THE PROBLEM

There is a serious question as to whether the fourth exemption of the Freedom of Information Act (FOIA) and the Federal Advisory Committee Act (FACA) as interpreted by the courts, adequately protects the intellectual property rights in unfunded research protocols, hypotheses, or designs (research proposals) submitted to the Federal Government for support by an investigator at a university or nonprofit organization to verify his ideas.

The Associations believe that failure to protect the ideas contained in such research proposals will seriously hamper the timely application of innovative ideas which are aimed to solve serious national problems. Evidence indicates that the successful transfer of positive but undeveloped findings which may result from funded research proposals to industry and the marketplace, in many instances, may depend on the existence of licensable property rights. Adequate safeguards for the protection of intellectual property rights of such investigators are necessary to maintain licensable patent rights. Clearly, protection of such important rights is in the interest not only of such investigators but also of society generally.

The need to adequately protect these inchoate or identifiable rights prior to Government funding becomes more apparent when it is realized that only approximately one-third of these proposals are in fact ultimately funded. Thus, if disclosure of these proposals on receipt by the Government becomes the rule rather than an exception, the intellectual

property in the two-thirds of unfunded proposals will be forever destroyed without an identified quid pro quo to the submitting investigator or the public. Such destruction substantially precludes the possibility for obtaining support from other sources, if available. We believe adequate safeguards for the protection of intellectual property rights of unfunded investigators with research proposals before the Federal Government is a matter of basic equity and sound policy. Protection of intellectual property is a right recognized by the Congress and the courts in implementing Article I, Section 8, Paragraph 8 and the common law protection afforded those who wish to maintain their innovative ideas as secrets. Moreover, the remarkably productive partnership between the Federal Government and the non-Federal research community is based in part on the principle of protection of the verified ideas of such investigators and is considered to be in the interest of the American people. We will discuss this partnership at greater length below.

THE EFFECT OF DISCLOSURE OF UNFUNDED RESEARCH PROPOSALS FROM UNIVERSITY AND NONPROFIT ORGANIZATION INVESTIGATORS

To the extent FOIA or FACA require on Government receipt the disclosure of such research proposals, the inchoate or identified intellectual property rights are clearly jeopardized. Within the patent laws, publication has been broadly defined as any unconditional disclosure by its owner of information on an innovation of interest. For example, even a thesis available on the shelves of a university library but not necessarily reviewed by any researcher has been deemed within the patent laws, a

publication of the innovation disclosed therein.[1/] Patent laws of both the United States and foreign countries are drafted against the interest of those parties making or permitting publication of their innovation prior to the filing of a patent application. In the United States, publication of an invention prior to the filing of a patent application initiates a one-year statutory period during which time a patent application must be filed on the innovation disclosed, so that valid patent protection can be established. The laws of most foreign countries preclude obtaining valid protection for a disclosed invention if a patent application had not been filed prior to the date on which the information was first disclosed.

To the extent that FOIA or FACA require disclosure prior to funding, it is unrealistic to expect that investigators or their institutions could take steps independently under patent laws to protect their intellectual property rights by filing a patent application at such an early stage of investigation. The clinical or other corroborating data necessary to support a patent claim would obviously be lacking. The filing of a patent application without such data, if possible at all, would be based on the uneconomic, speculative basis of possible future findings.

To the extent the unfunded investigator before the Government with a research proposal wishes to afford himself of the common law

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1/ Hamilton Laboratories v. Massengill, 111 F. 2d 584, 45 USPQ 594 (6th Cir. 1940); Indiana General Corp. v. Lockheed Aircraft Corp., 249 F. Supp. 809, 148 USPQ 312 (S.D. Cal. 1966); Gulliksen v. Halberg, 75 USPQ 252 (Bd. App. 1937); Ex parte Hershberger, 96 USPQ 54 (Bd. App. 1952).

available to protect innovative ideas as secrets, he would be precluded to do so to the extent that disclosure is required under FOIA and FACA.

COURT INTERPRETATIONS OF THE FREEDOM OF INFORMATION ACT AND FEDERAL ADVISORY COMMITTEE ACT

The disclosure of information generally required under the FOIA and FACA as interpreted by the courts appears to greatly narrow the protection intended by the Congress and certainly undermines the protection that has been accorded research proposals from universities and nonprofit organizations in the past by the Government.

It seems axiomatic that FOIA and FACA require that unfunded research proposals be reviewed on an individual case basis as to whether they are exempt from disclosure under the fourth exemption. It is equally axiomatic that it is difficult (if not impossible) to determine at the design phase of an experiment exactly what is or is not exempt under the fourth exemption. As to those portions that might be deemed exempt under the fourth exemption, it is even more difficult to segregate data of value from those of no value. In fact, the experiment itself, if funded, is conducted to answer these questions. This quagmire illustrates how in a practical manner the FOIA and FACA can substantially weaken the protection available for unfunded research proposals.

