTIFICATION, PROTECTION AND THE TRANSFER OF THEIR INVENTIVE RESULTS TO INDUSTRIAL CONCERNS THAT MIGHT MAKE USE OF THEM.

IT WAS PERCEIVED THAT THE MERE EXISTENCE OF A BODY OF RESEARCH PUBLICATIONS AND OTHER TECHNICAL INFORMATION WAS NOT ENOUGH TO RESULT IN SIGNIFICANT INDUSTRIAL INVOLVEMENT IN FURTHERING DEVELOPMENT.

SECOND, WAS THE "NOT-INVENTED-HERE" SYNDROME. INDUSTRIAL ORGANIZATIONS HAVE COMMERCIAL POSITIONS IN MOST AREAS OF THEIR RESEARCH. THERE IS AN IN-HOUSE INCENTIVE FOR SUCH ORGANIZATIONS TO FURTHER DEVELOP THE RESULTS OF THEIR OWN RESEARCH IN ORDER TO IMPROVE THEIR COMMERCIAL POSITION. THERE IS A LESSER INCENTIVE FOR INDUSTRY TO FURTHER DEVELOP THE RESULTS OF UNIVERSITY RESEARCH, SINCE SUCH RESEARCH WAS NOT UNDER INDUSTRY EVALUATION THROUGH ALL STAGES OF ITS DEVELOPMENT.

THIRD, WAS THE UNCERTAINTY OVER OWNERSHIP OF INVENTIONS MADE AT UNIVERSITIES THAT MAY BE COLLABORATIVELY DEVELOPED OR ARE INITIALLY GENERATED THROUGH A COLLABORATIVE RELATIONSHIP.

INDUSTRY REFUSAL TO COLLABORATE WITH UNIVERSITIES IN BRINGING HEW-FUNDED INVENTIONS TO THE MARKETPLACE, UNLESS PROVIDED SOME PATENT PROTECTION AS QUID PRO QUO FOR THE ADDITIONAL INVESTMENT AND DEVELOPMENT REQUIRED, WAS SUBSTANTIATED

BY A HARBRIDGE HOUSE STUDY AND A 1968 GAO REPORT. INDUSTRY FELT DHEW PATENT PRACTICES AT THAT TIME FAILED TO TAKE INTO CONSIDERATION THE LARGE PRIVATE INVESTMENT NEEDED BEFORE UNTESTED CHEMICAL COMPOUNDS SYNTHESIZED WITH DEPARTMENT SUPPORT COULD BE MARKETED AS DRUGS. I BELIEVE THIS SAME RELUCTANCE TO COLLABORATE WITHOUT PATENT PROTECTION WILL OCCUR IN REGARD TO MEDICAL DEVICES WHICH REQUIRE PRE-MARKET CLEARANCE DUE TO THE INCREASE IN RISK CAPITAL REQUIRED TO GENERATE CLINICAL DATA NECESSARY FOR CLEARANCE.

THE EXPERIENCES ALREADY NOTED IN UNIVERSITY DEALINGS WITH THE PHARMACEUTICAL INDUSTRY AND SOME MEDICAL DEVICE MANUFACTURERS INDICATED THAT THERE WILL BE THE SAME RELUCTANCE TO COLLABORATE WITH UNIVERSITIES IN BRINGING OTHER HIGH-RISK INVENTIONS TO THE MARKETPLACE IF SOME PATENT EXCLUSIVITY IS NOT FIRST PROVIDED TO THE DEVELOPER.

FOURTH, IS THE PROBLEM OF CONTAMINATION. "CONTAMINATION" MEANS THE POTENTIAL COMPROMISE OF INDUSTRY PROPRIETARY RIGHTS DUE TO EXPOSURE TO IDEAS, COMPOSITIONS, AND/OR TEST RESULTS ARISING FROM GOVERNMENT-SPONSORED UNIVERSITY RESEARCH. IF THE COMPANY INCORPORATES INTO ITS RESEARCH PROGRAM SOME OF THESE IDEAS, COMPOSITIONS OR TEST RESULTS AND THEN DEVELOPS A MARKETABLE PRODUCT PATENTABLY DISTINCT FROM ANY OF THE UNIVERSITY'S IDEAS, THE COMPANY FEARS THAT THE GOVERNMENT IS IN A POSITION TO ASSERT CLAIMS TO THEIR PRODUCT.

