GOVERNMENT PATENT POLICIES: INSTITUTIONAL PATENT AGREEMENTS

HEARINGS

BEFORE THE

SUBCOMMITTEE ON MONOPOLY AND ANTICOMPETITIVE ACTIVITIES

OF THE

SELECT COMMITTEE ON SMALL BUSINESS UNITED STATES SENATE

NINETY-FIFTH CONGRESS

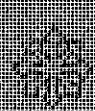
SECOND SESSION

ON

GOVERNMENT PATENT POLICIES

PART 2: APPENDIX

MAY 22, 23, 24, 25, 26, 27, AND 28, 1964



Printed for the use of the Select Committee on Small Business

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United States Senate
SELECT COMMITTEE ON SMALL BUSINESS
WASHINGTON, D.C. 20510

July 18, 1978

Lester A. Fettig, Administrator
Office of Federal Procurement Policy
Office of Management and Budget
Room 9001 New Executive Office Building
Washington, D. C. 20503

Dear Mr. Fettig:

The Monopoly and Anticompetitive Activities Subcommittee of the Senate Select Committee on Small Business now has completed five days of hearings on the history, legal basis and implications of Institutional Patent Agreements (IPAs) as an implement of Government patent policy.

As you know, the hearings were held because the General Services Administration announced that a newly worded IPA was being incorporated in Federal Procurement Regulations for Government-wide use effective March 20. At my request, you agreed to stay the new patent regulation for 120 days, until July 18, to permit it to be scrutinized by congressional committees and the Executive Office of the President.

The subcommittee invited 17 witnesses to testify at the hearings May 22-23, June 20-21 and 26. As the concluding witness on June 26, you said, according to the unedited transcript of the hearing:

> The stay order I requested does run out on July 18th, and, frankly, I have not decided what the most appropriate course of action will be at that time.
>
> Clearly we will need to consult with a wide variety of interests, Dr. Baruch, and his Committee, other interests, other interests in OMB, and the White House, and certainly the interests of this Committee.

If they are correct, the GSA patent regulation should not be allowed to go into effect unless and until it represents OMB policy.

2. Dr. Jordan Baruch, speaking as chairman of the Interagency Committee on Intellectual Property and Information (CIPI) of the Federal Coordinating Council for Science, Engineering, and Technology, testified that CIPI's 16 member agencies are presently studying such questions as:

-- How does Federal patent policy affect competition and economic concentration withinthe private sector?

-- How can Federal patent policy better promote technological innovation?

He said CIPI's goal is to recommend to the President "a set of options with enough detail so that his choices can be welded together into a coherent policy with a clear delineation of who benefits and who bears the costs," that he was sure one of CIPI's recommendations would address the structure and performance of IPAs, and that it probably would take CIPI six months to arrive at a set of recommendations.

While Dr. Baruch disclaimed concern about the GSA patent regulation going into effect before CIPI makes its recommendation to retain, modify or withdraw it, I would like to raise these points about doing so:

a. The GSA patent regulation does not confer authority upon an agency to use an IPA (4). Any authority an agency believes it has to use an IPA it has already. If the GSA patent regulation does not go into effect, agencies presently using their own IPAs would be free to continue using them, and agencies not now using IPAs would remain free to develop their own (17). In other words, putting the GSA patent regulation into effect would not add to an agency's existing authority and options, and staying it would not take away anything an agency may already have. Where then is the compelling public need to implement the GSA patent regulation in the short run while the structure and performance of IPAs undergo study by a committee advising the President?

b. The Department of Health, Education and Welfare and the National Science Foundation presently use their own IPAs and would have to switch over to the standard IPA

that the reports it has received on the status of inventions "have not followed any consistent format and have not always been complete or timely," and conceded, "Moreover, our record keeping has not been sufficiently systematic." HEW appears to have much more detailed information, but some of the information submitted to the subcommittee (1) raised questions of currency and completeness, e.g. the list of IPA holders presented at the hearing of May 22 was current to December 7, 1977, more than five months earlier; the list of patent management organizations utilized by IPA holders omitted University Patents, Inc., and A. D. Little.

One witness proposed that the GSA patent regulation be given a "fair trial" (12), but could offer no suggestion of what would be counted as evidence against the Government-wide IPA in such a trial.

THE GOVERNMENT-WIDE IPA

Two defects of substance and one of procedure mar the standard IPA contained in the GSA patent regulation:

1. The Government-wide IPA provides, "The Institution shall administer those Subject Inventions to which it elects to retain title in the public interest . . .," but it does not define the phrase.

What does the phrase mean? It cannot be left to each institution holding an IPA to define "the public interest." Each institution wanting to negotiate an IPA will have to provide the agency with a copy of its "established patent policy, together with the date and manner of its adoption." Will the Government abdicate its policy-making role and allow universities to define "the public interest" in terms of their own perceptions and interests?

On this point, the NSF witness (2) declared in his prepared statement:

> Ultimately, in any event, I have concluded and advised the Director of the Foundation that under the President's Statement as it now stands, as well as under NSF's basic Act, the legal propriety of the IPA mechanism depends ultimately on a determination of where the public interest lies. That, of course, comes down to a policy judgment for policymakers -- which is, again, as we think it should be.

met before an exclusive license may be issued.

3. Universities and other insiders dominated the process by which the Government-wide IPA was developed. When the draft of the standard IPA was forwarded to Federal Procurement Regulations staff, GSA solicited comments on it from 32 Government agencies, 41 professional associations and 66 educational institutions (4). There was no solicitation of public comment through the Federal Register, on grounds that the Administrative Procedure Act exempts contract matters from the public rule-making requirement "and our practice over the years has been to invoke that exemption" (4).

That old APA provision notwithstanding, most agencies do publish such proposals for public comment, and I understand that both your office and GSA favor revising the APA provision. Furthermore, in your prepared statement you explored the distinctions between procurement and assistance transactions set forth in Public Law 95-224. You explained that in Section 4 it defines a procurement transaction and directs the use of a procurement contract under certain circumstances, and that in Sections 5 and 6 it defines an assistance transaction and directs the use of grants or cooperative agreements under certain different circumstances. You added:

> Federal research and development involves both procurement and assistance and it is important to consider the type of transaction when we consider patent policy.

The Government-wide IPA is too important in terms of policy and procedure to be drafted privately by agency patent counsel, university grantees and their agents. It should be redrafted in public view.

OTHER FACTORS

In closing, I want to mention two factors that relate to the discussion of Government patent policy but do not bear directly on your decision whether or not to continue the stay of the GSA patent regulation:

1. Witnesses at the hearings often shifted their ground from performance to principle and back again. In arguing that the Government should not take title to inventions

JUL 17 1978

Honorable Joel W. Solomon
Administrator
General Services Administration
Washington, D.C. 20405

Dear Jay:

On March 22, 1978, I requested that you take the necessary action to stay for 120 days the final rule amending the Federal Procurement Regulation on Institutional Patent Agreements. This rule was contained in the February 2, 1973, Federal Register.

I understand that under its terms the stay will automatically be lifted at the end of the 120-day period on July 18, 1978. I concur that the stay should be lifted at this time but request that this action be noted in the Federal Register and that the notification include a statement that the Institutional Patent Agreement regulations are subject to change when there is an executive branch resolution of Federal patent policy. Tom Williamson of my Office has discussed this matter with Phil Read.

Many thanks for your help.

Sincerely,

/s/ Lester A. Fettig

Lester A. Fettig
Administrator

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[From the Congressional Record, May 19, 1978, pp. S7881–S7883]

PATENTABLE MATERIAL AND THE FREEDOM OF INFORMATION ACT

Mr. NELSON. Mr. President, Government patent policy generates a snbstantial flow of information in connection with its outlays for research and development.

For example, as a result of its expenditures of about $100 billion for research and development from fiscal year 1970 through 1975, the Government received 52,996 invention disclosures.

Patent right clauses in the Armed Services Procurement Regulations and Federal Procurement Regulations require a Government contractor to submit a complete technical disclosure of each invention conceived or first actually reduced to practice under the contract.

The definition covers any invention or discovery "which is or may be patentable under the laws of the United States of American or any foreign country."

In its study of Government patent policy, the Monopoly and Anticompetitive Activities Subcommittee of the Select Committee on Small Business has noted the substantial flow of preinvention information to the Department of Health, Education, and Welfare which is, nonetheless, claimed to involve patentable material.

From 1969 through 1974, roughly 100,000 grant applications and contract proposals were submitted to HEW. During that period, the Department estimates, universities filed patent applications on 329 inventions which were either generated or corroborated by HEW-funded grants and contracts.

The Freedom of Information Act was in effect throughout that period. On January 5, 1973, the Federal Advisory Committee Act went into effect, requiring that meetings of Federal advisory committees be open to the public but allowing certain meetings to be closed on the same grounds that the FOIA allows certain documents to be exempt from mandatory public disclosures.

Typically, the advisory committees of the National Institute of Health that review grant applications and contract proposals for scientific and technical merits —commonly known as "peer review" committees—would close their meetings on grounds that the FOIA exemptions for trade secrets and invasion of personal privacy applied to the matters to be discussed.

As of early March 1977, NIH notices in the Federal Register announcing that a peer review panel meeting would be closed in accordance with the Federal Advisory Committee Act and exemptions 4 (trade secrets) and 6 (personal privacy) of the Freedom of Information Act customarily asserted:

"The (grant) applications contain information of a proprietary or confidential nature, including detailed research protocols, designs, and other technical information; financial data, such as salaries; and personal information concerning individuals associated with the applications."

However, on or about March 11, 1977, the eve of the effective date of the Government in the Sunshine Act, the wording of NIH notices changed. Here is an example from page 13603 of the Federal Register of March 11, 1977, which was meant to apply to meetings dealing with contract proposals and/or grant applications:

"These proposals and applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposals and applications."

Mr. President, I asked the Congressional Research Service to determine whether use of the phrase "patentable material" could be justified either by statutory law or by judicial interpretations of exemption 4. The CRS reply says in part:

"Patentable material is not automatically exempt; it must satisfy the criteria of Exemption Four and its judicial gloss."

However, it also acknowledges a frankly commercial aspect urged by commentator James T. O'Reilly. The reply was:

"A threshold consideration in determining the applicability of Exemption Four to research grant applications and proposals is the motivation of the researcher or organization. In the words of one commentator, "in the research area, the motive of the researcher to make his findings profitable in the commercial sense is considered a prerequisite to b(4) protection for the research."

I find that view somewhat bizarre. It raises the prospect of grant applications being judged by the commercial gleam in the applicant's eye, instead of their scientific and technical merit. Would the peer review system go cash-and-carry?

Also, it raises doubts about the use of institutional patent agreements—giving universities first option to own the rights to inventions resulting from

scientists to H.E.W. were not exempt from disclosure because "[i]t is clear enough that a non-commercial scientists' research design is not literally a trade secret or item of commercial information, for it defies common sense to pretend the scientist is engaged in trade or commerce." 504 F. 2d at 244 (footnote omitted).

Once it is determined that commercial or financial information is involved, it must further be shown that the information is "privileged or confidential". Privileged information refers to the tradition commonlaw privileges, such as doctor-patient, attorney-client, and has received little judicial attention. See, Project, Government Information and the Rights of Citizens, 73 Mich. L. Rev. 971, 1065 (1975). For information to be "confidential", the test is "if disclosnre of the information is likely to have either of the following effects: (1) to impair the Goverment's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained." *National Parks Conservation Association* v. *Morton*, 498 F. 2d 765, 767 (D.C. Cir. 1974), after remand, 547 F. 2d 673 (D.C. Cir. 1976.)

Thus, to qualify for exemption under the Acts, the information must either be a trade secret, or, confidential commercial or financial information. Patentable material is not automatically exempt; it must satisfy the criteria of Exemption Four and its judicial glass. The NIH notices propose to close meetings because they could reveal "confidential trade secrets or commercial property such as patentable material". Patentable material is used as an example of "commercial property". Commercial property which is privileged or confidential under the *National Parks* test is exempt from disclosure under Exemption Four. Thus, to the extent "patent-material" is congruent with confidential (under *National Parks*) commercial information, it is descriptive of a class of information which may be withheld under the FOIA. Of course, if the patentable material meets the criteria of a trade secret, it is also exempt from disclosure.

Grant applications and research protocols may well contain information which is patentable and has a "trade or commercial character". *Washington Research Project* did not preclude, even in the case of information submitted by non-profit organizations, the possibility of commercial activity entitling the information to the protection of Exemption Four. The court pointed out that it was the agency's burden to demonstrate the "trade or commercial character of the research design information" and that it failed to introduce "a single fact relating to the commercial character of any specific research project." 504 F. 2d at 244–5 n. 6. A threshold consideration in determining the applicability of Exemption Four to research grant applications and proposals is the motivation of the researcher or organization. In the words of one commentator, "in the research area, the motive of the research to make his findings profitable in the commercial sense is considered a prerequisite to b(4) protection for the research." O'Reilly, supra. § 14.07.

House Subcommittee hearings in 1977 on Exemption Four did not examine the problem of research grant and contract proposals in depth. The Subcommittee did receive, however, communications for the record from various individuals and groups expressing concern that Exemption Four did not provide sufficient protection for the scientist and researcher seeking funds from the Federal Government to conduct his projects. See generally, Hearings on the Business Record Exemption of tbe Freedom of Information Act Before a Subcomm. of House Government Operations Comm., 95th Cong., 1st sess. 302–345 (1977). It was pointed out in some of the communications that the material submitted to the Government by potential grantees often contained patentable ideas of potential commercial value. *Id.*, 318.

Furthermore, many projects were used to generate income for further research and education and enhancement of the institution involved. *Id.*, 321. Researchers thus may have proprietary interests as well as pure research motivations. *Id.*, 318. Under such circumstances, information contained in grant of contract applications may qualify for protection under Exemption Four of the FOIA and the Government-in-the-Sunshine Act, *Washington Research Proj., Inc.* v. *Department of HEW*, 504 F. 2nd 238, 244–5 n. 6 (D.C. Cir. 1974) cert. denied 421 U.S. 963 (1975).