Equally weakening the protection afforded to research proposals has been court interpretations of the fourth exemption. The Freedom of Information Act exempts from disclosure "trade secrets and commercial and financial information which is privileged or confidential" (U.S.C. 552 (b)(4)). The decision, however, from the leading case on this exemption (National Parks and Conservation Association v. Morton,

498 Fed. 765 (1974), D.C. Circuit Court) states that the exemption applied if it can be shown that disclosure was likely either, first, to impair the Government's ability to obtain necessary information or, second, to cause substantial harm to a competitive position of a person providing the information. The court toughened the qualification in Petkas v. Staats (501 F. 2d 887 (1974)) by refusing to accept a Government assurance of nondisclosure in a regulation requiring information where filing the information was conditioned on confidentiality. The court held that the Government assurance and the corporations' respective filings conditioned on confidentiality were not determinative and remanded the case for disposition in accordance with the test of the National Parks case noted above. Consequently, a pledge of confidentiality by the Government in and of itself may not prevent disclosure.

As a result of the above cases, the Office of Legal Counsel of the Justice Department has advised that Government protection of intellectual property and its withholding under the "trade secrets" exemption in a Freedom of Information Act suit is, at best, very unpredictable.[2/]

Further, Title 18 U.S.C. 1905 appears to have little effect in a Freedom of Information Act suit. This statute, if applicable, would impose criminal penalties on Government officials who disclose proprietary information in the possession of the Government. It is a deterrent to unauthorized disclosure, but it takes effect only after the disclosure

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2/ Nov. 18, 1975 letter from Michael M. Uhlmann, Assistant Attorney General, Office of Legislative Affairs, Department of Justice, copy attached as Appendix A.

and the damage to the owner. Title 18 U.S.C. 1905 has been ignored by some courts in Freedom of Information Act suits because of a general exemption contained in the statute "unless otherwise provided by law." Courts generally have interpreted the quoted passage as exempting disclosure under the Freedom of Information Act. The penalties specified in Section 1905, therefore, would not be applied to an official who disclosed proprietary information in response to a Freedom of Information suit.

It seems clear in practice and as a matter of law that a university or nonprofit organization investigator seeking Federal support to verify his innovative ideas will not be able to protect his inchoate or identified intellectual property under the first test of the National Parks case, since the Government controls the preponderance of the financial resources now devoted to research at universities and nonprofit organizations, especially in the area of biomedical research. Accordingly, investigators are not in a position to refuse to disclose their research proposals if it is a condition of funding due to the leverage provided to the Government through its control of the substantial portion of research funding available to university and nonprofit organizations.

Even though commercial concerns might with predictable difficulty meet the second or "substantial harm to a competitive position" test of the National Parks case, universities and nonprofit organizations wishing to control access to their unfunded research proposals appear to have little hope of meeting this test in light of Washington Research Project, Inc., v. Weinberger (504 F. 2d 238 (U.S.C.A.D.C., 1974)). In that case

Washington Research Project, Inc., sought access to a number of research proposals from different universities and nonprofit organizations in order to investigate the ethics of the experiments in question. Washington Research Project, Inc., supported its claim to access to the proposals with indications that "it is essential for researchers to be held accountable, and the research process has to be something other than the closed society which it is now." The court indicated, in denying the use of the "trade secrets" exemption, that:

> "It is clear enough that a noncommercial scientist's research design is not literally a trade secret or item of commercial information, for it defies common sense to pretend that the scientist is engaged in trade or commerce. This is not to say that the scientist may not have a preference for or an interest in nondisclosure of this research design, only that it is not of trade or commercial interest . . ."

Certainly an argument can be made that protection, under law, of the intellectual property of investigators employed at universities and other nonprofit institutions ought to be equal to that protection accorded commercial firms. Further, the protection provided investigators at universities and other nonprofit institutions should be predictable. This unpredictability and unequal treatment discussed is directly attributable to the courts adhering to the National Parks test, its further narrowing by the Washington Research Projects case and the rejection of 18 U.S.C. 1905 as defining the breath of what is protectable under the fourth exemption of FOIA and FACA. If 18 U.S.C. 1905 were considered to cover the information protectable under the fourth exemption,

it seems clear that universities and nonprofit organizations would as a minimum occupy a position equal to commercial concerns under FOIA and FACA, since the protection anticipated by 18 U.S.C. 1905 clearly extends to organizations in addition to commercial concerns. Further, such an approach would assure more predictable protection due to 18 U.S.C. 1905's more definitive identification of proprietary information and the Government's need to observe the definition due to the penalties proscribed.

