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THE UNITED STATES GOVERNMENT
DEPARTMENT OF COMMERCE
BUREAU OF ECONOMIC ANALYSIS
WASHINGTON, D. C. 20540

COMMENTS TO US

1. The Department of Commerce is pleased to receive your comments on the proposed regulations concerning the treatment of certain foreign-sourced income for purposes of the foreign tax credit.

2. The Department is particularly interested in your views on the proposed treatment of certain foreign-sourced income for purposes of the foreign tax credit. We would appreciate your comments on the proposed treatment of such income.

3. The Department is also interested in your views on the proposed treatment of certain foreign-sourced income for purposes of the foreign tax credit. We would appreciate your comments on the proposed treatment of such income.

4. The Department is also interested in your views on the proposed treatment of certain foreign-sourced income for purposes of the foreign tax credit. We would appreciate your comments on the proposed treatment of such income.

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8. The Department is also interested in your views on the proposed treatment of certain foreign-sourced income for purposes of the foreign tax credit. We would appreciate your comments on the proposed treatment of such income.

IN THE
Supreme Court of the United States

OCTOBER TERM, 1977

No. 77-922

CHRYSLER CORPORATION, *Petitioner*

v.

HAROLD BROWN, et al., *Respondents*

On Writ of Certiorari to the
Court of Appeals for the Third Circuit

BRIEF AMICUS CURIAE
ASSOCIATION OF AMERICAN MEDICAL COLLEGES

OPINIONS BELOW

The opinion of the court of appeals is reprinted as Appendix A to the Petition for a Writ of Certiorari. The opinion of the district court is reported at 412 F. Supp. 171.

JURISDICTION

The jurisdiction of this Court rests on 28 U.S.C. § 1254 (1).

CONSENT TO FILE*

This Amicus Curiae brief is being filed with the consent of all the parties to the proceeding.

* Letters of consent of all parties to the case have been filed with the Clerk of the Court.

INTEREST OF AMICUS

The Association of American Medical Colleges is a voluntary, nonprofit, non-governmental corporation established under the laws of the State of Illinois, having its principal place of business in the District of Columbia. Its corporate purpose is the advancement of medical education. Its institutional membership includes all one hundred twenty one accredited and operating nonprofit medical schools and medical colleges in the United States. Its membership also includes over 400 teaching hospitals in which undergraduate and graduate medical education is conducted, and 63 academic and professional societies, the members of which are actively engaged in medical education and the conduct of biomedical research.

The members of the Association of American Medical Colleges (AAMC) conduct a substantial proportion of the nation's Federally supported biomedical research. Health related research and development is in large measure supported by the Federal Government; it provided nearly \$2.8 billion for this purpose in 1975 out of a total national investment of more than \$4.6 billion. Of this, \$1.74 billion was expended in institutions of higher education. The National Institutes of Health, chief sponsor of medical research and development awarded \$1.07 billion in Federal research grants and contracts to institutions of higher education of which \$808 million was awarded to medical school members of the Association of American Medical Colleges and an additional \$24.5 million to member hospitals.¹

¹ Figures taken from Tables 2 and 21, Basic Data Relating to the National Institutes of Health, DHEW Publication No. (NIH) 77-1261, 1977.

Thus the institutions represented by *amicus* have a major role in the nation's system for conducting Federally sponsored research. Its interest in this case stems from the impact of the operation of the Freedom of Information Act (FOIA)² and the Federal Advisory Committee Act (FACA)³ on that system. *Amicus* believes that a measure of confidentiality is a necessary feature of governmental review, evaluation and handling of research grant applications. Protection from premature disclosure of an investigator's ideas is necessary to assure that the full fruits of government funded research are available to the public and are essential to the preservation of important intellectual property rights.

QUESTIONS PRESENTED

The questions before the Court include whether Exemption 4 of the FOIA is permissive or mandatory; whether agency regulations promulgated pursuant to 5 U.S.C. § 301 constitute "authorization by law" within the meaning of 18 U.S.C. § 1905 for disclosure of private, confidential business information; whether a submitter of information is limited to judicial review of the agency record as his only recourse in the event of an agency determination adverse to interests he asserts are protected by Exemption 4 and/or 18 U.S.C. § 1905.