II

The second inquiry is whether invention disclosures made pursuant to the provisions of the Institutional Patent Agreement proposed for Government-wide use would be disclosable under Exemption Four of the Freedom of Information Act.

marketing of such inventions and receipt of income therefrom is to be accomplished by nonprofit organizations. In the words of the court in *Washington Research Project*, such institutions would, therefore, seem to have "a commercial or trade interest" in the invention and information relating to it. 504 F. 2d at 244 n. 6. Under such circumstances, the information may be exempt under Exemption Four.

In summary, with respect to invention disclosures for which no patent application is to be filed by the institution, the institution waives its right to nondisclosure under the terms of the Institutional Patent Agreement, Proposed Agreement, Section (e) (3) ; 43 Fed. Reg. 4425. Once a patent application is filed, the information would appear to be protected by 35 U.S.C. 122. *Irons* v. *Gottschalk*, supra. It is those invention disclosures which the institution intends to patent but has not yet filed an application, to which Exemption Four would be applied in determining disclosure. The criteria of trade or commercial character and confidentiality outlined in Part One would be the standards governing access. This would not be creating a new class of information that could be withheld from the public; it would be applying the general terms of the FOIA to a specific piece of information.

We hope the foregoing is responsive to your inquiries. If further analysis is desired or additional questions arise, please contact us.

THE LIBRARY OF CONGRESS,
CONGRESSIONAL RESEARCH SERVICE,
Washington, D.C., May 16, 1978.

To: Senate Subcommittee on Monopoly and Anticompetitive Act. Attention: Gerald Sturges.
From American Law Division.
Subject Patentable Material and the FOIA.

This memorandum will expaud on a conclusion of a prior memorandum of May 8 on the applicability of Exemption Four of the Government-In-the-Sunshine Act to certain NIH peer review meetings. Federal Register notices of closure of meetings of the National Institutes of Health dealing with contract proposals and/or grant applications state that the proposals and applications and the discussions could reveal "confidential trade secrets or commercial property such as patentable material . . ."

Trade secrets and confidential commercial information are exempt from disclosure under both the FOIA and the Sunshine Act. Therefore, "patentable material" must meet the criteria of either a trade secret or confidential commercial information to he exempt from mandatory disclosure. Such material alone cannot justify withholding or nondisclosure. The presence of a trade or commercial interest is necessary before Exemption Four applies.

Patents may be obtained in the absence of a commercial interest or use. The statutory requirements of a patent in 35 U.S.C. 101 do not include trade or commercial use or interest. To be patentable, a "process, machine, manufacture, or composition of matter" must be "useful." 35 U.S.C. 101. However, " 'commercial usefulness', i.e. progress in the development of a product to the extent that it is presently commercially salable in the marketplace, has never been a prerequisite for a reduction to practice and the subsequent patentability of any of the classes of patentable subject matter set forth in § 101 . . ." *Application of Anthony*, 414 F. 2d 1383 (Ct. Cust. Pat. App. 1969). Furthermore, "it does not follow from the fact that a patent has never been put into commercial use, never been recognized by the trade, aud its possessor received no royalty for its license, that the patent is lacking in those novel features which support in fact and in law the essential requirements of a valid patent." Deller's Walker on Patents, § 229 (1965).

Thus, as stated in our prior memorandum, patentable material must satisfy the requirements of either a trade secret or confidentiality and commercial use before it is subject to withholding. It is not per se exempt nor is it necessarily synonymous with confidential commercial property, as the language in the NIH notices seems to indicate. In that regard, the closure notices would seem to be overly broad since any "patentable material" which may be involved must also meet the specific criteria of Exemption Four in order to justify closure.

organisms. In one case, an appellate court has already answered in the affirmative, and a second case is waiting decision.

Many experts believe the issue will remain narrowly focused on microorganisms in food, drug, chemical and similar products, and that the courts can be counted on to avoid any science fiction horror extensions of patentability. At least a few others, though, contend the principle affirmed by the court could easily be applied in far-out and scary directions; to patent products of recombinant DNA technology, cloning, cell fusion and other genetic engineering, perhaps organic modification of animals or even humans.

The patent law, dating back to the earliest days of the republic, authorizes patent protection for the invention or discovery of "any new and useful process, machine, manufacture or composition of matter." The idea, of course, is to encourage research and invention by guaranteeing a temporary monopoly on the product. A 1930 law exteuded coverage to certain "asexually reproduced" new plant varieties.

It's long been assumed that the processes for producing a particular microorganism and the methods for using it could be patented, but the question of patenting the organism itself—without doubt, a form of life—hadn't been seriously addresed until recently. Then Upjohn Co., sought a patent for a microorganism it had isolated from a soil sample and produced in a biologically pure culture, useful for preparing the antibiotic lincomycin.

A government patent examiner ruled the microorganism a "product of nature" and therefore not entitled to patent protection. A three-man appeals board within the Patent and Trademark Office also refused the patent, by a two-to-one vote, but the majority gave a different reason: A microorganism is "a living organism" and Congress never meant living things to be patentable.

Upjohn appealed to the Court of Customs and Patent Appeals, and a three-to-two vote last fall overturned the board and authorized granting the patent. The majority, which included a judge from another appellate court sitting in for an ailing regular member, insisted its ruling was very limited. "We are not deciding," it said, "whether living things in general, or, at most, whether any living things other than microorganisms, are within (the patent law). These questions must be decided on a case-by-case basis."

Nonetheless, other statements seemed quite broad. The majority flatly declared that the fact that the culture was "alive" did not remove it from patent protection. In fact, it added, it is precisely "because it is alive that it is useful." The judges said that microorganisms, like inanimate chemical compounds, were essentially manufacturing "tools," and declared that "the fact that microorganisms, as distinguished from chemical compounds, are alive is a distinction without legal significance."

The minority judges, including a former U.S. Senator, maintained that "the nature of organisms, whether microorganisms, plants or other living things, is fundamentally different from inanimate chemical compositions." Moreover, they said, there was no reason to believe that any legal distinction could be drawn "between microorganisms and more complex living things." The whole subject, they argued, should be left for Congress to determine.

The government has about a month left to decide whether to appeal this decision to the Supreme Court. Meanwhile, another application is raising the issue in a somewhat broader form, one that even attorneys who support the court's Upjohn ruling concede moves a significant step closer towards recombinant DNA technology.

In this case, General Electric Co. is seeking a patent for a bacteria that contains extra-chromosomal geuetic material that produce oil-degrading enzymes—a discovery of obvious use in combating oil spills. A different patent examiner and a different three-man PTO appeals board have unanimously turned down the application, and GE has appealed to the Patent Appeals Court. Argument was heard in December—with the previously ill judge back on the hench—and the court hasn't yet made its ruling.

Ever since the Upjohn case started making waves, there's been intense discussion in legal circles. Several attorneys think that, as Wisconsin law professor John Stedman puts it, "the court will find a way to keep things within bounds," without any need for Congress to step in. Says patent attorney Donald Dunner: "As soon as you discuss patenting living organisms, people have visions of 1984. But I think it's raising more passion than perhaps necessary."

Other students, though, reject the relaxed view. "I'm not sure the court's ruling is quite as limited as it says," asserts one corporate attorney. "It raises the ques-

No references have been cited against claim 5 because the novelty and unobviousness of the biologically pure culture claimed are not questioned. Neither has utility been questioned.

The examiner's sole ground of rejection of claim 5, as stated in his final rejection, was:

"Claim 5 is rejected under 35 USC 101 as non-statutory subject matter. Claim 5 claims a product of nature (Streptomyces vellosus NRRL 8037)." See In re Mancy et al. 182 USPQ 303 at page 306, second sentence before [4]:

Appellants responded with a request to reconsider this rejection supported by affidavits of three Upjohn microbiologists, Dr. Joseph E. Grady, Dr. Thomas L. Miller, and "the well-known microbial taxonomist Alma Dietz," pointing out that the microorganism did not exist as a biologically pure culture in nature and asserting that such a culture is a "manufacture" under § 101, which reads:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

In so arguing, appellants made the point that the pure culture is "a product of a microbiologist." The examiner adhered to his position and appeal was taken to the board.

Since the only ground given by the examiner in support of his nonstatutory-subject-matter rejection was that the culture was a product of nature, that was the only point argued by appellants in their brief before the board, in which they cited a number of precedents for holding that a *pure* product could be patentable over a known impure product of similar kind.

The Examiner's Auswer—only two pages of the printed record—merely summarized his product-of-nature position and cited two cases in addition to *In re Mancy*, supra previously cited by him, namely, *Guaranty Trust Co. of New York* v. *Union Solvents Corp.*, 54 F. 2d 400, 12 USPQ 47 (D. Del. 1931), *aff'd*, 61 F. 2d 1041, 15 USPQ 237 (CA 3 1932), and *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948). With reference to the cases cited by appellants as precedents for patenting pure materials, the examiner noted that they were all pure chemical compounds "as contrasted with the instant microorganism." He noted that the cases cited by him all "involve isolated or biologically pure microorganisms." Appellants replied briefly, taking exception to the last-quoted statement of the examiner:

"* * * since (1) none of the decisions cited, nor any known decision, has held that a 'biologically pure culture' is unpatentable, and (2) there is no evidence that a 'biologically pure culture' was in issue in any of the cited decisions."

On the issue thus framed, the case went to the board.

THE BOARD OPINIONS

The opinion of the majority of the board is quite out of the ordinary. While it affairms the "decision" of the examiner, that is to say his rejection of claim 5, it wholly disregards his reason for rejecting it to the point of expressly declining to consider it. Instead, the board majority decided that claim 5 is not directed to statutory subject matter within the meaning of § 101 because it is for "a living organism," an issue entirely new to the application at bar, so far as the record shows. The dissenting board member's opinion confirms in its first paragraph that that it, strictly, the basis of the majority's decision. Without stating a new ground of rejection was being made (cf. 37 CFR 1.196(b), the majority opinion commences its explanation of its reasoning as follows:

"We have extensively researched prior court decisions for guidance to the question of whether or not a microorganism, being a living thing, is or is not within the realm of statutory patentable subject matter, but, other than possibly noncontrolling dicta, have not found any case directly in poiut.

"It is our view that 35 U.S.C. 101 must be strictly construed and, when so interpreted, precludes the patenting of a living organism. We reach this conclusion on the basis that only those categories of subject matter specifically enumerated in the statute are patentable and a living organism does not fall within the scope of any of those categories listed. An analogous result has been reached by the courts with respect to non-patentability of mental processes, printed matter or methods of doing business none of which are also expressly excluded by the indicated section of the statute, but neither can they be said or have been held to be included thereby."

dicated at oral argument that he was not sure the board had removed it entirely, we state that we find it wholly lacking in merit. The biologically pure culture of claim 5 clearly does not exist in, is not found in, and is not a product of, "nature." It is man-made and can be produced only under carefully controlled laboratory conditions.

We take note of the fact that, since their appearance before the board, appellants have added another statutory category string to their bow. Before the board, they argued that the claim 5 pure culture is a "manufacture" under § 101. Before us they also argue that it is a "composition of matter," which is another § 101 category. This is not a matter of great moment siuce there is considerable overlap between these two broad categories, notwithstanding what some textwriters have said. The arguments have not made a distinction between the two. If it is either, it is statutory subject matter, and it is not intellectually profitable to attempt a distinction in this regard.

We therefore proceed to a decision solely on the basis of the issue as the solicitor has stated it, deeming it to involve the single question of whether the uncontroverted fact that the biologically pure culture, *as claimed*, is *alive* removes it from the categories of inventions enumerated in § 101. Our conclusion is that it does not.

As to what the issue is, however, we make one further clarifying observation. We do so in part because of the solicitor's statement that a similar issue was present hut not decided in *In fe Merat*, 519 F. 2d 1390, 186 USPQ 471 (CCPA 1975), a case involving chicken breeding, and in part because of the board's reasoning herein. The solicitor's statement about *Merat* is correct, but we emphasize that we are not here deciding the issue left open in *Merat* or anything other than the issue before us in this case, whether the subject matter of claim 5 is within either of the terms "manufacture" or "composition of matter" in § 101. In other words, we are uot deciding whether living things in general, or at most, whether any living things other than microorganisms, are within § 101. These questions must be decided on a case-by-case basis and anything said herein is to be taken as said in the context of a discussion of the subject matter of claim 5 and § 101.

As presented to us, the question is clearly one of first impression. There is a substantial volume of literature bearing on it, both directly and indirectly, which the solicitor has helpfully collected in his brief, containing some private views on the question on which, it seems to be agreed, no court has passed.

One of the peripherel court comments, the first to be cited, is from our opinion in *In re Mancy*, 499 F. 2d 1289, 182 USPQ 303 (CCPA 1974). All that the case has been cited for is a bit of dictum bearing on a hypothetical situation which was not before us. The case involved claims to a *process* of producing a particular known antibiotic by aerobically cultivating a particular strain of *Streptomyces bifurcus*. The claims were rejected for obviousness under 35 USC 103 on references showing various strains of other Streptomyces species used for the same purpose. We reversed, holding that *In re Kuehl*, 475 F. 2d 658, 177 USPQ 250 (CCPA 1973), was controlling and that the new *Streptomyces bifurcus* strain *discovered by Mancy* himself as part of the invention being claimed could not be used as prior art in determining the obviousness under § 103 of his cleams to a process of using it to produce the old antibiotic. In comparing the facts of the case before us in *Mancy* with the facts of *Kuehl*, we said (499 F. 2d at 1294, 182 USPQ at 306):

"We recognize the differences between this case and the situation in *Kuehl*, where the novel zeolite used as a catalyst in the claimed hydrocarbon cracking processes was itself the subject of allowed claims in the application. Here appellants not only have no allowed claim to the novel strain of *Streptomyces* used in their process but would, we presume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a "product of nature." However, it is not required for unobviousness of the method-of-use claims that the new starting material by patentable * * *."