According to Representative John E. Moss, known as the "Father of FOIA," this was intended under the fourth exemption of FOIA (and now FACA). In a summary of a November 10, 1975 meeting on FOIA with Representative Barry Goldwater, Jr.,

> "Mr. Moss indicated that, as an original author of the Freedom of Information Act, it was his intent and understanding that exemption (b)(4) would authorize the withholding from disclosure under that Act of all 'confidential information' protected by 18 U.S.C. 1905 in the criminal code. He further indicated that 18 U.S.C. 1905 was not intended as the authority to withhold such information under the Freedom of Information Act, but rather it was to be the test for what information was authorized to be withheld under the authority in exemption (b)(4). He expressed disappointment that recent court holdings have not correctly interpreted this connection and often have held to the contrary that 18 U.S.C. 1905 information is not necessarily protected under (b)(4), based on the adoption by the courts of various other tests for exemption (b)(4) coverage." 3/

## THE PROCEDURE FOR WITHHOLDING AN UNFUNDED RESEARCH PROPOSAL UNDER PRESENT CASES COVERING THE FOURTH EXEMPTION OF FOIA AND FACA

As noted above, the protection that Federal agencies are able to provide unfunded research proposals of university and nonprofit investigators

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3/ The full Summary of the Nov. 10, 1975 meeting is attached as Appendix B.

is considerably less than that which can be afforded commercial concerns. This is demonstrably evidenced by the procedure a Federal agency would need to follow in order to utilize the fourth exemption under present case law.

In order to deny information, the Federal administrator handling the request must apply the National Parks test to the situation and provide to the Department Public Information Officer a written prima facie case recommending denial. (The case would need to include arguments on how a nonprofit organization could have a competitive position in order to overcome the negation of such possibility by the National Parks and Washington Research Projects, Inc., cases.) If the information the Federal administrator believes should be denied involves a disclosure of an idea, invention, or discovery, a prior art review indicating that such idea, invention, or discovery is in fact novel in comparison to the prior art would need to be conducted before a prima facie case could be made. If novelty cannot be shown, it seems clear that the Government could not prevail in a suit to show that there will be "substantial harm to the owner's competitive position." It is worth asking whether a Federal administrator, even with the aid of the investigator whose idea is involved, can show prior to the funding of a research proposal, that such proposal is novel compared to the prior art. The primary purpose of conducting the research is to demonstrate that the idea is, indeed, novel.

Even if the Federal administrator is able to make a prima facie case establishing that the research proposal falls within the fourth exemption,

there is no guarantee that the Department Public Information Officer would make the recommended denial in light of the May 5, 1977 instructions from the Attorney General to the Agencies of the Executive Branch that

> "The government should not withhold documents unless it is important to the public interest to do so, even if there is some arguable legal basis for the withholding. In order to implement this view, the Justice Department will defend Freedom of Information Act suits only when disclosure is demonstrably harmful, even if the documents technically fall within the exemptions in the Act." 4/

## THE PARTNERSHIP BETWEEN THE FEDERAL GOVERNMENT AND THE NON-FEDERAL RESEARCH COMMUNITY

The Associations believe they are able to estimate to some extent the potential harm that can come to the nation's research effort if protection of individual intellectual property by Government agencies remains in its present state of unpredictability. The Associations have been concerned with the problems of transfer of research progress, technology, and information from the "bench to the public."

A number of studies have yielded evidence of a clear link between the need to protect intellectual property rights and the successful transfer of research innovations to the delivery of health care. In a 1968 report, "Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry" (GAO Report No. B-164031 (2)), the General Accounting Office pointed out that from 1962 to 1968 there was a virtual industry boycott of development of drug research leads generated by research sponsored by the National Institutes of Health. This report

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4/ Letters to Heads of All Federal Departments and Agencies re "Freedom of Information Act" dated May 5, 1977 from Griffin B. Bell, Attorney General, copy attached as Appendix C.

by the General Accounting Office made a forceful point. Where substantial private risk investment is involved, such as required for premarket clearance of potential therapeutic agents and, now, of some classes of medical devices, there is an identified likelihood that transfer will not occur if the entrepreneur is not afforded some property protection in the innovation offered for development.

The most obvious problem affecting ultimate utilization of an innovation depicted in a research proposal eventually enhanced or corroborated in performance of research funded by the Federal Government at universities or other nonprofit organizations is the fact that these organizations do not engage in the direct manufacture of commercial embodiments. It is industry that must bring such innovation to the marketplace.