Reformulated in terms reflecting the perspective of *amicus*, the fundamental question is: May the Federal government, as possessor of valuable information as a

² 81 Stat. 54, 5 U.S.C. § 552 (P.L. 90-23, 90th Congress, 1st Session (1967), as amended).

³ 86 Stat. 770 (P.L. 92-463, 92nd Congress, 2nd Session (1972), as amended).

consequence of its offer to support research projects it deems to be in the public interest, at its discretion, effect a diminution of the value of the ideas to submitting investigators, foreclose the transformation of the ideas into commercially valuable intellectual property, and deprive the public of potential benefits from Federally funded research?

Amicus recognizes that the specific items of information giving rise to this case are conceded by the parties to fall within the scope and coverage of Exemption 4. Accordingly, it recognizes that arguments as to the merits of including information contained in EEOC reports, affirmative action plans and the like within the scope of Exemption 4 are not pertinent to this case. *Amicus* will, however, direct some discussion to issues related to the scope of Exemption 4 in order to illustrate to the Court the injury to the public interest that will result from any determination that the exemption is discretionary rather than mandatory.

SUMMARY OF THE ARGUMENT

Creative ideas are valuable to a research investigator as his stock-in-trade and to society as a means of facilitating solutions to important national problems. To the extent that it may result in product innovations, an investigator's work is both of commercial significance and of public benefit in making available useful materials, such as, for example, life saving drugs or medical devices. Preservation of these values, however, requires that the investigator's ideas and works not be given premature public disclosure.

The FOIA and the FACA affect the timing of disclosure and should be interpreted in a fashion to protect both the investigator's and the public interest. Such

an interpretation is consistent with sound public policy, with Congressional intent, and with Constitutional directives.

ARGUMENT

I. An Investigator's Ideas and Creative Work Are Valuable

A. TO THE INVESTIGATOR BECAUSE:

The advancement, remuneration, professional recognition, and personal satisfaction of a scientist depend upon the soundness of his ideas and the skill with which the scientist applies them to a research problem. The problems selected by applicants in seeking Federal research support and the results of the research (in terms of contribution to science, recognition of the effort as an original product, being the first to publish the research findings, and the like) are thus of substantial "proprietary" interest to him and are traditionally treated in this regard by the scientific community and by the Federal granting authorities,⁴ regardless of the locus of research.

B. TO SOCIETY AT LARGE FOR THEIR CONTRIBUTION TO THE RESOLUTION OF PROBLEMS OF PUBLIC SIGNIFICANCE BECAUSE:

1. They illuminate our understanding of human problems. Federal agencies support academic research

⁴ One member of an NIH initial review group (Dr. Walter Eckhart of the Salk Institute) characterized the importance of an application to an applicant as follows: the 4 to 5 hours a primary reviewer may spend studying an application "is done not so much because of a sense of responsibility or what the other members may think of your presentation, but because one knows that for the applicant it's a matter of life or death". Quoted in Wade, "Peer Review System: How to Hand Out Money Fairly", 179 *Science* (No. 4069) 158, 159 (1973).

because of public recognition of the contributions such research may make to the solution of human problems. For example, the Department of Health, Education, and Welfare is authorized to "encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and [to] promote the coordination of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control and prevention of physical and mental diseases and impairments of man . . ." 42 U.S.C. § 241. Specifically, the Department of Health, Education, and Welfare is authorized to make "grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects." 42 U.S.C. § 241 (c).

The recognized preeminence of the United States in the field of biomedical research, the scientific capabilities of modern medicine, the advances made in alleviating or ameliorating previously devastating disease problems testify to the success of this approach. The continual increase in appropriations for the programs of the National Institutes of Health,⁵ testify to the Congressional and public support of this as an appropriate public policy.

2. They are a source of innovations resulting in useful products.

"From 1969 through the fall of 1974 estimates of the Department show that the intellectual property rights to 329 innovations either generated, en-

⁵ NIH appropriations have increased from \$34.8 million in 1950 to over \$2.5 billion in 1977. Basic Data Relating to the National Institutes of Health, DHEW Publication No. (NIH) 77-1261, 1977, Table 12.

hanced, or corroborated in the performance of Department [of Health Education and Welfare]—funded research were under control of university patent-management offices . . .”⁶

These innovations included drugs and therapeutic agents which promise great benefit in improving health and improving the quality of life of mankind.

