is a necessity if you are to have control of your "life" and "liberty". I might add inferentially that it is contended by some that the free enterprise system is dependent on/or sprang from these words, since without the protection of private property from arbitrary intrusion, that system could not exist. Certainly the words distinguish our society from the various forms of the world's collectivist societies.

Now, we all know that the word "property", even at the time of the framing of the Constitution, included "intellectual property". But notwithstanding the generic protection of property in the fifth amendment, the framers chose to be even more explicit about this specific category of property, and provided this language in Article I, Section 8:

> "The Congress shall have power to . . . promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writing and discoveries."

Why -- this special handling of this category of property?

There was no recorded debate in the Convention on September 5, 1787, when Article I, Section 8, was presented, and it was approved unanimously. That the products of the mind should prospectively receive legal protection, even from a centralized Government to be formed, was a principle upon which no one disagreed, probably due to some positive prior experience and examination. Within the eighteenth-century context of natural laws or rights, intellectual property had received affirmative expression not only in English and Commonwealth laws, but in the Declaration of

Independence, which provided that "All men are endowed by their Creator with certain unalienable rights", and "that to secure these rights, governments are instituted among men . . .".

Madison, the chief architect of the Constitution, did not end his interest in intellectual property with the Constitutional Convention. He made the following illuminating statements in support of the prospective Federal authority to award patents and copyrights:

In the Federalist on January 23, 1788:

> "The utility of this power will scarcely be questioned. The copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides in both cases with the claims of individuals. The States cannot separately make effectual provision for either of the cases, and most of them have anticipated the decision of this point by laws passed at the instance of Congress."

In a letter to Thomas Jefferson on October 17, 1788, he made a more important insight:

> "With regard to monopolies, they are justly classed among the greatest nuisances in Government, but is it clear that as encouragements to literary works and ingenious discoveries they are not too valuable to

be wholly renounced? [These two sentences appear to be an attempt by Madison to distinguish between past monopolies of commodities granted as personal favors and the suggested monopoly for novel intellectual property.] Would it not suffice to reserve in all cases a right to the public to abolish the privilege at a price to be specified in the grant of it? [This appears to be the first reference to Government "march-in" rights!] Monopolies are sacrifices of the many to the few. Where the power is in the few, it is natural for them to sacrifice the many to their own partialities and corruptions. Where the power, as with us, is in the many, not in the few, the danger cannot be very great that the few will be thus favored. It is much more to be dreaded that the few will be unnecessarily sacrificed to the many." (Parenthetical sentences and emphasis added.)

In this statement, and especially the last sentence, the answer to the need for specific protection of intellectual property, notwithstanding its generic inclusion in the fifth amendment, seems apparent. First, the use of the term "monopolies" suggests that Madison knew that the nature of an individual piece of intellectual property is such that it could be useful to all people and at the same time be susceptible of ownership by one person, while on the other hand, diversity of ownership of all other categories of property precluded the possibility

of monopoly. The strong possible argument against an indefinite monopolization of valuable intellectual property and its end product under only the fifth amendment and his recognition that "The States cannot . . . make effectual provision", suggests that Madison knew that the rights of the creative few would be in danger without clarification in the Constitution. Thus, a compromise was struck under which intellectual property was to be owned for only a limited term in exchange for the creator's right to exclude. It was under these circumstances that intellectual property -- that property which makes possible the use of all other property -- obtained special consideration in the Constitution.

There is little that I've presented that appears to be subject to question. Even those who have difficulty with the intellectual property clause do not advocate its repeal. Their argument has not been directed against the Government's responsibility for protection of private property and the special reward promised by the intellectual property clause, but erosion of the concept through convincing of an immediate need to limit the reward in the "public interest" or because of public involvement in the difficult delivery process which intellectual property must move through before reaching the public in useable form. These arguments, used in inappropriate situations, are probably what Madison considered "to be dreaded".

As we discussed on previous occasions, since the inception of the patent system, this country has moved from a rural to a highly industrialized nation. In the process, resources and creators flowed into highly sophisticated industrial research organizations. Such creators were

required to assign their creative rights to the organization without any added compensation over and above their salaries. As I noted on that occasion in greater elaboration, this arrangement was tolerated by society and confirmed in the courts as to private organizations and their employees.

When the 17 billion dollars of Federal funds began flowing into research some twenty-five-or-so years ago, through the funding of the Federal Government's contract and grant system, the simplistic policy that "What the Government (or public) pays for (or even partially pays for), it should own" was applied in practice to the total inventive result of some Government funded research programs. This was really an extension of the already developed and accepted concept applied to private industry, discussed above, that an employer (here, the Federal Goverment) can take assignment from an employee (in this case, the Government's grantees or contractors).