TO OVERCOME THESE BARRIERS TO TECHNOLOGY TRANSFER, IT WAS DEEMED ESSENTIAL TO THE SUBCOMMITTEE THAT THE GOVERNMENT PERSUADE UNIVERSITIES TO PROVIDE A MANAGEMENT CAPABILITY WITHIN THE INSTITUTION THAT WILL SERVE AS A FOCAL POINT FOR IDENTIFICATION, RECEIPT AND PROMPT PROTECTION OF THE INVENTIVE RESULTS OF UNIVERSITY RESEARCH FOR LATER DISSEMINATION TO INDUSTRIAL CONCERNS. THE SUBCOMMITTEE FELT THAT THIS MIGHT BE ACCOMPLISHED BY GUARANTEEING TO UNIVERSITIES AT THE TIME OF FUNDING, PATENT RIGHTS IN GOVERNMENT-SUPPORTED INVENTIONS IN RETURN FOR ESTABLISHMENT OF SUCH A MANAGEMENT CAPABILITY.

I BELIEVE THAT ONE OF THE PRIMARY BASES FOR THE RECOMMENDATION WAS THE REALIZATION THAT A SUBSTANTIAL MAJORITY OF INVENTIVE IDEAS REQUIRES "ADVOCATES" IN ORDER TO REACH THE MARKETPLACE, AND THAT EXPERIENCE INDICATES THAT THE INVENTING ORGANIZATION, IF INTERESTED, IS A MORE LIKELY "ADVOCATE" THAN A LESS PROXIMATE AND NOT AS EQUALLY CONCERNED GOVERNMENT STAFF.

HISTORY IS REPLETE WITH EXAMPLES OF INVENTIONS NOW ACCEPTED AS PART OF OUR CULTURE, WHICH REACHED FRUITION ONLY DUE TO THE PERSEVERANCE OF AN ADVOCATE. IT IS SAID THAT THE INVENTOR OF XEROX, CHESTER CARLSON, CONTACTED OVER 100 CONCERNS BEFORE HE WAS ABLE TO OBTAIN A FINANCIAL COMMITMENT FOR

DEVELOPMENT. SIMILARLY, SAMUEL B. MORSE ARGUED THROUGH FIVE YEARS BEFORE HE WAS ABLE TO OBTAIN $30,000 FROM CONGRESS TO BUILD A TEST LINE FOR HIS TELEGRAPH BETWEEN WASHINGTON AND BALTIMORE. THERE IS NO EVIDENCE THAT A GOVERNMENT ORGANIZATION WOULD BE WILLING TO DUPLICATE THAT KIND OF ADVOCACY, NOR IS IT APPARENT THAT MANY ORGANIZATIONS OR PERSONS WOULD, ABSENT A PROPERTY RIGHT.

THE GUARANTEE OF PATENT RIGHTS TO THE UNIVERSITY CARRIES WITH IT THE RIGHT TO LICENSE COMMERCIAL CONCERNS, THUS CREATING THE INCENTIVE NECESSARY FOR DEVELOPMENT IN THOSE SITUATIONS WHERE COLLABORATION WOULD NOT OTHERWISE BE ACCOMPLISHED AND LESSENING OR ELIMINATING INDUSTRY FEAR OF CONTAMINATION. FURTHER, UNDER SUCH A POLICY, COLLABORATIVE ARRANGEMENTS COULD BE MADE WHEREIN INDUSTRY'S PARTICIPATION IS PROTECTED BEFORE IT IS EVEN CLEAR WHETHER OR NOT INVENTIONS WILL BE MADE. SUCH PRIOR ARRANGEMENTS SHOULD MINIMIZE THE PROBLEM OF THE "NOT-INVENTED-HERE" SYNDROME.