II. An Investigator's Ideas, Properly Developed, Often Are Transformed Into Commercially Valuable Property.

It is clear from the preceding quotation that an investigator's ideas and research efforts often result in patentable innovations. It should also be apparent that when this work has matured from a concept to a patented innovation it is transformed into identifiable “intellectual property” and its owner acquires substantial protection under U.S. patent and property laws. Furthermore, an idea or innovation may be commercially valuable, even absent the protections of a patent, if it is managed in a manner suitable to acquiring and preserving the character of a trade secret.

Patented innovations are of little direct concern in this case because of their protection in law. Of direct and substantial concern to *amicus*, however, are those inchoate forms of intellectual property represented by an innovation which may be patentable, but is not yet at a stage where it can be patented, and those insights which may form the basis for a commercially valuable trade secret. The possibility of obtaining a patent is jeopardized and, in some cases foreclosed, by uncondi-

⁶ Report of the President's Biomedical Research Panel—Disclosure of Research Information, at 15. DHEW Publication No. (OS) 76-513, June 30, 1976.

tioned disclosure prior to the filing of the patent application. A trade secret loses its value upon disclosure to the public.

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 unpatented invention initiates a one-year statutory period for filing a patent application on the innovation or valid patent protection is precluded. In most foreign countries valid protection is precluded if a patent application had not been filed *prior* to the date on which the information was *first* disclosed.

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 in the context of the patent laws, to be a publication of the innovation disclosed therein.⁷

III. Exemption 4 of the FOIA Is of Crucial Significance in the Protection of an Investigator's Ideas.

A. PREMATURE DISCLOSURE DIMINISHES AN INVESTIGATOR'S STOCK-IN-TRADE.

Traditionally, Federal granting agencies have recognized and protected a scientist's proprietary inter-

⁷ *Hamilton Laboratories v. Massengill*, 111 F. 2d 584, 45 U.S.P.Q. 594 (6th Cir. 1940); *Indiana General Corp. v. Lockheed Aircraft Corp.*, 249 F. Supp. 809, 148 U.S.P.Q. 312 (S.D. Cal. 1966); *Gulliksen v. Halberg*, 75 U.S.P.Q. 252 (Bd. App. 1937); *Ex parte Hershberger*, 96 U.S.P.Q. 54 (Bd. App. 1952).

est in his work. Applications submitted for funding and the research protocols they contained have been withheld from disclosure under the authority of Exemption 4. It was clearly recognized that making the preliminary research, research designs and protocols public at the time of application would violate the proprietary rights of applicants and greatly enhance the danger that the applicant's ideas (his stock-in-trade) will be appropriated by others. Another researcher might modify the original proposal, be awarded the grant and be the first to publish findings thereby not only causing loss of the research opportunity and grant to the initial applicant but also crediting the subsequent applicant with the idea.

These concerns of the research scientist are very real and highly important, and preoccupy them constantly. The essence of this concern was expressed by Dr. James Dewey Watson, Nobel laureate and Professor of Molecular Biology, Harvard University, when he candidly said that "we [scientists] all know too well that the types of jobs we eventually get are very much dependent upon how much we produce. There is little enthusiasm for those who always come in second."⁸ Professor Watson, in observing that "success in generating new ideas usually being more than the simple combination of native intelligence and a good measure of luck", pointed out that "(a)ll too often science resembles playing poker for very high stakes, where re-

⁸ Watson, "The Sharing of Unpublished Information," second Frank Nelson Doubleday Lecture for 1973-74, at the National Museum of History and Technology, January 29, 1974, prepared remarks at 4.

vealing one's hands prematurely makes sense only when you have all the low cards."⁹

This policy of governmental protection of a scientist's ideas was challenged by the Washington Research Project, Inc. when denied access to research protocols funded by the National Institutes of Mental Health.¹⁰ The court concluded, 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. . . ."¹¹

While the court allowed, in a footnote, that it might have reached a different result had there been a demonstration of the commercial character of the research projects at issue, *amicus* contends that this overly narrow reading of Exemption 4 focuses unduly on the nature and organizational locus of the submitter rath-

⁹ *Id.* at 3.