Since 1968 there have been specific efforts through the patent program of the Department of Health, Education, and Welfare to close the identified gap between the fundamental innovation the Department supports and the private industrial developers who may be necessary to the delivery of end items to the marketplace. The main thrust of the Department's patent policy has been to assure that the innovating group has the right to convey whatever intellectual property rights are necessary for possible licensing of industrial developers. Not all transfers of potentially marketable innovations from such organizations require an exchange of intellectual property rights in the innovation, but it is unpredictable in which transfers the entrepreneur will demand an exchange to guarantee his collaborative aid.

From 1969 through the fall of 1974 estimates of the Department show that the intellectual property rights to 329 innovations either initially generated, enhanced, or corroborated in performance of Department-funded research were under control of university patent-management offices for the purpose of eventually soliciting industrial support for development. During the period from 1969 to 1974, 44 nonexclusive and 78 exclusive licenses had been negotiated under the patent applications filed through these university patent-management offices. According to the figures furnished by the Department, the 122 licenses negotiated have generated investments of around $100 million of private risk capital, in complete contrast to the period 1962 to 1968, during which there was almost no industry interest in research leads of Department-funded research. In the period 1969 to 1974, two licenses resulted in the marketing of two drugs, while a number of other licenses cover potential therapeutic agents in various stages of pre-market clearance. This record is even more impressive in view of the fairly lengthy period required to obtain approval to market a new drug.

In the above context, it is apparent that the existence of licensable patent right may be a primary factor in the successful transfer of a university innovation to industry and the marketplace. The Associations are concerned that the failure to protect and define such right may fatally affect a transfer of a major health innovation.

For this reason, the Associations are seriously concerned that the unpredictability of Government protection for intellectual property rights,

owing to the uncontrolled and unconditioned disclosure of research information under current court interpretation of FOIA and FACA is likely, in the Associations' view, to stifle industry interest in developing potentially important research innovations. Without industry involvement, the transfer of research findings to clinical practice will be impeded. In the judgment of the Associations, there are strong reasons to conclude that the interface between research and health care delivery, an area of vital national interest, is likely to be impaired unless adequate protection is provided for intellectual property rights of investigators whose research is conducted with Federal financial support.

Surveys conducted to date suggest that the preponderance of inquiries concerning research proposals from university and nonprofit investigators are made to give better definition to other investigators' research, or to improve the competitiveness of the inquirer's own proposal for research support at the expense of the pending proposal.[5/] These data indicate intellectual property rights of researchers may not be sufficiently protected because they are subject to disclosure that could not only benefit less innovative researchers but could also jeopardize the original researcher's intellectual property rights under the patent or common laws.

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5/ Report of the President's Biomedical Research Panel - Disclosure of Research Information, Page 16, DHEW Publication No. (OS) 76-513.

Disclosure of Research Information under the Freedom of Information Act - The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, p. 35-36 - DHEW Publication No. (OS) 77-0003.

Furthermore, the Associations believe complete "openness" constitutes a distinct danger that industrial developers will, as in the 1962 to 1968 period described in the General Accounting Office report, find little incentive to develop research leads generated by investigators under support provided by the Government. The patentability or secrecy of eventual discoveries and innovations having been precluded by disclosure, it is not unreasonable to surmise that industrial developers will hesitate to risk capital investment when they are unlikely to gain rights to the intellectual property. For example, the request of one public interest group for appreciable numbers of research applications raises the prospect of large-scale multiple requests under a short deadline for reply. Since it is difficult or impossible to ascertain whether research at an early stage may contain information regarding potentially patentable innovations, the effect of disclosure on patentable material will be to thwart or to nullify any present measures agencies may use to attempt to provide some protection to intellectual property rights of researchers. This additional uncertainty is likely to deter industrial developers from exploring research leads generated by Federally supported research, which at present amounts to more than three-fifths of all the nation's health research and development.

In light of the effect of disclosure of research information on intellectual property rights and in light of the importance of such rights to the transfer of research innovations to the delivery of health care, it

is clear that complete "openness" attempts to ensure public accountability at the cost of sacrificing protection of intellectual property rights of demonstrable potential benefit to the nation.

CONCLUSION

1. The Associations strongly support appellant's contention that an agency determination that information falls within the fourth exemption of FOIA or FACA should result in required denial of access to such information. To permit the agency the discretion to release such information notwithstanding its identification as a "trade secret" or "confidential information" is constitutionally suspect as being a disposition of property without due process of law. Further, the courts' upholding of the appellant would add over a period of time to the ability to determine what information falls within the fourth exemption and, accordingly, enhance its predictability.