TO A LARGE EXTENT THE SEPTEMBER 23RD RECOMMENDATIONS ARE A RATIFICATION OF THE PRACTICES IMPLEMENTED BY DHEW SINCE 1969 AND THE NATIONAL SCIENCE FOUNDATION SINCE 1974. THE DHEW PRACTICES, IN TURN, WERE INITIATED IN PART THROUGH THE IMPETUS CREATED BY THE CRITICAL REMARKS FROM THE 1968 GAO STUDY MENTIONED PREVIOUSLY ON THE LACK OF TIMELINESS IN PROCESSING

PETITIONS FOR WAIVERS OF IDENTIFIED INVENTIONS AND THE NEED TO CLARIFY THE USE OF INSTITUTIONAL PATENT AGREEMENTS WHICH GUARANTEE FUTURE INVENTION RIGHTS TO UNIVERSITIES WITH TECHNOLOGY TRANSFER CAPABILITIES.

IN OCTOBER 1974 THE DEPARTMENT COLLECTED SOME ROUGH STATISTICS ON MANAGEMENT OF PATENT RIGHTS LEFT TO UNIVERSITIES. THIS STUDY INDICATED THAT 167 PATENT APPLICATIONS WERE FILED SINCE 1969 BY INSTITUTIONS WHICH CHOSE TO EXERCISE THEIR FIRST OPTION TO INVENTION RIGHTS UNDER THEIR INSTITUTIONAL PATENT AGREEMENT. UNDER THE 167 PATENT APPLICATIONS FILED, THE UNIVERSITIES HAVE NEGOTIATED 29 NONEXCLUSIVE LICENSES AND 43 EXCLUSIVE LICENSES. SEVENTEEN JOINT-FUNDING ARRANGEMENTS WITH COMMERCIAL ORGANIZATIONS, INVOLVING ONLY THE POSSIBILITY OF RIGHTS TO FUTURE INVENTIONS, HAVE BEEN MADE. WE WERE ADVISED THAT ON THE BASIS OF ALL THE AGREEMENTS NOTED, APPROXIMATELY 24 MILLION DOLLARS OF RISK CAPITAL MAY BE COMMITTED TO THE DEVELOPMENT OR MAKING OF INVENTIONS EVOLVING WITH DHEW SUPPORT.

UNDER OUR DEFERRED DETERMINATION POLICY, WHICH IS APPLICABLE TO ALL UNIVERSITIES WHO HAVE NOT YET ESTABLISHED A TECHNOLOGY TRANSFER CAPABILITY, IT WAS DETERMINED THAT SINCE 1969, 178 PETITIONS FOR WAIVER OF AN IDENTIFIED INVENTION HAVE BEEN REVIEWED AS OF OCTOBER 1974. OF THESE 178, 162 PETITIONS WERE GRANTED. UNDER THE 162 GRANTED, THE INSTITUTIONS

INVOLVED AND RESPONDING HAVE GRANTED 15 NONEXCLUSIVE LICENSES AND 35 EXCLUSIVE LICENSES. THESE LICENSES HAVE GENERATED A POSSIBLE COMMITMENT OF RISK CAPITAL OF AS MUCH AS 53 MILLION DOLLARS.

SINCE 1974 TO THE END OF FISCAL YEAR 1976 THE NUMBER OF INVENTIONS HELD BY UNIVERSITIES INCREASED DRAMATICALLY FROM 329 TO 517. I HAVE SOME EXAMPLES OF INVENTIONS LICENSED BY UNIVERSITIES WHICH HAVE REACHED OR ARE NEAR REACHING THE MARKETPLACE SINCE OUR 1974 SURVEY. NOTEWORTHY IS THAT THIS INCOMPLETE LISTING OF SOME 17 INVENTIONS INVOLVES A COMMITMENT OF RISK CAPITAL OF APPROXIMATELY 60 MILLION DOLLARS. MEDICAL DEVICES ON THE LIST ARE (READ FROM LIST).

WE KNEW OF NO COMPARABLE SITUATIONS AT THE TIME OF THE GAO REPORT IN 1968.