¹⁰ Washington Research Project, Inc. v. Weinberger, 504 F.2d 238 (D.C. Cir. 1974), *cert. denied*, 421 U.S. 963 (1975).

¹¹ 504 F.2d at 241. The Court, in rejecting the "stock-in-trade" contention, did not take cognizance of the very extensive activities of many colleges and universities in licensing their inventions for commercial development. For example, the [University] of Wisconsin Alumni Research Foundation has, over a 51 year period, licensed inventions resulting in nearly \$2 billion in sales and the return of substantial royalties utilized for university research. Hearings on the Business Record Exemption of the Freedom of Information Act before a Subcommittee of the House Committee on Government Operations, 95th Cong., 1st Sess. (1977), at 321.

er than the character of the information and the interests at stake. 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. If Exemption 4 were considered to cover the information protectable under 18 U.S.C. § 1905, 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 non-commercial organizations as well as to commercial enterprises. Further, such an approach would assure more predictable protection because 18 U.S.C. § 1905 contains a definitive identification of proprietary information and because Government officials would carefully adhere to this definition due to the penalties prescribed.

In the view of Representative John E. Moss, known as the "Father of FOIA," it was the Congressional intent that there be a close identification of 18 U.S.C. § 1905 and Exemption 4. 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 exemp-

tion (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."¹²

B. PREMATURE DISCLOSURE DESTROYS THE TRADE SECRET VALUE AND POTENTIAL PATENTABILITY OF INNOVATIONS.

Notwithstanding the decision in *Washington Research Project*, and assuming *arguendo* that it correctly states the law with respect to funded applications where no specific showing of a commercial interest is made, there remains a basic and difficult problem regarding the treatment of inchoate intellectual property resulting from judicial interpretations of Exemption 4 and the administrative difficulties of agency compliance.

To the extent that FOIA requires disclosure prior to the funding of research projects, it is unrealistic to expect that investigators or their institutions would be able to protect their intellectual property rights by filing a patent application at this 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. The unfunded investigator with a research proposal before the Government would be foreclosed from

¹² 121 Cong. Rec. H 12379 (Dec. 11, 1975). The full Summary of the Nov. 10, 1975, meeting is attached as Appendix A.

the protection of his innovative ideas as trade secrets under the common law to the extent that disclosure is required under FOIA.¹³

FOIA would appear to require that unfunded research proposals be reviewed on an individual case basis as to whether they are exempt from disclosure under Exemption 4. However, it is difficult (if not impossible) to determine at the design phase of an experiment whether and to what extent it is exempt from disclosure under this authority. As to those portions that *might* be deemed exempt under Exemption 4, at that stage it is even more difficult to segregate data of potential commercial significance from those that do not have this value. In fact, the experiment itself, *if* funded, is conducted to answer these questions. This administrative quagmire demonstrates the practical difficulty of providing adequate protection for unfunded research proposals under the FOIA.

This difficulty is compounded by court interpretations of Exemption 4. The decision from the leading case on this exemption (*National Parks and Conservation Association v. Morton*, 498 F. 2d 765 (D.C. Cir. 1974)) states that the exemption applies if it can be shown that disclosure was likely either, first, to impair the Government's ability to obtain necessary infor-

¹³ In other circumstances, an application for governmental assistance does not constitute a waiver of an innovator's claim to protection from disclosure of a trade secret. *See, e.g., Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1970) (the enactment of the U.S. patent laws do not deprive States of their ability to protect trade secrets); *Sears v. Gottschalk*, 357 F. Supp. 1327 (E.D. Va. 1973), *aff'd*, 502 F. 2d. 122 (4th Cir. 1974) (patent applications denied patent protection are nevertheless protected from disclosure under the FOIA by Exemption 4 as trade secrets).

mation, or second, to cause substantial harm to a competitive position of a person providing the information. The standard was further restricted in *Petkas v. Staats* (501 F. 2d 887 (1974)) where the court refused to accept a Government assurance of nondisclosure contained in a regulation requiring information. A corporation's reliance on this assurance, and the filing of the information conditioned on confidentiality, were not considered determinative and the court 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.