It is not clear from the context that we were not discussing what is or is not statutory snbject matter within § 101 but only a difference between two cases which we found not to be a reason for distinguishing them, and that we were not expressing any view, even by way of dictum, on the patentability of living organisms as such, we uow make it explicit that the thought underlying our presumption that Mancy could not have obtained a claim to the strain of microorganism he had described was simply that it *lacked novelty*. We were thinking of something preexisting and merely plucked from the earth and claimed as such, a far cry from a biologically pure culture produced by great labor in a laboratory and

We cannot agree with the board majority's view that § 101 "must be strictly construed." But even a "strict construction," whatever that may entail, fails to lead inexorably to the exclusion of a manufacturer or composition of matter because it is alive. The statute makes no distinction between manufactures and compositions on the one hand and processes on the other. If the board is right in excluding products because there is life in them, then logic dictates that it should take the same position with regard to processes. But it does not do so. Indeed, in light of what the courts have done over the past seventy years in holding such process claims valid, it could not properly do so. We have never heard of a case holding that the categories of patentable subject matter, as enumerated in § 101 or any of its predecessor statutes, should be strictly construed and the board has cited none.

In 1932, when the Board of Appeals was faced with an examiner's contention that a biological process for producing butyl and isopropyl alcohols by bacterial action was unpatentable because the bacteria were doing only what by nature they are capable of doing, its response was that *if such a view were accepted, it would hardly be possible to grant a patent on any chemical process,* indicating an early appreciation of the essential similarity of what we normally think of as "chemical reactions" and the complex *chemical* procedures wrought by the *life* processes of microorganisms. *Ex parte Prescott,* 19 USPQ 178 (1932). As a result of that decision, according to the report of the case, patent No. 1,933,683 was issued Nov. 7, 1933, for "Production of Butyl and Isopropyl Alcohols" with process claims. The board said (19 USPQ at 180):

"We are unable to agree with the Examiner that processes involving bacterial action do not involve patentable subject matter * * *."

What we have before us is an industrial product used in an industrial process—a useful or technological art if there ever was one. See *In re Waldbaum,* 59 CCPA 940, 457 F.2d 997, 173 USPQ 430 (1972). The nature and commercial uses of biologically pure cultures of microorganisms like the one defined in claim 5 are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses. According to an article cited but not relied on by the so icitor entitled "Microbiological Applications and Parents" by Harvey W. Edelblnte in *The Encyclopedia of Patent Practice and Invention Management* at 567, edited by R. Calvert (1964), microbiological processes have long been used "to make beer, wine, cheese, bread, pickles and sauerkraut, rett flax, age tobacco, bate leather, produce silage and digest sewage."

But more to the point here, in recent years, according to Edelblute, they have come to be used to "produce a vast variety of chemicals and drugs such as alcohols, ketones, fatty acids, amino acids, vitamins, antibiotics, steroids, and enzymes." Edelblute provides a "far more complete list" of chemical reactions carried out by microorganisms, which he names, which include oxidation, reduction, condensation, esterfication, amination, deamination, phosophorylation, hydrolysis, decarboxylation, methylation, dismultation, acylation, and dehydration.[2] In short, microorganisms have come to be important tools in the chemical industry, especially the pharmaceutical branch thereof, and when a new and useful tangible industrial tool is invented which is unobvions, so that it complies with the prerequisites to patentability other than the enumerated statutory categories, we do not see any reason to deprive it or its creator or owner of the protection and advantages of the patent system by excluding it from the § 101 categories of patentable invention on the sole ground that it is alive. It is because it is alive that it is useful. The law unhesitatingly grants patient protection to new, useful, and nnobvious chemical compounds and compositions, in which category are to be found the products of microbiological processes, for example, vitamin B–12 and adrenalin, referred to in note 1 above, and countless other pharmaceuticals. We see no sound reason to refuse patent protection to the microorganisms themselves—a kind of tool used by chemists and chemical manufacturers in mnch the same way as they use chemical elements, compouuds, and compositions which are not considered to be alive, notwithstanding their capacities to react and to promote reaction to produce new compounds and compositions by chemical processes in much the same way as do microorganisms. We think it is in the public interest to include microorganisms within the terms "manufacture" and "composition of matter" in § 101. In short, we think the fact that microorganisms, as distinguished from chemical componnds, are alive is a distinction without legal signi-

[2] "Bacteria are universal biochemists * * *." A. Bryan, C. A. Bryan, & C. G. Byran, *Bacteriology* v (6th ed. 1962).

"The nature and commerical uses of biologically pure cultures of microorganisms like the one defined in claim 5 are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses."

Such a distinction is purely gratuitous and clearly erroneous. The nature of organisms, whether microorganisms, plants or other living things, is fundamentally different from that of inanimate chemical compositions. For example, both the microorganisms claimed herein and honeybee are alive, reproduce, and act upon other materials to form technologically useful products (lincomycin and honey, respectively). This cannot be said of chemical compositions. The weakness of the majority's position is further apparent from its failure to advance any rationale for distinguishing between different types of living things—particularly between a biologically pure culture of a microorganism and plants—for purposes of 35 USC 101.

I agree with the broad majority that 35 USC 161, *et seq.*, whose original precursor was the Plant Protection Act of 1930 (1930 Act), and the legislative history of the 1930 Act support the conclusion that living organisms (*e.g.*, plants and biologically pure cultures of microorganisms) were not intended by Congress to be within the scope of 35 USC 101.

That Congress believed it necessary to enact a statute extending patent protection to certain plants (see *In re LeGrice*, 49 CCPA 1124, 1139, 301 F. 2d 929, 939, 133 USPQ 365, (1962)) and to continue this protection in a *separate* provision of the present law demonstrates that Congress never intended that plants or other organisms be within the scope of the terms "manufacture" and "composition of matter." If, indeed, organisms were within the scope of such terms, the 1930 Act would have been superfluous. Presumably the 1930 Act was not superfluous, and the majority opinion here contains nothing to rebut that presumption. See *Platt* v. *Union Pacific Railroad*, 99 U.S. 48, 58 (1878); *In re Finch*, 535 F. 2d 70, 71, 190 USPQ 64, 65 (CCPA 1976); *Skovgaard* v. *The M/V Tungus*, 252 F. 2d 14, 17 (CA 3 1957), *aff'd* 458 U.S. 588 (1959); *United States* v. *Korpan*, 237 F. 2d 676, 680 (CA 7 1956), *rev'd on other grounds*, 354 U.S. 271 (1957); *United States* v. *C. J. Tower & Sons*, 44 CCPA 1, 5, C.A.D. 626 (1956).

Moreover, the Senate committee report accompanying the bill which became the Plant Patent Act of 1930 (S. Rep. No. 315, 71st Cong., 2d Sess. (1930)) stated:

"The purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry, . . . The bill will remove the existing discrimination between plant developers and industrial inventors." [*Id.* at 1.]

This underscores Congressional understanding that plants were not patentable subject matter under the law then in effect, since, if they were, agriculture would already have been afforded "the same opportunity to participate in the benefits of the patent system." See *Bobsee Corp.* v. *United States*, 411 F. 2d 231, 237 n. 18 (CA 5 1969).

If, prior to the 1930 Act, plants had been within the scope of the patent statutes, as the majority opinion apparently assumes, a plant patent would have had to comply fully with what is now 35 USC 112; but after the 1930 Act, a plant patent for certain plants need not do so (since a plant patent could not be declared invalid if its description "is made as complete as is reasonably possible"—see section 2 of the Plant Protection Act of 1930, 46 Stat. 376). This would have constituted a repeal of the full-compliance requirement in the case of such plants without any Congressional discussion thereof. Repeal by implication is not favored statutory construction. *FTC* v. *A.P.W. Paper Co.*, 328 U.S. 193, 202, 69 USPQ 215, 219 (1946). The conclusion follows that, prior to the 1930 Act, plants were not within the scope of the patent statutes.

The Plant Variety Protection Act, 7 USC 2321 *et seq.*, although enacted long after the original use of the terms "manufacture" and "composition of matter" appearing in 35 USC 101, further supports the conclusion that Congress did not intend organisms to be included within the scope of such terms. Both the Senate Judiciary Committee report (S. Rep. No. 91–1246, 91st Cong., 2d Sess. 3 (1970)) and the House Committee on Agriculture report (H.R. Rep. No. 91–1605, 91st Cong., 2d Sess. 1 (1970)) accompanying the bill (S. 3070) which became the Plant Variety Protection Act stated:[1]

[1] The bill was also reported on by the Senate Committee on Agriculture and Forestry (S. Rep. No. 91–1138, 91st Cong., 2d Sess. (1970)), which included a letter from the Under Secretary of Agriculture stating that the proposed legislation would provide the "incentive for private enterprise to undertake the research and development required to produce novel varieties of sexually produced plants."

IN THE MATTER OF THE APPLICATION OF ANANDA M. CHAKRABARTY:
DECIDED: MARCH 2, 1978

(Appeal No. 77-535; Serial No. 260,563)

Rich, Judge.

This appeal by an applicant for a patent, assignor to General Electric Company, is from a decision by the United States Patent and Trademark Office (PTO) Board of Appeals (board) affirming the rejection of claims 7-9, 13, 15, 17, 21, and 24-26 of application serial No. 260,563, filed June 7, 1972, entitled "Micro-organisms Having Multiple, Compatible Degradative Energy-Generating Plasmids and Preparation Thereof." We reverse.

THE INVENTION

In view of the legal issue presented, it is unnecessary to describe in detail the subject matter of the appealed claims, which is described in complicated biological terminology and is of a highly technical nature involving the modification of bacteria to solve man's practical needs. In this instance, the immediate need is the important one of controlling oil spills, as one example, by the degradation of complex hydrocarbons such as crude oil and "Bunker C" oil through the action of microorganisms. Microorganisms, that is to say bacteria, are modified for this purpose by what is sometimes referred to as "genetic engineering," a term appearing in appellant's specification. It is also disclosed therein that prior to appellant's invention microbial strains were know that can decompose individual components of crude oil, any given strain degrading only a particular component of the oil. For this reason biological control of oil spills had involved the use of a mixture of strains on the theory that the cumulative degradative actions would consume the oil and convert it into a cell mass which, in turn, serves as food for aquatic life. However, in the use of such a mixture there was ultimate survival of but a portion of the initial collection of bacterial strains with the result that the bulk of the oil spil remained unattacked for a long period. Appellant's invention involves the creation of a new strain of bacteria by the incorporation in a single cell, by transmission thereinto of a plurality of compatible "plasmids," of a capacity for simultaneously degrading several different components of crude oil with the result that degradation occurs more rapidly. To make this nontechnical description somewhat more intelligible we quote from the specification but two of its many definitions:

Extrachromosomal element . . . a hereditary unit that is physically separate from the chromosome of the cell; the terms "extrachromosomal element" and "plasmid" are synonymous; when physically separated from the chromosome, some plasmids can be transmitted at high frequency to other cells, the transfer being without associated chromosomal transfer.

Degradative pathway . . . a sequence of enzymatic reactions (e.g. 5 to 10 enzymes are produced by the microbe) converting the primary substrate [i.e., oil] to some simple common metabolite, a normal food substance for microorganisms.

This sketchy background, it is hoped, will give some idea of the nature of the invention at bar as defined in illustrative claim 7 which reads:

7. A bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.[1]

The specification disclosure contains examples of bacterial strains with four hydrocarbon degradative pathways and the statement: "If there is an upper limit to the number of energy generating plasmids that will be received and maintained in a single cell, this limit is yet to be reached."

The PTO, speaking through the examiner as well as the board, has not questioned that appellant has invented and adequately disclosed strains of bacteria, within the definitions of his rejected claims, which are new, useful, and unobvious.

Neither has any question been raised by the PTO about the inventions of the rejected claims being in the useful or technological arts so that their protection for a limited time by patent would be an implementation of the Constitutional purpose of promoting progress in the "useful arts." Art. I, sec. 8, clause 8.

[1] As a matter of general interest, the assignee of appellant's invention has been granted British patent 1,436,573 containing this and other claims to the bacterium.

follow, therefore, that * * * appellant has *already* met the requirements of Section 101.

The PTO has advanced but a single reason to support its contention that this is not so, namely, that the new bacterium is alive. That is precisely the single issue we had to pass on in *Bergy*. The decision of the board herein was rendered and the main briefs of the parties hereto were filed before we handed down our *Bergy* decision. Thereafter we invited the parties to file briefs on the bearing of the *Bergy* decision on this case. Appellent opined that "the *Bergy* decision appears to be controlling precedent * * *." The PTO brief said *Bergy* "might be considered dispositive of the issue presented [herein] if that decision remains a viable precedent." It then pointed to the fact that in *Bergy* the claim was directed to a "biologically pure culture" and that we had made it clear in our *Bergy* opinion that we were not deciding anything other than the question whether that claimed invention was a manufacture or a composition of matter within § 101, adding that "the Commissioner is uncertain whether *Bergy* has any bearing at all" in view of the fact that no claim here involved is so limited.

We do not consider the differences between the claims here and the claim in *Bergy* to be of any significance on the issue before us. In both cases the claims are directed to microorganisms and in both the only asserted objection to their patentability is that microorganisms are alive and, for that reason alone, not within the § 101 categories of inventions which may be patented. We dealt fully with that identical issue and with the identical PTO arguments in *Bergy*. Nothing in the facts of this case requires that we add anything to what we there said. *Bergy* is, in this court at least, a controlling precedent.

The decision of the board is reversed.

[U.S. Court of Customs and Patent Appeals]

IN THE MATTER OF THE APPLICATION OF ANANDA M. CHAKRABARTY

(Appeal No. 77-535; Serial No. 260,563)

Markey, Chief Judge, concurring.