As I indicated previously, I thought utilizing this concept in all Government contracting situations to be poor policy,as it did not maximize delivery of inventive results to the public, or protect the equities of all the parties involved, in my experience or that of others. This was explicitly pointed out to DHEW by the GAO in its 1968 Report to the Congress on "Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry", which provided;

> "On the basis of our observations, we proposed that the Department direct its efforts toward timely determination of rights to potentially patentable

> inventions in order to reduce uncertainties as to the status of invention rights. We proposed also that the Department clarify the intended use of Institutional Patent Agreements, of which only limited use has been made, but which appeared be a useful device for assigning ownership rights while protecting the public interest."

After my review of the Constitution, I believe that the legal basis for this finds some support.

Now, the primary argument of advocates of a Government-title policy without reservation maintain that those Government research programs utilizing a Government-license policy result in an "unjustified windfall" in the contractor. Notwithstanding the fact that no Government research program really utilizes a Government-license policy without reservation, consistency would lead one to the belief that a Government-title policy without reservation results in an "unjustified windfall" in the Government. If there really were such a "windfall" in the Government, the policy would be constitutionally suspect, since there is a suggestion that "private property" is being "taken for public use without just compensation", since the chain of title, as provided by Article I, Section 8, must start with the inventor, and proceeds to the Government only through contractual assignment.

In truth, "just compensation" for future inventions generated under Government contracts cannot possibly be determined at the time of contracting, no matter what patent clauses are used, and any equitable

policy in which the Government wished to retain exclusive rights would have to be based on compensating the owner of the exclusive rights at a time when its commercial value could be assessed. Compensation would ordinarily be in excess of the contract price, unless the invention were the specific object of the contract, which ordinarily is not the case. In fact in the area of grant research it is by definition never the case. (I would point out that anyone supporting a Government-title policy without reservation at the time of contracting would need to establish that all future inventions were the specific object of their contracts; otherwise, the Government would be the recipient of a "windfall".)

Now, I consider it nonproductive to belabor the arguments supporting the two extremes of possible Government patent policy. I have chosen to fault the one extreme not for the purpose of supporting the other, but merely because it is the former that has become the more vocal. Unfortunately, when one extreme surfaces and the other remains silent, the Government policies that sit in the middle become pressured to give ground to the vocal extreme. Since as you all know, DHEW patent policy already sits in a middle ground, we cannot responsibly move without abandoning the protection of some of the equities of the parties involved. But, unfortunately, this type of resistance provides to the extremist the argument that we, in turn, are extremist in our position.

Now, of all the variant policies one finds under the President's Statement of Patent Policy, which in itself provides the framework within

which reasonable men can find a middle ground, I believe DHEW's to be the most acceptable. It emerged from the crucible of debate with the clear recognition of the Government's obligation to protect the equities of all the parties, including the general public.

DHEW has two methods of making disposition of invention rights. Its standard policy is to defer determination until the invention is identified. We never take title at the time of contract, thus obviating any possible claim of unjust enrichment. In the majority of cases in which the inventing organization seeks to retain the exclusive rights to an identified invention they have made, we grant the request, subject to the kind of conditions Madison discussed. Thus, there is a requirement that if the organization chooses to license its rights, it first determines whether nonexclusive licensing will result in obtaining further development funds. If exclusive licensing appears necessary on the basis of market conditions, then we limit such licensing to five years from first commercial sale or eight years from the license, whichever occurs first. You all know that there are other "march-in" conditions that needn't be detailed here. If the organization itself chooses to develop the invention, the limitation on its exclusive position parallels that which it could give to a licensee. The grant of a request is nearly always based on the fact that further risk capital is necessary to develop and bring the invention to the marketplace and the Department does not intend to provide these funds, ordinarily because such funds have not been appropriated. This is equivalent to a decision that the invention was not the specific object of the contract,

and we do not wish to pay "just compensation" over and above the contract in order to maintain full rights in the invention. The decision to retain rights in an identified invention in the instances where this has been done was based on a finding that there was an intention to contribute the additional funding necessary to bring the invention to the marketplace. This is tantamount to a decision that the invention was the specific object of the contract and, therefore, the contract price plus the additional investment is "just compensation" for the taking.