Further, Title 18 U.S.C. § 1905 appears to be given little effect in Freedom of Information Act suits. This statute, when applicable, imposes criminal penalties on Government officials who disclose proprietary information in the possession of the Government. It is a deterrent to unauthorized disclosure, although it takes effect only after the disclosure and the damage has been suffered by the owner. Title 18 U.S.C. § 1905 contains a general exemption, "unless otherwise provided by law", and has not been given effect by some courts in Freedom of Information Act suits. These courts have interpreted the quoted passage as permitting disclosure under the Freedom of Information Act, or as the court below, under agency disclosure regulations. The penalties specified in Section 1905, therefore, have not been applied to an official who disclosed proprietary information in response to a Freedom of Information request.

Since the Government controls the preponderance of the financial resources now supporting research at universities and non-profit organizations, especially

in the area of biomedical research, it is clear in practice 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 *National Parks* (impairment of government's ability to obtain material). If susceptibility to disclosure is a condition of seeking Federal funding, investigators will not be in a position to refuse to submit their research proposals for funding because of the financial leverage possessed by the Government.

Even though commercial concerns might, with some 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 an even greater burden in meeting this test in light of *Washington Research Project, Inc.*¹⁴

C. THE WITHHOLDING OF A RESEARCH PROPOSAL IS INADEQUATELY PROVIDED FOR UNDER PRESENT CASES COVERING THE FOURTH EXEMPTION OF FOIA.

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 for 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 Project, Inc.*, cases.) Before a *prima facie* case could be made to deny a disclosure request involving an idea, invention, or discovery, a prior art

¹⁴ *Supra*, note 10.

review would need to be conducted indicating that such an idea, invention, or discovery is in fact novel in comparison to the "prior art". 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, especially 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 accede to 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."¹⁵

The need to adequately protect these inchoate or identifiable rights prior to Government funding becomes more apparent when it is realized that only

¹⁵ Letter 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 B.

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 offsetting benefit to the submitting investigator or the public. *Amicus* believes adequate safeguards for the protection of intellectual property rights of 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 of the Constitution 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 ideas of such investigators and is widely considered to be in the best interests of the American people.

IV. Harm to the Public Interest Results from Current Unpredictability of Protection from Disclosure.

Amicus believes it is possible to estimate, in a general sense, the potential harm that results if protection of individual intellectual property by Government agencies remains in its present state of unpredictability. *Amicus* has long been concerned with the problems of transfer of research progress, technology, and information from the "laboratory 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 innova-

tions to the delivery of health care. In a 1968 report, "Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry,"¹⁶ the General Accounting Office pointed out that from 1962 to 1968 there was a virtual industry-wide boycott on the exploitation of drug research leads generated by research sponsored by the National Institutes of Health. This report forcefully concludes that where substantial private risk investment is needed, such as that 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.

Since 1968 there have been specific efforts through the patent program of the Department of Health, Education, and Welfare to close the recognized gap between the discoveries made under research support and the willingness of private industrial developers to invest the funds necessary to deliver the innovations to the market place. 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 entrepreneurs will demand an exchange to guarantee their collaborative aid.

¹⁶ GAO Report No. B-164031 (2), 1968.

“During the period from 1969-1974, 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.”¹⁷

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

For this reason, *amicus* is seriously concerned about the unpredictability of Government protection for intellectual property rights, because of the uncontrolled and unconditioned disclosure of research information under current court interpretation of FOIA. This state of affairs is likely to stifle industry interest in developing potentially important research innovations. Without industry involvement, the transfer of research findings to clinical practice will be impeded.

¹⁷ Report of the President's Biomedical Research Panel, *supra* note 6 at 15.

In the judgment of *amicus*, 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.

V. The FOIA Must Be Interpreted Consistent With Relevant Constitutional and Statutory Provisions and with the Public Interest.