I join in full the well reasoned and cogently stated majority opinion of my Brother Rich. These few remarks are prompted, with all due respect, by the dissenting views expressed by my Brothers Baldwin and Miller.

The sole issue before us is whether a man-made inveution, admittedly novel, useful, and unobvious, is unpatentable because and only because it is "alive" (in the sense that microorganisms are "alive").

There are but two sources for manufacturers and compositions of matter. They are God (or "nature" if one prefers) and man.

As presented to us, the invention is admittedly a "manufacture" by man. It therefore falls squarely within the language of the statute. The Patent and Trademark Office desires to read into the statute the word "dead" before "manufacture" and before "composition."[1]

The statute is not ambiguous. No Congressional intent to limit patents to dead inventions lurks in the lacuna of the statute, and there is no grave or compelling circumstance requiring us to find it there.

The Plant Patent Act of 1930 has nothing to do with the case before us and is of no aid in a search for what the intent of Congress would have been were it confronted with the present invention. Moreover, it is not necessary that we assume plants to have been within the scope of the patent statutes prior to 1930. The legislative history of the Plant Protection Act of 1930 or of the Plant Variety Protection Act, referred to in dissent, does not establish that Congress thought it was overcoming an objection to plants as unpatentable solely because there were "alive."

If Congressional intent mnst be sought, I would look to its primary source—the words of the statute itself. The Constitution grants Congress the power to recognize the exclusive rights of inventors in their discoveries for a limited time to encourage progress in the useful arts. Acting under that grant, Congress has provided that a patent shall issue on a "manufacturer" or a "composition," where, as here, the invention meets the criteria established in the statute. It would thus in this case defeat the fundamental purpose of the Constitution, and

[1] If the oil degradating activity of the present invention were stopped, i.e., if the inventor had "killed" his invention, (and if the invention had some utility in its dead form) the Patent and Trademark Office reasoning would require allowance of appellant's application.

for which the unpatentable starting material was already suited does not change the essential nature of the starting material and does not make the modified thing statutory subject matter.[2]

[U.S. Court of Customs and Patent Appeals]

IN THE MATTER OF THE APPLICATION OF ANANDA M. CHAKRABARTY

(Appeal No. 77-535; Serial No. 260,563)

Miller, Judge, dissenting.

I do not agree that appellant's claimed micro-organisms are within the scope of 35 USC 101, and I join in the statement of the board—

We do not believe that Congress intended 35 U.S.C. 101 to encompass living organisms whether they be plants, modified micro-organisms (such as bacteria), or modified multicellular organisms (such as mammals).

In *In re LeGrice*, 49 CCPA 1124, 1139, 301 F. 2d 929, 939, 133 USPQ 365, 374 (1962), this court recognized that, under the Act of May 23, 1930, Pub. L. No. 245, 46 Stat. 376—

The patent law, as shown by the Committee Reports, was *extended* to plant patents in order to stimulate interest in the breeding and commercial development of new and valuable plant species. [Emphasis added.]

Both the Senate and House committee reports to which the court referred (S. Rep. No. 315, 71st Cong., 2d Sess. 1 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess. 1 (1930)) stated:

The purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry, and thus assist in placing agriculture on a basis of economic equality with industry. The bill will remove the existing discrimination between plant developers and industrial inventors.

The House Report, *Id.* at 2, added:

No one has advanced a just and logical reason why reward for service to the public should be extended to the inventor of a mechanical toy and denied to the genius whose patience, foresight, and effort have given a valuable new variety of fruit or other plant to mankind.

Thus, the legislative history clearly shows Congressional understanding that, under the patent law in effect prior to the Plant Patent Act of 1930, reward for service to the Public in developing new varieties of plants had not been extended to inventors. See *Bobsee Corp.* v. *United States*, 411 F. 2d 231, 237 n. 18 (CA 5 1969).[1]

As pointed out in my dissenting opinion in *In re Bergy*, 563 F. 2d 1031, 195 USPQ 344 (CCPA 1977), if, prior to the 1930 Act, living organisms had been within the scope of the terms "manufacture" and "composition of matter" (as the majority and concurring opinions must assume), the 1930 Act would have been superfluous. There is a basic presumption in statutory construction that Congress does not legislate unnecessarily. See *Platt* v. *Union Pacific Railroad*, 99 U.S. 48, 58 (1878); *In re Finch*, 535 F. 2d 70, 71, 190 USPQ 64, 65 (CCPA 1976); *Skovgaard* v. *The M/V Tungus*, 252 F. 2d 14, 17 (CA 3 1957), *aff'd* 458 U.S. 588 (1959); *United States* v. *Korpan*, 237 F. 2d 676, 680 (CA 7 1956), *rev'd on other grounds*, 354 U.S. 271 (1957); *United States* v. *C. J. Tower & Sons*, 44 CCPA 1, 5, C.A.D. 626 (1956). Neither the majority nor the concurring opinion is able to point to anything to rebut that presumption. If, after nearly two hundred years, it is desired to interpret the basic patent statute, for the first time, to cover living matter, the presumption poses a formidable and yet unrebutted challenge. Although advancement of technology would naturally be of interest to an appropriate committee of Congress, it has no relevance to the court's responsibility for determining Congressional intent. As noted by Chief Judge Markey in his concurring opinion in *In re McKellin*, 529 F. 2d 1324, 1333, 188 USPQ 428, 437 (CCPA 1976):

[The] patent law is statutory. Our representative form of government requires that the enactments of its Congress must always be, at the very least, the starting point. There being no common law of patents, we should take care to fill the

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[2] I agree with Judge Miller's thorough analysis of legislative history.

[1] Each of the above-cited committee reports, at page 3, quotes Thomas A. Edison that—

Nothing that Congress could do to help farming would be of greater value and permanence than to give to the plant breeder the same status as the mechanical and chemical inventors now have through the patent law.

Also included are the statement of the University of Wisconsin on Disposition of Inventions & Patents, dated 1969; the patent policy of the Regents of the University of California revised in 1973, and related patent policy documents; and the patent policy of Albert Einstein College of Medicine of Yesiva University, adopted by the Board of Overseers in 1973.

Mr. President, I ask that the material be printed in the RECORD.

[The material follows:]

TAX ASPECTS OF UNIVERSITY PATENT POLICY

The growth of scientific and technological research at universities has been unprecedented in recent years. Along with this growth, new and complex problems have arisen with respect to the appropriate disposition of patentable discoveries and inventions on behalf of inventors among the faculty or staff and the university. Many universities have no formalized patent policy or procedure; others have formalized their policies and procedures regarding patent management practice.[1]

Although the rights to an invention generally belong to the individual inventor who may then make a claim for a patent,[2] a university may contribute financially to the development of the patent property right. It may also be the assignee of a pateut by reason of the employment relationship between the university and its faculty and staff[3] or the recipient of patent property (a patent, an application or the rights to the invention) transferred by gift to it from the inventor.[4] Finally, the university may arrange or assist the inventor, through the facilities of the university, itself or through an affiliate of the university, to have the patent issued and to develop the patent to a point that it may be commercially exploited. Further exploitation of patents is usually accomplished by the granting to others, either by a sale or a license, of the right to make use or sell the invention covered by the patent and most universities share the proceeds obtained on the invention with the inventor, either under a prior contractual arrangement or by mutual agreement.[5]

This "article deals with the federal income tax[6] problems of the university which conducts a patent management program as a part of the functions of the university administration. Three tax aspects considered in this article: (1) the effect of the university's patent-related activities on its tax-exempt status; (2) the application of the tax on unrelated business income to the university's patent-related activities; and (3) the treatment of payments received by the university from its patent activities."

THE EFFECT OF PATENT MANAGEMENT ON THE TAX-EXEMPT STATUS OF THE UNIVERSITY

Patents, like other forms of intangible property, have historically been part of the portfolios of universities and used by them as a source of income, much as they hold securities in their endowment. The role of the university in the patent mauagement field may have an effect on the university's tax-exempt status, however, when substantial activity is undertaken by the university by reason of its involvement in the development or commercial aspects of patent exploitation.

THE QUESTION OF INUREMENT

A university is exempt from federal income tax under section 501(c)(3) of the Internal Revenue Code because it is operated for educational purposes, unless its tax exemption derives from its operation by a state or other government or unless it is a proprietary institution, that section reqnires that no part of the "net earnings" of the university inures to the benefit of any person who has a personal and private interest in the activities of the organization.[7]

The proscription against inurement of net earnings should not adversely affect the university by reason of its obligation to pay or to arrange for the payment of royalties to an inventor in consideration for the transfer of his patent to the university. It is recognized that this provision does not prevent an exempt organization such as a university from paying reasonable compensation for property and, since the university usually receives a portion of the royalties from licensees for its interest, there will be no benefit inuring from the university to the inventor by reason of the program.

Similarly, the proscription against inurement of net earnings should not adversely affect the ability of a university to provide any services or financial com-

Footnotes at end of article.

In general, any activity carried on for the production of income which possesses the characteristics of a "trade or business" within the meaning of I.R.C. section 162 will constitute a trade or business for purposes of the tax on unrelated business income.[12] The question of how much involvement a university may have in patent activities before such activities constitute the conduct of a trade or business has never been stated in a published opinion of the courts or the Internal Revenue Service. In other contexts, however, whether one is in the business of inventing or selling patents depends upon the continuity and regularity of the taxpayer's patent transactions.

It is fairly certain that the licensing of only one invention or the single and nonrecurrent sale of patent rights will be sufficiently isolated and casual so as not to be treated as conduct of a trade or business. However, if the university's objective has been to develop ideas and processes which would be patentable, and it has attempted to put any patents obtained to business and income producing uses through companies by means of licensing or sales, then the activities may be of a sufficiently sustained character to qualify as engaging in the trade or business and income-producing uses through companies by means of licensing or sales, the activities may be of a sufficiently sustained character to quality as engaging in the trade or by the university may nevertheless be a trade or business under these circumstances.

The principal exception to the treatment as an unrelated trade or business is I.R.C. section 513(a)(2) which excepts from the term "unrelated trade or business" any trade or business which is carried on in the case of a college or university primarily [13] for the convenience of its students, officers, or employees. If less than 50 percent of the patent development activities are conducted for persons other than students, officers or employees of the university, the activity should not be considered to be a trade or business.

The most likely circumstances in which a university would engage in the development of patents that do not result from university research would arise when a university receives a donation of valuable patents or purchases a substantial number of patents and engages in the exploitation of them on its own part. As a practical matter, however, it would be an unusual situation if the patent program of the university would be conducted to the extent that in excess of 50 percent of its activities of this kind are from non-university related persons.

REGULARLY CARRIED ON

If the patent development and commercial exploitation of patents is not primarily for the university's employees or students, it still must be regularly carried on by it in order to be subject to the tax. In this regard, the regulations indicate that frequency and continuity with which the activities productive of income are conducted and the manner in which they are pursued are pertinent considerations.[14] If the university merely attempted to exploit and market the products resulting from one or a few patents, it would be possible to argue that the patent development program is not an activity regularly carried on by it.

RELATED VS. UNRELATED

Once it is ascertained that the university's involvement in patent development activities is a trade or business that is regularly carried on, it is necessary to determine whether the activity is "substantially related" to the performance of those purposes or functions with respect to which the university was granted exemption. As discussed *supra*, university patent policies usually encourage the use of inventions and other patentable processes produced at the university for the greatest possible public benefit. This normally includes the widest possible dissemination and use of the inventions or processes in a manner that emphasizes public benefit over profit-making, either by the university or the individual inventor. Against this background, it should be fairly clear that the income derived from the university patent activities contributes importantly to the accomplishment of its exempt purposes other than the need for income.

Nevertheless, if the university's involvement is conducted on a size or to an extent greater than is reasonably necessary for the performance of such activity, the gross income attributable to that portion in excess of the university's needs will be considered gross income from an unrelated trade or business. A good

Footnotes at end of article.

exclusive rights constituted the only practical way to utilize the invention for the benefit of the public.

THE TREATMENT OF INCOME RECEIVED BY THE UNIVERSITY FROM PATENT SALES AND LICENSES

The foregoing discussions are intended to provide the basis for determining whether university involvement in patent sales or licenses or other patent activities is related to the exempt function of the university or at least does not constitute income from "an unrelated trade or business" regularly carried on, thus making it unnecessary to reach the question of whether the income constitutes exempt royalties or capital gains. However, if the patent management activities are not considered to contribute in any manner to the accomplishment of the university's exempt purposes and the activities of the university are sufficient to constitute a trade or business, then the factors which raise the question as to the relatedness of these activities and whether they constitute a trade or business may also be relevant to the determination of whether gain or income derived from the sale or licensing of patents is excluded from the university's unrelated business income under express statutory exceptions.[17]

GAIN FROM THE SALE OF PATENTS

Proceeds from the sale or exchange of patents may be excluded from unrelated business taxable income by reason of I.R.C. section 512(b)(5) which excludes gains from the sale or exchange of property from the computation of unrelated business taxable income. Where there is a sale or exchange, the capital gains exclusion applies, rather than the exclusion for royalties[18] and is applicable whether the proceeds are paid in a lump sum or are based on a percentage of sales or production.

One of the problems that limits the availability of the capital gains exception is the fact that, consistent with a university's purpose of dissemination in such a manner as to give widest use, many patent policies of universities call for non-exclusive licensing. As a result, a transfer or assignment may not consist of substantially all of the patent rights and may therefore fall outside of the capital gains exception to the tax on unrelated business income. Moreover, the principles previously stated as to the degree of development and promotion by the university as well as the frequency of its sales may give rise to the argument that it is in the "business" of developing and selling patents and therefore the proceeds are not capital gains.[19] Under these circumstances, refuge may have to be taken in the royalty exemption.