2. The Associations strongly support appellant's contention that 5 U.S.C. 301 does not constitute authorization by Law within 18 U.S.C. 1905 for disclosure of private, confidential business information. Such a decision, as well as being supported in law by appellant, is vital to placing the protectability of information submitted to the Government by universities and nonprofit organizations on an equal footing with information submitted by commercial concerns, as 18 U.S.C. 1905 clearly covers universities and nonprofit organizations. The Associations believe this to have been the original Congressional intent of the drafters of FOIA and FACA, as noted by Representative Moss and the appellant's brief.

This intent was later overturned by the National Parks case and the Washington Research Project, Inc. cases, supra. The court's equating the information covered by 18 U.S.C. 1905 to that covered by the fourth exemption would also go far toward improving the predictability of the information covered by the fourth exemption due to 18 U.S.C. 1905's more definitive description of propertary information.

The Associations believe the ideas of scientists are equivalent to "trade secrets" and, therefore, should be protected. We hold that ideas, the key to the vigor and productivity of the nation's scientific and technological effort, are a scientist's principal stock-in-trade. The advancement, remuneration, and prestige of a scientist, particularly of a young scientist, depend upon the soundness of these ideas and the skill with which the scientist applies them to a research problem. Furthermore, success in obtaining support for a biomedical investigator's research is mainly dependent on and proportional to the value of these ideas, as judged by the primary source of funds, the Federal Government. The court's equating the information covered by 18 U.S.C. 1905 to that covered by the fourth exemption will tend to endorse our belief.

3. The Associations further support the appellant's contention that persons supplying information believed to fall within the fourth exemption or the protection of 18 U.S.C. 1905 is entitled to a trial de novo prior to disclosure of such information by the Government. The Associations believe that the Government's unilateral ability to release privately owned intellectual property falling within the definition of inchoate or identifiable patentable subject matter or information protectable at

common law as secret is constitutionally suspect as a disposition of property without due process of law and demands the ability of the submitter to enjoin such release or be irreparably damaged.

4. Preserving the ability to keep research proposals in confidence best serves the public interest by assisting in the protection of the quality of the peer review process as used by the Government. For example, the hope of the public for improvement in the quality of life through biomedical research has resulted in the development in the United States of the world's leading biomedical research enterprise.

In any large activity, and especially in one involving a heavy investment of public monies, the process by which those funds are invested is of critical importance. An essential feature of the almost thirty-year history of the review process for research proposals has been the unusual confidence in it of all parties involved, based in large measure on their faith that the proposals presented and the discussions about them will be held in strict confidence. This arrangement has prompted the nation's finest scientists to reveal in great detail their research ideas, and the nation's leading biomedical experts to discuss in a very candid and, therefore, effective manner the content of these applications. As Attorney General Edward H. Levi has recently stated, "... complete disclosure would render impossible the effective operation of government. Some confidentiality is a matter of practical necessity." 6/

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6/ From address by Edward H. Levi, Attorney General of the United States, before the Association of the Bar of the City of New York, April 28, 1975.

A complex society cannot make decisions "in the marketplace" in the manner of simpler societies no matter how much we may wish to return to simpler days. In the same way, not all citizens can or should have complete information about all decisions. Thus, decision-making must be delegated but, at the same time, the decision makers must be held responsible. The complex decisions about biomedical research are now made by an extensive process which is, and must be, accountable to the public. If, however, the research proposals are disclosed, and if the Government should be forced in the future to open their review sessions, it seems probable that many investigators, particularly younger scientists seeking to establish their reputations while protecting their nascent scientific ideas from competitors, would be less willing to disclose sufficient detail to permit the present quality of Government assessment. Furthermore, as a consequence of the members being less candid in open sessions, there is no question but that the discussions would be less thorough. There is also a need to protect the privacy of the investigator whose applications are criticized and rejected and, conversely, to protect the evaluators from harrassment by disappointed applicants.

There have been very few charges of "plagiarism" of ideas in the review system over the past twenty years. Most observers of the system concur in the conclusion that an unusual set of mores has evolved during its history which has kept such possibilities to a remarkable minimum. This record appears to be in significant contrast to the charges which have occurred in other systems where similar attitudes have not developed.

Perhaps the deliberations of the court will be illuminated by a passage from an October 17, 1788 letter by James Madison to Thomas Jefferson in support of Article 1, Section 8, Paragraph 8 of the then proposed Constitution:

> "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? 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? 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 unnecessarilly sacrificed to the many. (Emphasis added)