The Freedom of Information Act contains no provision for according submitters of information due process of law in any decision to disclose information of value to the submitters. Nor does the Act contain a provision to compensate the submitter for the value of information destroyed by its disclosure to the public. As asserted above, the result of disclosure is a general harm to the long range public interest. These considerations argue forcefully that the Congress never intended a submitter of information to be dispossessed of valuable property by operation of the FOIA. Instead, Congress intended, as stated by Mr. Moss, that Exemption 4 would preserve the confidentiality of such valuable information and that it would be read in conjunction with Section 1905 of Title 18. A contrary reading of Exemption 4 has the effect of subverting the Constitutional mandate that Congress promote the useful arts, Article I, Section 8, Paragraph 8, and would be violative of the clear mandate of the Fifth Amendment of the Constitution prohibiting the deprivation of property without due process of law. These considerations in turn lead to the conclusion that Exemption 4 constitutes a mandatory prohibition against the disclosure by government agencies of information described therein and in Section 1905 of Title 18.

CONCLUSION

It is the position of *amicus* that the public interest is served by a governmental policy which accords adequate recognition to the concept that the research investigator's ideas are valuable and constitute actual or inchoate intellectual property. Untimely disclosure or unrestricted access to materials contained in research grant applications through the operation of the FOIA will result in the destruction of valuable property rights, will undermine the effectiveness of the system for awarding grants on the basis of scientific merit, and will inhibit and in some cases preclude the transfer of technology from the "laboratory to the patient bed." These conclusions are supported by and reflected in the recommendations of two independent Congressionally commissioned studies of the implication of disclosure of information contained in research protocols, research hypotheses, and research designs obtained by the Secretary of Health Education and Welfare in connection with applications or proposals submitted to the Secretary for a grant, fellowship, or contract under the Public Health Service Act.¹⁸

¹⁸ Report of the President's Biomedical Research Panel—Disclosure of Research Information, DHEW Publication No. (OS) 76-513, June 30, 1976.

Disclosure of Research Information under the Freedom of Information Act—The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, DHEW Publication No. (OS) 77-003, 1977.

While each of these reports conclude that new legislation will be required to assure these objectives, *amicus* contends that they will be achieved through a proper construction of Exemption 4 of the FOIA and 18 U.S.C. § 1905, by this Court.

1. Consequently, we conclude and urge this Court to hold that Exemption 4 of the FOIA must be interpreted as a mandatory prohibition of agency action to disclose information described therein or in Section 1905 of Title 18.

2. *Amicus* strongly supports petitioner'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. This conclusion, is essential to prevent the evisceration of Exemption 4. Finally it is consistent with sound public policy to provide protection to information submitted to the Government by universities and nonprofit organizations on an equal footing with information submitted by commercial concerns.