INCOME FROM PATENT LICENSING

I.R.C. section 512(b)(2) excludes from unrelated business taxable income "all royalties . . . whether measured by production or by gross or taxable income from the property. . . ." and deductions related thereto Neither I.R.C. section 512 nor the regulations promulgated thereunder attempt to define royalty income; however, Treas. Reg. § 1.512(b)-1 states that whether an item is royalty income depends upon the facts and circumstances of the case.[20] Thus, the terms of each licensing agreement should be closely examined in light of the established definitions of royalty as well as the treatment of the payments under the particular circumstances to determine the exposure the university may have to a claim by the Internal Revenue Service that the licensing income it is receiving is not in fact royalty income.

As defined in *Webster's Third New International Dictionary of the English Langauge. Unabridged* (1961), the term "royalty" means:

"A share of the product or profit of the property reserved by the owner when the property is sold, leased or used or a payment (as a percentage of the amount of property used) to the owner for permitting another to exploit, use or market such property (as natural resources, patents or copyrights) which is often subject to depletion with use."

Similarly, under the personal holding company regulations, the term "royalties" includes amounts received for the privilege of using patents.[21] Although payments received from licensees by the university or its affiliate should be treated as royalties under these traditional definitions, the inquiry does not stop with the nomenclature of the payment.

Footnotes at end of article.

tion that the distinction is most difficult to darw and that many factors are involved.

If technical assistance is provided, the Internal Revenue Service will more likely characterize the payments as being for services. If, however, the university simply lends its know-how to the licensee to assist it in the initial designing and building of the product under the patent this alone should be insufficient to warrant the recharacterization of part of the royalty payment as being for services, even if the services by the university are provided as part of an effort to increase and/or continue the income from its patent licensee. If at the time the licenses are granted, it is not anticipated that engineering or other services will be needed, the royalty payment cannot be recast into compensation for services.[24]

On the other hand, a more difficult problem is presented when the license agreement is entered into and either the university agrees with the licensee (verbally or otherwise) to furnish it with engineering services which the parties anticipate will be and which are substantial or the requirement to provide such services is implicit because the stage of the development of the patent is such that services by university personnel will be needed. In this type of case, the Internal Revenue Service would probably look outside the contract itself to discover the true nature of the payments in question. For example, if it is ascertained that when the license agreement was entered into the payments were fixed at a much higher percentage of production or selling price than would have been the case had the payments been for the use and manufacture of the patented invention or process alone, the university may be subject to tax and should be prepared to show that at the time the contract was entered into it did not anticipate nor did it verbally agree to provide such services.

In defending against such an attack, various provisions in the agreement itself may indicate that no agreement was made for the payments for personal services. If the agreement is not subject to cancellation, except with a substantial penalty to the licensee, this would indicate that the services are incidental to the contract because the licensees could not be protected in their right to any services that are not specifically set forth in the agreement. The provision for a penalty would indicate that the licensee did not anticipate the need for services from the university or its staff. On the other hand, if the license is cancellable at the option of the licensee without a substantial penalty, this fact together with the fact that payments are based on sales or production would lend support to the argument that part of the payments are for services since it would be in the university-licensor's self interest to furnish the services which might enlarge the market for the product.

To reduce the risk that the Internal Revenue Service might attempt to recast the royalty payments as being in part for services, the licensing agreement should specifically recite that it contains the entire understanding and agreement between the parties, that the licensees do not desire the university to furnish them any services, that there are no oral agreements or understandings between the university and the licensee that the university or its employees should furnish them any services, and that there is no agreement that a portion of the payments to be made by the licensee should constitute payment for services of for anything else except payment for the use of the patent. However, if, despite such provisions or in the case of contracts which do not contain such provisions, payments are determined in fact not to be exclusively in the nature of royalties, the university should be prepared to offer a reasonable basis for the allocation of the aggregate amount received to payments for royalties and to payments for other purposes.[25]

Provision for engineering and development work which the university anticipates at the time it enters into the license to be necessary to further commercial development of the patented process or machine should be made the subject of a separate agreement. The agreement should call for the employment of the university or members of its staff to provide such services and to work in cooperation with the licensee in developing and exploiting the patent.[26] Alternatively, the university should consider the possibility of granting a leave of absence for a period of time or permitting particular faculty or staff members to undertake the additional work as independent contractors. Whichever course is taken, however, these understandings should be the subject of a separate employment agreement and no provision should be included in the licensing agreement itself which conditions the right to payment of royalties on the satisfaction of the terms of the employment contract. A service agreement should not, however, be utilized in

Footnotes at end of article.

ship of a joint venture [31] as between themselves will depend upon their intention to be gathered from the agreement and their conduct in carrying out its provisions.

The university may be called upon to share part of development costs incurred by the licensee in preparing and adapting the patent to commercial usage. In such a case, the fact that there is no provision for sharing losses is not controlling and the element of profit sharing would appear to be the important factor in determining whether a joint venture exists.[32] Although the payments under the agreement may be characterized as royalties, such a characterization would not be conclusive if from the surrounding facts it is clear that they are, in fact, profits from operations. However, the risks of this type of characterization should be relatively small if the allocation of payments to the university is based on a share of production regardless of the realization of profits by the licensee.[33] Other factors bearing on the lack of intention to operate as a joint venture would be the maintenance of the separate interests of the university and the licensee and of separate books and records for accounting.

There may be situations, however, in which, for example, the university is called upon to share in a venture and its payments will be proportionate to the share of capital it invests in developing, promoting and exploiting a patent. In this situation, the Internal Revenue Service could strongly argue that the payments received are in fact profits from a joint venture as opposed to "royalties."

CONCLUSION

In this article, the authors have considered the various federal tax aspects of a university patent program. The basic point is that a university should be cautious in the degree of patent exploitation activities in which it engages. We have set forth certain guidelines which are recommended where the university operates its own patent program and grants licenses. These guidelines, while designed to minimize the financial involvement of the university in development and promotion, nevertheless require careful attention to operations and expenditures in administering the university's patent program. If attention to these guidelines and operations are burdensome, then the university has the alternative of contracting with an independent organization for patent management, such as that described in Rev. Rul. 73–193, in which case the university's position in receiving tax-exempt royalties should be assured under the rules of I.R.C. section 512(b)(2).

FOOTNOTES

[1] See generally, A. Palmer, *University Research and Patent Policies, Practices and Procdeures* (1962).

[2] See generally, Stedman, *The Employed Inventor, The Public Interest, and Horse and Buggy Law in the Space Age*, 45 *N.Y.U. Rev.* 1 (1970)

[3] *Id.* at 10–11. Sponsors of research, whether governmental, universities or industry, may reserve patent rights or otherwise specify the terms or conditions for patent ownership or licensing created by individuals either hired to invent or hired to perform certain types of services under the overall restriction that all inventions be disclosed and assigned to the employer.

[4] Rev. Rul. 58–260, 1958–1 C.B. 126.

[5] A. Palmer, *University Research and Patent Policies, Practices and Procedures* 10 (1962).

[6] Except as otherwise indicated, all statutory reference are to the Internal Revenue Code of 1954, as amended (hereinafter "I.R.C.").

[7] See Treas. Reg. (hereinafter "Reg.") § 1.501(a)–1(c).

[8] Compare *Edward Orton, Jr. Ceramic Fdn.*, 9 T.C. 533 (1947), aff'd 173 F.2d 483 (6th Cir. 1949), *nonacq.*, 1947–2 C.B. 6.

[9] Reg. § 1.50(c)(3)–1(c)(1). This limitation does not, however, preclude a university from operating an unrelated trade or business as an insubstantial part of its activities. Reg. § 1.50(c)(3)–1(e)(1) recognizes that exempt organizations may operate a trade or business in furtherance of exempt purposes, as long as the organization does not operate in an unrelated trade or business, as defined in I.R.C. section 513, as its primary purpose. See also Reg. § 1.501(c)(3)–1(d)(5)(v).

[10] Reg. § 1.501(c(3)–1(d)(5)(iii)(*a*).

[11] L.R.C. section 512(bX8).

[12] Reg. § 1.513–1(b).

contractual provisions obligating the transfer of all or some proprietary rights in such an invention to a third party, the inventor at The University of Wisconsin has been free to dispose of his rights in the manner of his own choosing.

Within the past decade, however, the alternatives available to inventors receiving financial support from Federal agencies and from the major national health and medical foundations have, in general, been sharply curtailed. Some Federal agencies require assignment of all rights to inventions to the government; some require only the granting of a royalty-free license to the government. Between these poles the agencies vary in their requirements. The National Science Foundation (NSF), for example, reserves for itself the right to determine the disposition of inventions made or conceived with the assistance of NSF funds. On the other hand, the National Aeronautics and Space Agency (NASA) in general practice takes title to all inventions made in connection with its grants or contracts.

In every case, the University, as the recipient of the grant or contract, has the primary responsibility for complying with the agencies' contractual provisions. Consequently, it has become necessary for the University to scrutinize with care the funding which has assisted the making of the invention to be sure that all of the obligations attaching to the contract or grant have been met.

INSTITUTIONAL AGREEMENT

In the interests of expanding the public use of inventions supported by government grants, one Federal agency, the Department of Health, Education and Welfare (DHEW), has changed the procedure for handling inventions generated at The University of Wisconsin with the assistance of DHEW funds. The DHEW and the Board of Regents of The University of Wisconsin have entered into an "Institutional Agreement" which affords University inventors greater latitude and advantages than in the past and prescribes how inventions resulting from DHEW-supported research at the University are to be routinely reported and processed. The provisions of the Agreement apply equally to all personnel, whether staff, faculty or graduate students, assisted by DHEW funds.

The Agreement, which became effective December 1, 1968, makes it possible for the University to accept assignment of these inventions or to designate a nonprofit patent management organization to act for it in a patent management capacity, provided such organization meets the requirements and criteria established by the DHEW, and provided also that these functions are carried out within the guidelines of the Institutonal Agreement. Inasmuch as the University itself is not in a position to provide patent management services, it has, with the approval of the DHEW, designated the Wisconsin Alumni Research Foundation (WARF), to perform these functions in its behalf. WARF has administered patents voluntarily assigned to it by University of Wisconsin inventors siuce 1925 and has the necessary experience, personnel and facilities to discharge these special responsibilities.

Under the terms of the Agreement, all members of the University staff and faculty or graduate students whose work is supported wholly or partially by DHEW funds will execute a Patent Agreement (Form UW–P–1, Appendix A, pages 9–10). All such personnel whose inventions emanate from research under grants made by the DHEW may, after having complied with the University's established reporting procedure, choose either of two options:

Option 1. He may submit the invention to WARF which will thoroughly examine the invention and will, when it considers such action is warranted in the public interest, accept assignment of the invention, prepare and file patent applications, and thereafter exercise its best judgment to bring the invention quickly and effectively into public use. In keeping with its traditional policies, WARF will pay the inventor annually 15% of the net royalties earned by his invention.

Option 2. He may assign the invention to the Federal government to dispose of as it sees fit.

Although the inventor may, if he chooses, recommend that the invention not be patented, and normally such recommendation will prevail, the final decision will be made by the government.

Disposition of all inventions generated at the University which are not covered by the Institutional Agreement will, as in the past, be subject to review by the Dean of the College in which the invention originated. Business Office of the University and the Central Administration to determine if any obligation exists in connection with and as the result of the funding of the research leading to the invention.

Whether an invention or discovery is patentable may best be judged by those experienced in patent law and often requires painstaking study of its relationship to the pre-existing knowledge in the art to which the invention belongs.

If there is doubt as to patentability and utility, expert opinion should be sought promptly. The Wisconsin Alumni Research Foundation (Licensing and Development Division) is prepared to assist any University inventor in helping him to judge whether or not the invention or discovery contains patentable subject matter.

WISCONSIN ALUMNI RESEARCH FOUNDATION

Inasmuch as the Wisconsin Alumni Research Foundation has long been active in providing technical consultation and services to University of Wisconsin inventors, and its now the University's official patent management designee under the University-DHEW Institutional Agreement, some background information on WARP and its relationship to the University and its inventors is relevant.

The Foundation is a not-for-private-profit organization incorporated in the State of Wisconsin and is separate and distinct from the University. It has administered numerous inventions originating at The University of Wisconsin since 1925 when it received assignment of the Harry Steenbock inventions and patent applications relating to the production of vitamin D by means of ultraviolet irradiation. Other inventions WARF has managed in behalf of University of Wisconsin inventors are the anticoagulant compounds Dicumarol and warfarin, both from the laboratories of Karl Paul Link, the life-saving Javid-Settlage formulation for reducing intracranial pressure in cases involving cerebral trauma, Raymond G. Herb's vacuum pumps, an air suspension process invented by Dale E. Wurter for coating small particles, O. J. Attoe's slow release fertilizer packet, C. A. Ernstrom's direct acidification process for manufacturing cottage cheese, James Asplin's soil grinder and many others.

Patent royalties and income from investments provide the funds given by WARF to The University of Wisconsin for buildings and research equipment and for the support of research projects solely of the University's choosing. Although the emphasis of WARF grants has been placed on research in the natural sciences, all disciplines, including the social sciences and humanities, have participated in such grants. The University has also allocated WARF funds to projects in branches of the statewide University system other than the Madison campus.

In addition to providing grants for research and for a number of Professorships, WARF has given funds to the University for obtaining major research equipment and for helping to construct 17 campus buildings and building additions. WARF is also a source of "seed" money which has assisted promising research and special projects when their investigations are too nebulous to attract financial support from Federal or State agencies or from private donors. One example is the Institute for Enzyme Research which was launched with a WARF grant for the construction of the Institute building.

During its first 40 years of service to The University of Wisconsin, WARF has given the University approximately $49,000,000 in grants, buildings and equipment. In the same 40 year period, its annual grants have grown from $1,200 to more than $3,000,000.

Considering the nature and extent of its services both in the management of patents for the University's inventors and as a major donor to the University's inventors and as a major donor to the University's research and educational programs, the Wisconsin Alumni Research Foundation is a unique and valued agency for The University of Wisconsin and one of its more essential arms.