MORE SIGNIFICANT THAN THE FIGURES ARE REPORTS FROM THE UNIVERSITY COMMUNITY THAT INDUSTRY INTEREST IN UNIVERSITY RESEARCH HAS SIGNIFCANTLY INCREASED IN RECENT YEARS. I BELIEVE THIS TO BE THE RESULT OF THE UNIVERSITY COMMUNITY'S ACTIVE SOLICITATION OF COLLABORATIVE ARRANGEMENTS, WHICH IN TURN WAS PARTLY MOTIVATED BY THE FLEXIBILITY PROVIDED BY OUR PATENT POLICY.

ITEM C

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

Inventor	University	Invention	Licensee	Approximate Investment
Chas. Heidelberger	Wisconsin	Use of F_3TDR for Herpes Infections of the Eye	Burroughs Wellcome Co., Research Triangle Park, N.C.	Approx. $5,000,000 NDA expected by end of 1977
Charles Fox	Columbia Univ.	Silver Sulfadiazine used in treatment of burns	Marion Labs., Kansas City, Mo.	Now on market - Approx. $5,000,000
R. Fischell	Johns Hopkins	Rechargeable Cardiac Pacemaker	Pacesetter Systems Sylmar, Calif.	On market since Feb. 1975 - Approx. $720,000
Monte Holland	Tulane Univ.	Method of Reducing Intraocular Pressure in the Human Eyes	Cooper Labs., Bedford Hills, N.Y.	$2,000,000 - Development leading to DNA is in process and on schedule
Berton Pressman	Univ. of Miami	Application of X-537A in the Cardiovascular System (for stimulation in cardiogenic shock, congestive heart failure, etc.)	Hoffmann-LaRoche, Nutley, N.J.	$500,000 to $1,000,000 Clinical evaluations still in progress
Willard Higley	Natl. Institute of Scientific Research	Polycarbonate Dialysis Membranes	C.R. Bard, Inc., Murray Hill, N.J.	Over $1,000,000. Market introduction expected imminently
Talbot/Harrison	Johns Hopkins	Ballistocardiograph apparatus	Royal Medical Corp. Huntsville, Ala.	Approx. $330,000. Now on market
Stanley Plotkin	Wistar Institute	Rubella Vaccine	1) Wellcome Foundation 2) L'Institut Merieux 3) Swiss Serum and Vaccine Institute and others (Merck, an Italian firm, etc.)	Approx. millions - Now on market

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

Inventor	University	Invention	Licensee	Approximate Investment
McKensie Walzer	Johns Hopkins	Keto-Acid analogs of Amino Acids for treatment of uremia	Pfrimmer of Germany and Syntex of U.S.A.	Millions - Clinical trials in process. Expected to be marketed in 6 mos. in Europe
Tadeusz J. Wiktor	Wistar Institute	Rabies Vaccine	Wyeth Laboratories	On the market - millions
Barton Kamen et al	Case Western Res.	Methotrexate Assay	Diamond Shamrock Corp.	Being test-marketed. Production scheduled for late 1977. Millions.
Lillehei/Kaster	Univ. of Minnesota	Pivoting Disc Heart Valve	Medical, Inc.	Being sold in world-wide market since 1971. Millions
Blackshear et al	Univ. of Minnesota	Implantable Infusion Pump	Metal Bellows Co.	Undergoing clinical trials. $750,000.
DeLuca	Univ. of Wisconsin	25-Hydroxycholecalciferol	Rousel-Uclaf (Hoechst)	Have applied for equivalent of NDA in France. Approximately $5 million.
			Upjohn	About to apply for an NDA and an NADA. Will spend about $10 million.
DeLuca	Univ. of Wisconsin	1-Alpha Hydroxycholecalciferol	Leo Pharmaceuticals	Applying for new drug applications in Denmark and Great Britain. May be marketed this year. Approx. $5,000,000.
DeLuca et al	Univ. of Wisconsin	1, 25-Dehydroxyergocalciferol	Hoffman-LaRoche Inc.	About to apply for NDA. Will spend about $10 million.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

Inventor	University	Invention	Licensee	Approximate Investment
Josef Fried	Univ. of Chicago	Prostaglandins	Richardson-Merrell, New York, N.Y.	Several millions. In process of development and testing for marketing here and abroad.