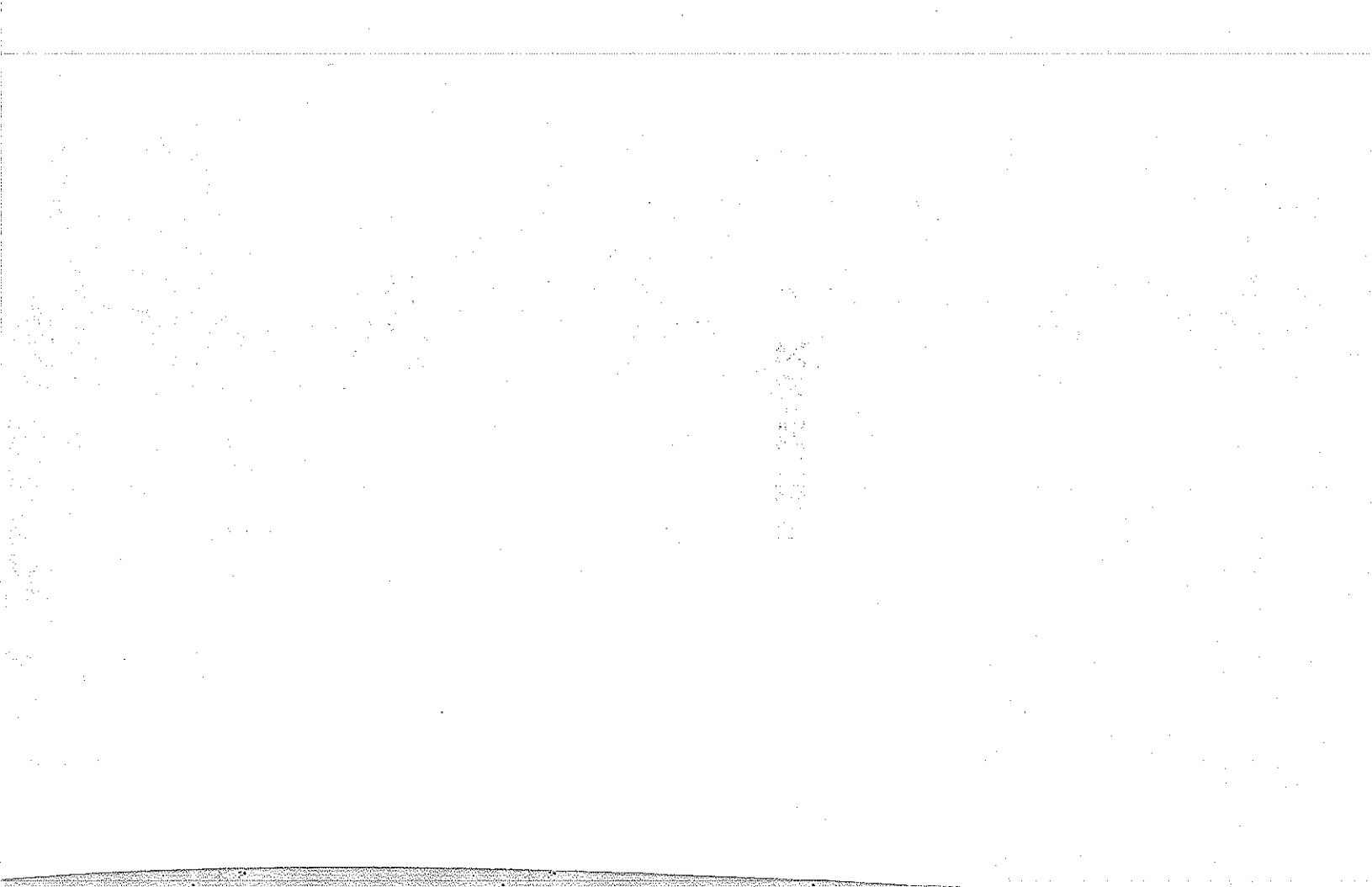
3. *Amicus* further supports the petitioner's contention that persons supplying information believed to fall within the Exemption or the protection of 18 U.S.C. § 1905 are entitled to a trial *de novo* prior to disclosure of such information by the Government. *Amicus* believes that the Government's unilateral ability to release privately owned intellectual property, inchoate or identifiably 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 thus requires adequate opportunity for the submitter to enjoin such release before irreparable damage occurs.

For the foregoing reasons, the decision of the circuit court should be reversed.

Respectfully submitted,

JOSEPH A. KEYES, JR.
Attorney for Amicus Curiae
Suite 200. One Dupont Circle, N.W.
Washington, D.C. 20036

June 5, 1978



APPENDIX A

CONGRESSIONAL RECORD—HOUSE

December 11, 1975

H 12379

**Summary of Meeting of Representative John E. Moss with
Representative Barry M. Goldwater, Jr., on the Freedom of
Information Act, Nov. 10, 1975**

1. We agreed that it is extremely important and in the national interest that ERDA have the full cooperation and participation of the private sector, particularly American industry, in the conduct of the national energy R&D effort. This cooperation and participation is essential to ensure the success of the national effort, by providing ERDA access to existing technology and access to past, present and future successes and failures in the private sector's energy R&D activities in order to most effectively manage the national effort.

2. We agreed that any lack of predictable protection of the private sector's proprietary information under the existing Freedom of Information Act exemption from mandatory disclosure for such information (5 U.S.C. 552(b) (4)) could seriously inhibit private sector cooperation and participation with ERDA to the detriment of the national energy research and demonstration program.

3. Mr. Moss acknowledged Mr. Goldwater's conclusion, based on an independent staff legal analysis, that protection under exemption (b) (4) is neither predictable nor adequate because of recent court interpretations of the exemption.

4. 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.