INVENTION RECORD AND REPORT

(Submit to the dean of your college)

Compiler , Date

1. Brief descriptive title:
2. Full name of inventor(s), home address(es), and position(s):
3. Recommendation of inventor(s) as to whether patent protection should be sought:
4. Object or results to be achieved by the practice of this invention:
5. Outline of means discovered for achieving above objects in terms of (a) the steps in a process, or (b) the components in a composition or groups in a chemical compound (include description of process of making) or (c) elements

University Policy Regarding Patents

PREAMBLE

The Regents of the University of California is disposed, as hereinafter stated, to assist members of the faculties and employees of the University in all matters related to patents based on discoveries and inventions developed in situations where the invention has been conceived or developed by them.

It is recognized that such inventions may, and frequently do, involve equities beyond those of the inventor himself. The use of University facilities or services, the particular assignment of duties, or conditions of employment, the possible claims of a cooperating agency, as in research supported from extramural funds; these and other situations may give rise to a complex of interrelated equities or rights involving the invention, the University, and a cooperating agency. Such rights or equities must be appraised and an agreement reached on the proper disposition of them. It is further recognized that the 15th All-University Faculty Conference of 1960 adopted a resolution urging further use of inventions as a source of intramural funds for research within the University. Therefore, to appraise and determine relative rights and equities of all parties concerned, to facilitate patent applications, licensing, equitable distribution of royalties, if any, to obtain funds for research, and to provide a uniform procedure in patent matters where such originate within the University, the policy herein set down is adopted.

STATEMENT OF POLICY

1. All matters relating to patents in which the University of California is in any way concerned shall be administered by an agency known as the University of California Board of Patents.

2. a. The Board of Patents shall be appointed by The Regents. It shall have full power of organization, except as hereinafter provided, subject to the provision that it meet at least once a year; and the members shall serve without extra compensation at the pleaseure of The Regents. The normal terms of appointment shall be for three (3) years.

b. The Board shall consist of eleven (11) persons selected from among the faculties and the administration of the University, and of such other groups as The Regents may determiue, but of this number the Committee on Committees of the Academic Senate shall select from the Senate at large one (1) person to serve as ex officio member for a period of three (3) years. The Chairman of the Board and the Administrator of Patents shall be approved by The Regents upon the recommendation of the President of the University.

3. The following powers and duties shall be exercised by the Board of Patents:

a. To appoint a committee of experts to examine the merits of each potentially patentable invention and to cause such committee to report its findings to the Board.

b. To determine the relative equities or rights held by the inventor and The Regents or by a cooperating agency, if any, and to reach an agreement among all parties concerned with respect to such equities.

c. To authorize applications for patent and to retain patent counsel, in association with the General Counsel, for matters pertaining to the filing of pateut applications, the prosecution thereof, and the litigation that may arise therefrom.

d. To release patent rights to the inventor in unusual circumstances where the equities so indicate, subject to his granting a shop right to The Regents.

e. To negotiate licenses and other agreements covering the manufacture, use and sale or lease of patented articles, or process resulting from patents or inventions.

f. To arrange for and direct the collection of royalties and fees and the distribution thereof to those entitled thereto.

g. To assist in negotiations with appropriate University officers to obtain from cooperating agencies agreements concerning patent rights to inventions or discoveries made as a result of research carried on under grants or contracts.

h. In its consideration of matters relating to each particular patent case or situation, the Board of Patents shall take into consideration the principles laid down in the patent laws and in the court decisions of the United States.

i. To make such reports and recommendations to The Regents as The Regents shall direct.

4. Members of the facilities and employees shall make appropriate reports of any inventions they have conceived or developed to the Board of Patents.

	1974–75	1975–76
Inventions reported	156	153
U.S. applications authorized for filing	15	14
U.S. applications authorized for filing at licensee's expense	1	10
Foreign applications authorized for filing	8	5
Foreign applications authorized for filing at licensee's expense	61	21
Options in effect	11	16
Licenses issued	9	13
Licenses in effect June 30, 1976	101	103
Proposals for applied research funding	5	4
Proposals for applied research funding approved	1	3

CHANGES IN THE PATENT FUND IN THE YEAR ENDED JUNE 30, 1976

Balance, July 1, 1975		$1,646,296
Plus:		
Net income from patent operations (attachment 2)	$394,579	
Investment income added to fund	186,191	580,770
		2,227,066
Less:		
Appropriations from principal:		
State's share of 1975–76 income to be used in 1977–78 general fund budget	145,193	
Special applied research programs	81,408	226,601
Balance, July 1, 1976		2,000,465

On the basis of estimated patent income for the two-year period July 1, 1976 through June 30, 1978. The Regents on October 22, 1976 approved the following allocations:

a. Patent expense	$200,000
b. Royalty obligations to inventors	400,000
c. State's share of net income applied to general fund budget	250,000
d. High priority research and other academic needs	1,620,000
e. Litigation and income estimate contingency	700,000
Total estimated allocations 1976–78	3,170,000

UNIVERSITY OF CALIFORNIA, OFFICE OF THE VICE PRESIDENT—BUSINESS AND FINANCE
COMPARATIVE STATEMENT OF INCOME AND EXPENDITURES

[Fiscal years 1974–75 and 1975–76]

	Year ended June 30—	
	1975	1976
Income from royalties (see attachment 3)	$618,967	$637,109
Expenditures for income producing inventions	36,173	29,153
Expenditures for nonincome producing inventions	52,830	48,118
Total expenditures for inventions	89,003	77,271
Patent Board expenses	716	1,484
Total expenditures	89,719	78,755
Payments to inventors (see attachment 4)	116,339	163,775
Total expenditures	206,058	242,530
Net patent income	412,909	394,579

LIST OF INCOME FROM ROYALTIES

ABC wastewater treatment	$5,000	$100
Artery constricting device	500	500
Artificial population sampler	1,737	810
B–12 coenzymes	4,266	2,817
Bonding lignocellulosic material	500	500
Bongo net	700	400
California tissue sectioner	3,243	4,224
Desalination membrane	49,542	30,142
Device for testing rocks in place	1,582	1,402
Durado plum tree		500
Electrocatheter meter		810
Electrocatheter probe		80
Electrocatheter velometer		80
Electro belt apparatus		1,800
Electromagnetic flowmeter	1,152	658
Electromagnetic flow transducer		15
Electrophoretic apparatus		80
Eradication of crown gall	976	1,239
Exhaust treatment system	2,500	1,875
Firmness tester for fruit	160	160
Fractionation apparatus		868

THE ALBERT EINSTEIN COLLEGE OF MEDICINE, OFFICIAL POLICY ON PATENTS[1]

I. GENERAL POLICY

The Albert Einstein College of Medicine of Yeshiva University (hereinafter sometimes referred to as the "College") is interested in research relating to the advancement of medical knowledge and in the publication and the use of the results of such research. It recognizes that the research conducted by its faculty, its technical staff and its students may lead to inventions and discoveries which should be patented for one of the following reasons:

(1) To protect the public interest;

(2) to comply with the requirements of research grants, fellowship awards and contracts for research;

(3) to promote the development of useful apparatus and processes which would not be developed without patent protection;

(4) to encourage invention and insure rewards for the inventors as herein provided; and

(5) to support facilities and programs of the College of Medicine for research and education by means of its share of income derived from royalties paid for the use of inventions and patents.

The patent policy of the College is intended to be consistent with these principles and purposes.

II. MANAGEMENT OF PATENTS

A. The College shall have the responsibility for the management of patents and may for this purpose employ another agency including the Research Corporation. The Committee on Patents, to be established under this policy (Section VII), shall consult with the inventor(s) who may recommend to the Committee the course of action to be taken in the filing and prosecution of the inventor's(s') patent application. This may include but is not limited to (a) patent management agency other than Research Corporation, (b) a qualified patent attorney or (c) the Yeshiva University Research Foundation.

B. Notwithstanding the terms of II. A. the inventor, at his or her sole discretion shall have the right and option to elect not to have another agency such as Research Corporation file and prosecute the inventor's patent application. The inventor(s) may select a patent attorney to file and prosecute a patent application, provided that this selection is approved by the College. This approval, in the opinion of the Patent Committee, shall not be unreasonably withheld.

C. The College may seek agreements with another agency such as the Research Corporation, New York, New York, a non-profit foundation for the Advancement of Science, to serve as a patent management agent for the College and for members of its faculty, its techuical staff and student body. Under the terms of the agreement, the agency shall be asked to handle the patent applications, patent management and commercial exploitation of such patentable inventions and discoveries as the College may offer or cause to be offered to the agency, as are acceptable to it under the terms of its charter, and as should, in its view, be patented either in the public interest or for the sake of revenne. The agreement shall specify that a percentage of all income from each patent so managed by the agency shall be paid to the inventor or inventors as provided in Section V and that the remaining income shall be shared by the College and the agency in such proportion as may be agreed upon, with the agency bearing all patent prosecution and management expenses from its share.

D. The provisions relating to patents and patent royalties shall also apply to the commercial licensing and the royalties obtained there from inventions which are not patented but which have commercial value or special technology or special art.

III. TITLE TO PATENTS

A. Patent rights resultiug from research carried on by faculty members, technical staff members or students in connection with projects supported entirely or partly by College resonrces sball be assigned to and controlled by the College, its agent and/or Research Corporation which shall pay to the inventor a fixed proportion of the gross financial returns from the sale or exploitation of such patents in accordance with the provisions of Section V hereof.

B. Research carried on by a student in fulfillment of course requirements or other requirements for a degree, including the preparation of a thesis or disserta-

[1] Adopted by the Board of Overseers May 8, 1973.

tion of the nature of such expenditures shall be solely the prerogative of the inventor stipulated on an annual basis and approved by the College. In no case may this sum exceed $100,000 per annum in direct costs. When an inventor leaves the employ of the College he/she will continue to receive their share of the royalties and if living retain the right to designate the use of a portion of the royalties for special programs at the College as provided above. The expenditure of such funds shall be in accordance with the usual accountability governing other Restricted Funds administered by the College. No overhead will be charged.

E. The balauce of all other sums received by the College shall be utilized by the College in support of its educatioual, research and clinical pursuits.

VI. PUBLICATION

The right to publish the results of sponsored research where patents may be involved shall be subject to the following conditions:

A. The College shall not bar or prohibit puhlicatiou of disclosures and inventions on which patent applications have beeu filed consistent with grant or governmental requirements.

B. An inventor has the obligation to file an invention disclosure statement with the College, and where appropriate or required by grant or contract, simultaneously with or prior to the submission of a paper for publication disclosing the invention. In order to obtain protection for foreigu patent rights, which are lost upon publication or public disclosure prior to filing a patent application in the United States, the inventor shall disclose his invention to the College through its Patent Committee a minimum of one month in advance of printed or oral disclosure, so that an application for a patent may be filed before public disclosure.

C. The College will, if requested, supply to a sponsor any proposed publication before publication.

VII. COMMITTEE ON PATENTS

A Committee on Patents shall be appointed by the Dean of the College and shall have the following responsibilities:

A. To recommend to the College administration (1) which inventions should be processed in accordance with Section III–A, (2) which ones should be referred to an outside agency, (3) which ones should be returned to the inventor for his/her own disposition and (4) which ones should be processed in other ways. Recommendations shall be made within 90 days after an invention is brought to the Committee's notice.

B. To determine, when necessary, whether a given invention by a faculty or technical staff member or a student resulted from research carried out in connection with a project supported entirely or largely by College Resources or whether it was a product of personal research.

C. To make recommendations generally regarding proposals to patent, or proposals which may lead to patent of inventions or discoveries related to the health field.

D. To make recommendations in regard to patent arrangements reqnested by non-government sources.

E. To act in an advisory capacity with regard to patents assigned to the College.

F. To resolve disputes arising on patent matters in accordance with this Patent Policy.

VIII. AGREEMENT WITH COLLEGE

A form of agreement with the College shall be signed and entered into by all faculty, students and staff acknowledging that snch personnel have received and read a copy of this Official Policy on Patents and agree to abide thereby, and, further, that such personnel agree to disclose in writing promptly to the College any invention or discovery made by such personnel and to assign to the College the entire right, title and interest in and thereto of Patent Rights as defined in Paragraph III—Title to Patents—hereof.

IX. DISCLOSURE OF INVENTIONS TO THE COLLEGE

Faculty, staff and students are required to report to the Dean of the College and/or the Committee ou Patents, all inventions related to their official dnties as soon as possible after conception or first actual reduction to practice. Such reports, on standard forms, should me made sufficiently descriptive to permit the invention to be understood and evaluated. Additional information will be added

"good science" would lead to new technology that could be marketed to some eternally grateful customer. So central research labs were a haven for scientists and engineers oriented toward scientific or technical accomplishment. Labs engaged in few research utilization activities, and when they did, these were limited to publications, symposia, speeches, and the like—scientifically acceptable activities suited to scientific audiences. The interplay between non-technical units of the company and central research was limited.

With increasing emphasis on the relevance of research in the last 1960s, the industrial lab's objectives shifted from furthering scientific goals to satisfying market needs. Labs lost kinship with academic departments in attempting to mimic embryonic technical, market-oriented businesses. The ivy was swept from the walls and replaced by large panoramic windows through which the researchers could see and be seen. Although some significant basic research and development is still carried out, the emphasis on this is far less now than in the past. The goals of a research organization became those of "developing new products" and "starting new businesses."

Shift in activities.—With the shift in objectives came a new set of activities. When scientific research and problem-solving dominated, management techniques (formalized plans and goals, control systems) and marketing issues (market research, competitive pressures) were considered irrelevant. Each scientist was a potential creative genius who would only be hampered by the ties of an organization's practices and politics. But, in the quest for relevance these sibboleths were vanquished too.