Further, in our Institutional Patent Agreement program, under which grantees with patent management capabilities are afforded a first option to any invention made under their grant, an objective decision was made by the Department that because of the basic nature of the research supported, any invention that evolved could not be the specific object of the grant and would always require further development which we would not support. Thus, in this situation, we basically decided that "just compensation" over and above the grant would always be required in order to maintain full rights in the Government, and that we did not wish to make such payment. I would add that the decision to permit the first option in the institution is conditioned, on the same limiting conditions utilized under our deferred determination policy.

Now, in practice, what has happened since the 1968 GAO Report? The statistics we have collected can be considered to be only approximate in that they were accumulated very rapidly through our files and with conversations with the parties in interest. The statistics are

on the low side, as not all the interested parties could provide information to us within the time frame necessary, and most that gave us statistics were conservative when they felt figures could not be readily verified.

First, in regard to the GAO comments on Department performance, I would note, that since January 1,1969, the Department has entered into 41 new Institutional Patent Agreements, bringing the total number to 56. Second, in regard to determinations under our deferred determination policy, average processing time is running between 15 and 20 weeks from time of receipt of a petition to final determination. This compares to a situation in 1968 when petitions basically were not processed.

Now, in regard to rights dispositions, our files indicate that 167 patent applications were filed since 1968 by institutions who 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. In addition, seven options to license have been negotiated. Seventeen joint-funding arrangements with commercial organizations, involving only the possibility of rights to future inventions, have been made. I consider this an important statistic since it indicates a willingness to make arrangements prior to the time that inventions have been made on the basis that the institution has the flexibility of providing to the concern some invention rights if an invention should evolve from the jointly funded effort. The institution gains this ability to negoti-

ate by virtue of its Institutional Patent Agreement. We are advised that on the basis of all the agreements noted, approximately 24 million dollars of risk capital was committed to the development or making of inventions evolving with DHEW support.

Under our deferred determination policy, it was determined that since July 1, 1968, 178 petitions has been reviewed. Of these 178, 162 petitions were granted. Under the 162 petitions granted, the institutions involved and responding have to date granted 15 nonexclusive licenses and 35 exclusive licenses. These licenses have generated a commitment of risk capital of approximately 53 million dollars. One of the petitions granted involved a burn ointment discovered at a university, which was patented for the university by Research Corporation, licensed to a pharmaceutical company, clinically tested under the direction of the company, and cleared by the Food and Drug Administration on the company's initiative. The drug is now commercially available.

To my knowledge, this is the only drug outside the Cancer Chemotherapy Program which was initially discovered with Department support and has reached the marketplace through the investment of risk capital from the drug industry. We are aware of at least five other drugs outside Cancer Chemotherapy at various states of development which were discovered with Department support and are now being developed with private support under licenses made possible under our deferred determination policy. (I cannot at this time advise whether the licenses granted under inventions retained under IPA's involve any drug development situations, but it is presumed they do.) These numbers compare to zero situations at the time of the GAO Report.

The approximately 75 million dollars committed to development of Department initiated inventions, although on the face appearing to be insignificant in comparison to the one-and-a-half billion dollars yearly devoted to research and development at DHEW, is in fact substantial when compared to the 100 million dollars devoted to directed research with profit-making organizations in 1973 and to lesser amounts in preceding years. The comparison to the 100 million dollars is deemed more realistic, since the 75 million dollars committed is substantially all for development purposes (directed research).

Much more significant than the figures involved is the information being provided by members of our audience which indicates that in the last two years industrial organizations have been actively pursuing university research, which I believe to be clearly the result of the audience's active solicitation of collaborative arrangements, which, in turn, was partly motivated by the flexibility provided by our patent policy. Thus, while the GAO Report indicated that in many instances investigators formerly could not reach the point of conclusive failure with their innovations, that pathway appears to be open, along with the hope of successful utilization.

In light of the above, I believe Mr. Madison would be pleased that DHEW had not "wholly renounced" monopolies as "encouragements to literary works and ingenious discoveries".

In times of stress, other countries have abandoned, to their ultimate regret, commitments to individual rights for what was claimed to be the immediate "public interest". The concept of individual rights and the intent to protect them stems from the natural law understanding that rational individual thought leads to survival of all, while collectivism leads to ultimate abuse of such rights.

We are asked now by some to "wholly renounce" the intellectual property clause on the basis of that portion of Government research funds commingled with those of the private sector in order to complete the arduous task of bringing an idea from the lab to a finished product in the marketplace. There are too few who understand that to do so could ultimately mean the liquidation of the private ownership of all intellectual property other than that kept secret, or the fractionalization of all collaborative effort involving Government funding. As the man said, "The price of liberty [and property] is eternal vigilance".

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