5. Mr. Moss indicated that exemption (b)(3), "specifically exempted from disclosure by statute" could be utilized to create a narrow statutory exemption in other statutes where Congress concluded that there was a legitimate national interest to be effectuated by withholding a class of information. In so concluding, Congress must strike a reasonable and acceptable balance between that national interest and the national interest in public access to Federal government information effectuated by the Freedom of Information Act.

6. We agreed that, in light of the apparent state of unpredictability of protection for proprietary information under exemption (b)(4) and the need for ERDA to provide such predictable protection in order to ensure the full cooperation and participation of the private sector, Congress could conclude that there was a legitimate national interest in ERDA's having the specific authority to predictably protect proprietary information. Further, Congress could strike a reasonable and acceptable balance of that national interest and the national interest in freedom of information and create a (b)(3) exemption for ERDA for that purpose.

7. Finally, we reviewed a draft of a provision to authorize such a (b)(3) exemption for ERDA. Mr. Moss did not comment on the specific language, but did indicate that in concept the approach of the provision was acceptable and in accordance with the preceding discussion and, further,

that he did not object to it. Subsequently, he indicated that the specific language could be improved, but again, that he had no fundamental objection to the approach represented by the draft provision. The statutory test for the class of information, consistent with basic FOIA principles, would, of course, be subject to judicial review under current FOIA procedure.

8. Mr. Moss emphasized that the proposed statutory language provides no authority to withhold information from Congress, or any committee or subcommittee of Congress. He also stated his belief that any Member of Congress should be able to have access to such information.

9. We agree that the above summary accurately reflects the substance of our meeting.

Signed,

JOHN E. MOSS,
BARRY M. GOLDWATER, JR.

APPENDIX B

Letter dated 5/5/77

OFFICE OF THE ATTORNEY GENERAL
WASHINGTON, D.C. 20530LETTER TO HEADS OF ALL FEDERAL DEPARTMENTS
AND AGENCIESRe: *Freedom of Information Act*

I am writing in a matter of great mutual concern to seek your cooperation.

Freedom of Information Act litigation has increased in recent years to the point where there are over 600 cases now pending in federal courts. The actual cases represent only the "tip of the iceberg" and reflect a much larger volume of administrative disputes over access to documents. I am convinced that we should jointly seek to reduce these disputes through concerted action to impress upon all levels of government the requirements, and the spirit, of the Freedom of Information Act. 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. Let me assure you that we will certainly counsel and consult with your personnel in making the decision whether to defend. To perform our job adequately, however, we need full access to documents that you desire to withhold, as well as the earliest possible response to our information requests. In the past, we have often filed answers in court without having an adequate exchange with the agencies over the reasons and necessity for the withholding. I hope that this will not occur in the future.

In addition to setting these guidelines, I have requested Barbara Allen Babcock, Assistant Attorney General for the Civil Division, to conduct a review of all pending Freedom of Information Act litigation being handled by the Division. One result of that review may be to determine that litigation against your agency should no longer be continued and that information previously withheld should be released. In that event, I request that you ensure that your personnel work cooperatively with the Civil Division to bring the litigation to an end.

Please refer to 28 CFR 50.9 and accompanying March 9, 1976 memorandum from the Deputy Attorney General. These documents remain in effect, but the following new and additional elements are hereby prescribed:

In determining whether a suit against an agency under the Act challenging its denial of access to requested records merits defense, consideration shall be given to four criteria:

- (a) Whether the agency's denial seems to have a substantial legal basis,
- (b) Whether defense of the agency's denial involves an acceptable risk of adverse impact on other agencies,
- (c) Whether there is a sufficient prospect of actual harm to legitimate public or private interests if access to the requested records were to be granted to justify the defense of the suit, and
- (d) Whether there is sufficient information about the controversy to support a reasonable judgment that the agency's denial merits defense under the three preceding criteria.

The criteria set forth above shall be considered both by the Freedom of Information Committee and by the litigating divisions. The Committee shall, so far as practical,

employ such criteria in its consultations with agencies prior to litigation and in its review of complaints thereafter. The litigating divisions shall promptly and independently consider these factors as to each suit filed.

Together I hope that we can enhance the spirit, appearance and reality of open government.

Yours sincerely,

/s/ GRIFFIN BELL
Griffin B. Bell
Attorney General