New environmental pressures (new regulations, changing raw material supplies, etc.) and new market needs required planning by research managers. A few major research labs now have gone so far as to hire market research firms to examine potential new products. Research labs started to test the limits of their charters. Some brought product prototypes into the marketplace in order to acquire enough data to convince management of a new product's merit. More and more often, economic, market, and other non-technical analyses were necessary to check the viability of a new product or process. Sometimes these tests were carried out at an early stage of development, before a potential new product received the internal support of the research managers. Researchers' roles also shifted; they became the "salespeople of technology." The myth that technology sells itself on its own merits or that "new" technology is inherently "good" was exploded. Researchers wishing to see the fruits of their labors utilized had to sell the seeds.

Activities to enhance industrial research utilization also shifted from passive to active, and were made formal with special procedures and arrangements—project teams, integrators, and personnel transfers—to facilitate transfer of research outputs. Research organizations, realizing that good will and good relations do more for technology utilization than any other factor, sought to develop better "customer" relations even in the absence of a technology to push. Several organizations carried out "user seminars" on topics of interest to potential users and proavided other services to promote customer good will.

Shift in the mix and balance of skills.—As demand for relevance increased, it became painfully obvious to many research managers that their teams were incomplete. The emphasis on the generation rather than the use of research had narrowed the lab's range of functions. While the creative scientists/engineers were best able to generate ideas, they were rarely the most appropriate people to argue persuasively for their ideas to top management, manage a diverse group of people, recognize the need for business, finance, and marketing involvement and enlist those groups effectively, and handle the applications-oriented period of the project. As a result, research labs started hiring more engineers—in many cases engineers with a strong financial or business aptitude. More and more labs hired marketing-oriented personnel to supplement the skills of their technical personnel. As a consequence, the balance of skills has shifted from idea generation to idea utilization, and the mix now includes marketing, business, and finance skills. (*See the discussion of "critical functions" in Professor Roberts' article in this series, "Generating Effective Corporate Innovation,"* Technology Review, *October/November, 1977, pp. 26–33.*)

THE FRUITS OF RELEVANCE

The increased emphasis on application rather than creation of research results is reflected in a less "academic" approach to science in industrial research organizations. Significant shifts in research activities— more emphasis on the "selling

line team member, whose division would ultimately carry the project through, was made project manager. He reported to a coordinating board on which sat one member of each division, who stood at a level just under division manager. In other words, each division's representative had broad resource allocation and decisionmaking authority. The coordinating board met monthly to evaluate project progress. This bi-level joint staffing and evaluation approach has proven extremely effective in facilitating cooperation and timely decisionmaking.

Organizational link-pins.—These approaches are especially useful and sometimes necessary for new ideas outside of the company's existing product lines or processes. Examples include: specialized transfer groups that contain engineering, marketing, and financial skills; use of integrators who act as third-party transfer coordinators; and new venture groups who look for and nurture new ideas. The groups operate to smooth the process through which a fragile new idea is tuned into an applied product or process. They become the "nuturing" organizations for the new idea after technical feasibility has been established. They become the father, mother, and pediatrician for the idea until it can battle for its own life.

Organizational link-pins are successful if the idea generators see them as means to promote research utilization, not as an additional obstacle the idea must get around. To promote research exploitation effectively, the members of the new ventures or intergrating units need to associate with the research project at an early stage and assist in focusing and problem-solving. If they come in near the end, they will be perceived inevitably as evaluators and nay-sayers. The experience of companies which have set up organizational link-pins demonstrates that link-pins must work closely with the idea generators, as a resource to them, from the start.

Several studies have provided persuasive evidence that market needs, rather than technological opportunities, are the main source for research projects with a high probability of utilization. Sumner Myers and Donald Marquis found that 75 per cent of the innovations judged most important by the company originated in response to perceived needs in the marketplace rather than from new technical potential.

Market factors and user needs are important in determining what technical problems to work on and what a "utilizable" solution to those problems will be. This argues for clear identification of the user, his or her needs, and the user's reaction to types of technological solutions before the technological problem-solving occurs.

Three pitfalls characterize the less effective approaches to research utilization, and an equal number characterizes the more effective approaches. We review them here:

Over-reliance on change motivated by new information.—The ultimate objective of achieving research utilization is a behavioral change on the part of the potential user. A rational approach to provoking this sort of change relies on transmitting information to the people whose behavior is to change, and expecting the irrefutable logic of the argument to motivate the change. The generons funds and enormous activity behind the government's immense information storage and retrieval mechanisms can be placed on the doorstep of this essential (but we believe faulty) assumption. While these mechanisms are the prime activity of most federal agencies examined by the authors, agriculture excepted (*see above*), industry and researchers investigating the process of change have been convinced for years that strategies that rely on purely rational components are doomed to failure. New information, the research tells us, can at best create awareness. New information produces no commitment to an opportunity, no skills to exploit the opportunity, nor any conviction as to the benefits of exploiting it. All of these are necessary for eventual trial and adoption of an innovation, and the willingness to entertain change.

Responding to technological opportunities.—An innovation in response to a market need has a greater probability of utilization than one generated primarily by a technological opportunity. The general failure of applications engineering programs—particularly in federal agencies—supports this finding. Remember, the shift in objectives of industrial research organizations from technical problem-solvers to "market-need fillers" was motivated by the need to achieve better utilization of their research results.

The utilized innovations originating from "technology push" are in the minority and are characterized by market-oriented adaptation expenses far in excess of initial expectations. Some causes contributing to the poor utilization record

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Edward B. Roberts holds four degrees from M.I.T.—in electrical engineering (S.B. and S.M., 1958), management (S.M., 1960), and economics (Ph.D., 1962). He has been a member of the Sloan School faculty specializing in system dynamics, entrepreneurship, the management of research and development, and more recently, health care management. He is co-founder and president of Pugh-Roberts Associates, Inc., management consultants, and he has worked for the success of several technology-based new enterprises as a member of their board of directors. This article is based on a reivew of research utilization approaches that Professor Roberts and Dr. Frohman prepared at the request of a pauel of the National Academy of Sciences.

Alan L. Frohman received his B.A. in psychology from the University of Rochester, and S.M. and Ph.D. from the M.I.T. Sloan School of Management. He then became senior consultant with Pugh-Roberts Associates, Inc., where he worked with a variety of North American corporations on problems of research and development management and organizational development. More recently, Dr. Frohman has returned to academia with a faculty position at Boston University School of Management, where he is Adjunct Associate Professor of Organizational Behavior, to continue research and teaching in the management of innovation.

How Federal Agencies Approach Research Utilization

Federal agencies have experimented with and used numerous approaches in their attempts to enhance the commercial use of their research results. They range from passive mechanisms, such as data retrieval centers, to active strategies, and even to redefining the role of the commercial spousorship of products. Most of the federal approaches have been ineffective in stimulating the diffusion of technological innovation.

SPREADING THE WORD

Highest in frequency and expense, yet lowest in impact, are the numerous information dissemination programs. The Department of Defense Documentation Center (D.D.C.) collects Defense Department contractor and inhouse research and development reports, and publishes and distributes periodic lists of report titles. Qualified subscribers to D.D.C. services can request copies of the reports when secrnity and proprietary interests permit. D.D.C. provides uo other port of entry to its massive library of defense techuology information. In a similarly passive fashion, H.E.W.'s National Library of Medicine permits computer-accessed information search and retrieval of its vast files of biological research reports. The Department of Commerce National Technical Information Service furnishes copies of unclassified and unrestricted documeuts produced by federal research and development projects, thereby centralizing a library of materials largely duplicated elsewhere.

A related information dissemination activity is N.A.S.A.'s distribution of S.T.A.R. reports and I.A.A. abstracts, library-oriented aerospace research functions. Even less vigorous attempts are made by the Science Iuformation Exchange (run under contract by the Smithsonian Institution) which limits itself

The program is based upon a national network of U.S.D.A. field agents at the county level, averaging three agents per county but ranging from one up to 20 or even more in agriculturally intensive regions of the country. The county agent is, in effect, a salesperson of new technology, drawing from research results at national level or in his local area, using U.S.D.A. field stations or pilot research farms as demonstration sites. The county agent creates awareness of new research by direct personal contact with all the farmers, is usually well qualified and locally respected, and develops personal rapport with local farmers over years of working with them. State land grant colleges are the primary backup for expertise and additional problem-solving research and development, and the farmer is not charged for these helpful U.S.D.A. services.

INCENTIVES FOR UTILIZATION

Patent incentives, direct financial stimuli, and other incentive approaches have also been used by the federal government. Profit motivations lead most industrial firms to desire, sometimes to require, patent protection before they will attempt commercial exploitation of a research result. The A.E.C. discouraged exploitation by keeping ownership on all its patented research outcomes. In contrast, the D.O.D. cedes to its industrial contractors all commercial rights to research results generated under contract. N.A.S.A. hedges on this score and reserves the right to keep patent rights, while claiming it will probably turn over exclusive patent rights to industry in most cases.

Utilization incentives in the areas of patent policy, seed financing, and other activities are now being subjected to experimental study by a relatively new program conducted by the National Bureau of Standards—the Experimental Technology Incentives Program. The E.T.I.P. looks promising in concept, but is too small to have much effect.

It is striking that all these governmental programs start to encourage utilization of research only after the research and development results have been generated. Yet the most effective industrial approaches to increased research utilization begin much earlier in the innovation process—as far back as when ideas are generated and selected for development—*E.B.R., A.L.F.*

CORPORATE GROWTH, R. & D. AND THE GAP BETWEEN

A funny thing seems to happen between research and development and corporate results. While research and development expenditures correlate well with company profitability, the correlation between profitability and new product introduction—supposedly the goal of successful research and development—is far less good.

Merck and Co.'s investment in research and development in 1976 was 8.2 percent of sales—one of the highest ratios among the 50 U.S. companies whose 1976 research and development expenditures were highest. Merck was the most profitable company among the 50, with income of 15.3 percent of sales.

After Merck, the next five most profitable compauies on the list were A.T.&T., Dow, Eastman Kodak, I.B.M., and Lilly; these six companies' average investment in research and development was 5.7 percent of sales.

In contrast, the six least profitable companies on the list—Boeing, Chrysler, Godyear, McDonnell-Douglas, Signal Companies, and United Technologies—averaged a research and development investment of only 3.5 percent of sales. These figures come from Technical Insights, Inc., New York-based publisher of *Inside R & D* newsletter.

From Marketing Development consultants of Concord Mass., comes the evidence of frustration in the marketplace: there is only a modest correlation between the introduction of "significant new products" and corporate growth during the three-year period before May, 1975.

North American Phillips is the classic case: 139 new products rated as "significant" by Marketing Development between 1972 and 1975, and 122 percent sales growth in the same period. Next in line: 3M Co.—120 new products but only 48 percent growth. And look near the bottom of the list of new-product producers for Schlumberger—only 51 new products but 98 percent sales growth in the three-year period.—*J.M.*

About 7 percent of the innovations were blocked by competition. Here, too, if management sees an overcrowded market ahead, the proposed innovation is rejected before it is developed.

Management also tends to reject would-be products or processes obviously susceptible to patent and antitrust problems. Factors arising from patent and antitrust laws accounted for stopping only 3 and 2.5 percent (respectively) of the innovations studied. In short, management takes a most conservative approach which usually avoids problems that can be spotted at the outset.

Management succeeds in anticipating some types of market and legal problems, but its performance with respect to capital and technology is poor. Some 11.5 per cent of our sample were adversely effected by technology, and one-quarter of these innovations stopped for technological reasons were, in effect, "scooped" by another company's superior technical approach which management had failed to anticipate.

Money was a problem for companies of all sizes, but to less of an extent than expected; management's estimates of the capital required to complete the innovation process are usually too low; lack of capital halted 15.5 per cent of the blocked innovations. The costs of pilot plant, installation, and changeover often overrun—so often that overruns accounted for almost one-third of the innovations blocked for capital-related reasons.

WHERE THE TROUBLE STARTS

Innovations are weeded out little by little until they enter the pilot test stage, where many more of them falter or fail entirely. Almost three quarters of the innovations entering the development pipeline made it all the way into pilot test before management decided to call a halt. Indeed, more innovations—23 percent—fail in the pilot test stage than in any other. The second largest number of innovations—19 percent—are stopped in the final and most expensive phase, production installation. Management must seriously consider the cost implications for companies when innovations pass the inexpensive early stages only to expire later. It is remarkable that 84 percent of all innovations in the sample continued to be funded beyond the low-cost phases of assessment and initiation—the stages where commonsense dictates that products less likely to succeed should be screened out.

LEARNING FROM FAILURE

To learn how, where, and why innovations actually run into trouble, we asked management officials who were directly involved in specific failures to tell us the story of what happened. Our respondents generally were the corporation presidents, vice presidents in charge of research and development, or heads of research and development divisions within the corporations attempting the innovations who personally made the tough decisions to cancel, shelve, or delay the innovations in question.

Memories were surprisingly sharp on the details of what happened, even down to the fine points. Once an innovation is funded, the decision to drop it seems sufficiently wrenching to be remembered by those involved. In any event, while managers tended to be hazy about how an innovation was started, they were very clear about how it ended.

Our respondents' stories were straightforward enough to be classified easily into the five broad categories: market, management, capital, technology, and laws and regulations. They also yielded additional lessons for innovators. For example:

The search for the capital necessary to develop an innovation through the marketing phase may end in a "Catch 22."—One company developed a new diagnostic x-ray machine with government research and development funding. Before the machine could be produced in marketable form, extensive field trials were required. Government funds could not be used to conduct such trials, and other possible suppliers of capital were unresponsive because marketability had not been demonstrated by available data—which could be obtained only through field tests. (The barrier in this case was classified as *capital.*)

A superior competing technological approach may cancel the development of a new product or process.—A major metals company undertook the development of vacuum deposition of aluminum as a substitute for tin plate in cans and other containers. The process was developed through completion of a full-scale, high-speed production line—which never went into full production because the

While managers may hope for the unsnarling of the regulatory process and companies may lobby for simpler controls, a more pressing task for industry is to examine its own practices. These are immediately controllable. Industrial managers who do this will see obvious mistakes that could have been avoided by asking seemingly trivial questions. Does the innovation have a clearly designated manager? Are staff capabilities matched to the innovation tasks? Is the cost analysis adequate? And so on. Obvious as these questions are, management often forgets to ask them until it is too late.

The real problem is to design and adopt a system that forces management to ask the right questions at the right time. Of the 200 cases in the study, 42 per cent might have benefitted from a systematic stepped technique of continuous evaluation.

Management systems with built-in forced questioning would perform two major functions:

They remind management to do the things that are so obvious that they are easily forgotten.

They force an appraisal of the assumptions and ideologies that underlie every innovation. It is a rare organization whose commonly held beliefs need never be examined, and such scrutiny is the task of management.

Another good way to get the right questions asked at the right time is to broaden the membership of product development teams to include people from outside the organization. Whatever their technical qualifications, such people may be perceptive enough to blow the whistle on innovations which are going to falter or fail.

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Sumner Myers graduated from M.I.T. in 1948. He is now Director of Technology and Transportation for the Institute of Public Administration. His "hands on" experience with the innovation process includes work as Production Analyst, Chief Industrial Engineer, and Plant Manager. He began his studies of the innovation process with an N.S.F.-sponsored analysis of 600 commercially successful innovations. This led to work on innovations in transportation and energy for D.O.T. and D.O.E., respectively. Mr. Myers' current focus at I.P.A. is on the "public use of private interests" in furthering socially desirable technologies.

Eldon E. Sweezy received his Bachelor of Science from Oklahoma State University, and his M.A. from the American University. As Army Research and Study Fellow, he spent 1957–58 at M.I.T. as a Special Student. For the past 27 years he served as adviser to managers of research and development in government and industry, and conducted a series of research projects on the evaluation of research and development activities and related innovation and information processes in the public and private sectors. He is now a senior associate, Institute of Public Administration, and also President, Management Counsel, Inc.

WHAT TO EXPECT IN YOUR COMPANY

The innovations of different size companies tend to encounter somewhat different patterns of obstacles. For example, we see in the facing diagram that:

New ventures, companies formed specifically to develop and market a particular new product, are highly vulnerable to capital problems. They run out of

merce, U.S. Department of Commerce, 14th and E Streets NW., Washington, D.C. 20230, and should be submitted by August 7, 1978.

Dated: July 14, 1978.

GUY W. CHAMBERLIN, JR.,
Acting Assistant Secretary for Administration.

[FR Doc. 78-20207 Filed 7-20-78; 8:45 am]

[From the Federal Register, vol. 43, No. 109, June 6, 1978, p. 24596]

NOTICES

[1610-01]

REGULATORY REPORTS REVIEW

NOTICE OF RECEIPT OF REPORT PROPOSAL

The following request for clearance of a report intended for use in collecting information from the public was received by the Regulatory Reports Review Staff, GAO, on May 30, 1978. See 44 U.S.C. 3512 (c) and (d). The purpose of publishing this notice in the Federal Register is to inform the public of such receipt.

The notice includes the title of the request received; the name of the agency sponsoring the proposed collection of information; the agency form number, if applicable; and the frequency with which the information is proposed to be collected.

Written comments on the proposed FTC request are invited from all interested persons, organizations, public interest groups, and affected businesses. Because of the limited amount of time GAO has to review the proposed request, comments (in triplicate) must be received on or before June 26, 1978, and should be addressed to Mr. John M. Lovelady, Assistant Director, Regulatory Reports Review, United States General Accounting Office, Room 5106, 441 G Street NW., Washington, D.C. 20548.

Further information may be obtained from Patsy J. Stuart of the Regulatory Reports Review Staff, 202-275-3532.

FEDERAL TRADE COMMISSION

The FTC requests clearance of a new, single-time, voluntary Idea Promotion Survey questionnaire to be sent to the offices of the attorneys general in the 50 states. The questionnaire, part of a major project currently being conducted, requests information and material concerning the level of business activity of idea promotion, invention promotion, or *patent development and marketing firms in the United States.* The overall purpose of the Federal Trade Commission's major project is to determine the net effect, if any, of Federal Trade Commission enforcement activity and various state regulations on the idea promotion industry. The FTC estimates respondents to be the 50 state attorneys general and reporting time to average 3 hours per response.

NORMAN F. HEYL,
Regulatory Reports Review Officer.

[FR Doc. 78-15678 Filed 6-5-78; 8:45 am]

[From the Federal Register, vol. 43, No. 48, March 10, 1978, pp. 9896-9908]

NOTICES

[3110-01]

OFFICE OF MANAGEMENT AND BUDGET

GRANTS AND CONTRACTS WITH CERTAIN NONPROFIT ORGANIZATIONS

PRINCIPLES FOR DETERMINING COST

MARCH 6, 1978.

This notice offers interested parties an opportunity to comment on proposed revisions to OMB Circular No. A-21, "Cost principles for educational institutions."

(c) Organized research.
(d) Other sponsored activities.
(e) Other institutional activities.
2. Sponsored agreement.
3. Allocation.

C. Basic Considerations
1. Composition of total costs.
2. Factors affecting allowability of costs.
3. Reasonable costs.
4. Allocable costs.
5. Applicable credits.
6. Costs incurred by State and local governments.
7. Limitations on allowance of costs.

D. Direct Costs.
1. General.
2. Application to sponsored agreements.

E. Indirect Costs.
1. General.
2. Criteria for distribution.

F. Identification and Assignment of Indirect Costs
1. Depreciation and use allowances.
2. Operation and maintenance expenses.
3. General administration and general expenses.
4. Departmental administration expenses.
5. Sponsored agreements administration.
6. Library expenses.
7. Student administration and services.
8. Offset for indirect expenses otherwise provided for by the government.

G. Determination and Application of Indirect Cost Rate or Rates.
1. Indirect cost pools.
2. The distribution basis.
3. Negotiated lump sum for indirect costs.
4. Predetermined fixed rates for indirect costs.
5. Negotiated fixed rates and carry-forward provisions.

H. Simplified Method for Small Institutions.
1. General.
2. Simplified procedures.

J. General Standards for Selected Items of Cost.
1. Advertising costs.
2. Bad debts.
3. Civil defense costs.
4. Commencement and convocation costs.
5. Communication costs.
6. Compensation for personal services.
7. Contingency provisions.
8. Deans of faculty and graduate schools.
9. Depreciation and use allowances.
10. Donated services.
11. Employee morale, health, and welfare costs and credits.
12. Entertainment costs.
13. Equipment and other capital expenditures.
14. Fines and penalties.
15. Fringe benefits.
16. Insurance and indemnification.
17. Interest, fund raising, and investment management costs.
18. Labor relations costs.
19. Losses on other sponsored agreements or contracts.
20. Maintenance and repair costs.
21. Material costs.
22. Memberships, subscriptions, and professional activity costs.
23. Patent costs.
24. Plant security costs.
25. Preagreement costs.
26. Professional service costs.
27. Profits and losses on disposition of plant equipment or other capital assets.
28. Proposal costs.

B. DEFINITION OF TERMS

1. *Major functions of an institution* refers to instruction (includes departmental research), organized research, other sponsored activities, and other institutional activities as defined below:

a. *Instruction* means the teaching and training activities of an institution. Except for research training as provided in c below, this term includes all teaching and training activities, whether they are offered for credits toward a degree or certificate or on a noncredit basis, and whether they are offered through regular academic departments or separate divisions, such as a summer school division or an extension division.

b. *Departmental research* means all research and development activities that are not organized research and, consequently, are not separately budgeted and accounted for. Departmental research, for purposes of this document, is not considered as a major function of an institution but as a part of the instruction function of the institution.

c. *Organized research* means all research and development activities of an institution that are separately budgeted and accounted for. This term includes research and development activities that are sponsored by Federal and non-Federal agencies and organizations, as well as those that are separately budgeted by the institution under an internal allocation of institutional funds. It also includes activities involving the training of individuals in research techniques (commonly called research training) where such activities utilize the same facilities as other research and development activities.

d. *Other sponsored activities* means programs and projects financed by Federal and non-Federal agencies and organizations which involve the performance of work other than instruction and organized research. Examples of such programs and projects include health service projects, community service programs, and agricultural extension services. However, when any of these activities are undertaken by the institution without outside support, they should be classified as other institutional activities.

e. *Other institutional activities* means all activities of an institution except: (1) Instruction, departmental research, organized research, and other sponsored activities, as defined above; (2) indirect cost activities identified in section F, and (3) specialized service facilities described in section J38. Other institutional activities include operation of residence halls, dining halls, hospitals and clinics, student unions, intercollegiate athletics, bookstores, faculty housing, student apartments, guest houses, chapels, theaters, public museums, and other similar auxiliary enterprises. This definition also includes any other categories of activities, costs of which are "unallowable" to sponsored agreements, unless otherwise indicated in the agreements.

2. *Sponsored agreement* means any grant, contract, or other agreement between the institution and the Federal Government.

3. *Allocation* means the process of distributing a cost, or a group of costs, to one or more cost objectives which they benefit, in reasonable and realistic proportion to the benefit provided. A cost objective may be a major function of the institution, a particular service or project, a sponsored agreement, or an indirect cost activity, as prescribed in section F. The process may entail a distribution of a cost(s) directly to a final cost objective or through one or more intermediate cost objectives.

C. BASIC CONSIDERATION

1. *Composition of total costs.* The cost of a sponsored agreement is comprised of the allowable direct costs incident to its performance, plus the allocable portion of the allowable indirect costs of the institution, less applicable credits as described in 5 below.

2. *Factors affecting allowability of costs.* The tests of allowability of costs under these principles are: (a) They must be reasonable; (b) they must be allocable to sponsored agreements under the standards and methods provided herein; (c) they must be given consisteut treatment through application of those generally accepted accounting principles appropriate to the circumstances; and (d) they must conform to any limitatious or exclusions set forth in these principles or in the sponsored agreement as to types or amounts of cost items.

3. *Reasonable costs.* A cost may be considered reasonable if the nature of the goods or services acquired or applied, and the amount involved therefor, reflect the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made. Major considerations

D. DIRECT COSTS

1. *General.* Direct costs are those costs that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity; or that can be directly assigned to such activities relatively easily with a high degree of accuracy.

2. *Application to sponsored agreements.* Identifiable benefit to the sponsored work rather than the nature of the goods and services involved is the determining factor in distinguishing direct from indirect costs of sponsored agreements. Typical costs charged directly to a sponsored agreement are the compensation of employees for performance of work under the sponsored agreement, including related fringe benefit costs to the extent they are consistently treated by the institution as direct rather than indirect costs; the costs of materials consumed or expended in the performance of the work; and other items of expense incurred for the sponsored agreement, including extraordinary utility consumption. The cost of materials supplied from stock or services rendered by specialized facilities or other institutional service operations may be included as direct costs of sponsored agreements: *Provided,* Such items are consistently treated by the institution as direct rather than indirect costs, and are charged under a recognized method of realistically computing actual costs, and conform to generally accepted cost accounting practices consistently followed by the institution.

E. INDIRECT COSTS

1. *General.* Indirect costs are those that are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or any other institutional activity. At educational institutions such costs normally are classified under the following indirect cost categories: Depreciation and use allowances, general administration and general expenses, research administration expenses, operation and maintenance expenses, library expenses, departmental administration expenses, and student administration and services.

2. *Criteria for distribution.* a. Base period. A base period for distribution of indirect costs is the period during which the costs are incurred. The base period normally should coincide with the fiscal year established by the institution, but in any event the base period should be so selected as to avoid inequities in the distribution of costs.

b. Need for cost groupings. The overall objective of the indirect cost allocation process is to distribute the indirect costs described in Section F to the major functions and specialized service facilities of the institution in proportions reasonably consistent with the nature and extent of their use of the institution's resources. In order to achieve this objective, it may be necessary to provide for selective destribution by establishing separate groupings of cost within one or more of the indirect cost categories referred to in Section E1. In general, the cost groupings established within a category should constitute, in each case, a pool of those items of expense that are considered to be of like nature in terms of their relative contribution to (or degree of remoteness from) the particular cost objectives to which distribution is appropriate. Cost groupings should be established considering the general guides provided in c below. Each such pool or cost grouping should then be distributed individually to the related cost objectives, using the distrihution base or method most appropriate in the light of the guides set forth in d below.

c. General considerations on cost groupings. The extent to which separate cost groupings and selective distribution would he appropriate at an institution is a matter of judgment to be determined on a case-by-case basis. Typical sitnations which may warrant the establishment of two or more separate cost groupings (based on account classification or analysis) within an indirect cost category include but are not limited to the following:

(1) Where certain items or categories of expense relate solely to one of the major functions of the institution or to less than all functions, such expenses should be set aside as a separate cost grouping for direct assignment or selective allocation in accordanee with the guides provided in Sections E2b and d.

(2) Where any types of expense ordiuarily treated as general administration or departmental administration are charged to sponsored agreements as direct costs, the similar type expenses applicable to other activities of the institution must, through separate cost groupings, be excluded from the indirect costs allo-

shown to the remaining indirect cost categories as well as to the major functions and specialized service facilities of the institution. Other cost categories may be allocated in the order determined to be most appropriate by the institutions. When cross allocation of costs is made as provided in (3) below, this order of allocation does not apply.

(3) Normally an indirect cost category will be considered closed once it has been allocated to other cost objectives, and costs may not be subsequently allocated to it. However, a cross allocation of costs between two or more indirect cost categories may be used if such allocation will result in a more equitable allocation of costs. If a cross allocation is used, an appropriate modification to the composition of the indirect cost categories described in Section F is required.

F. IDENTIFICATION AND ASSIGNMENT OF INDIRECT COSTS

1. *Depreciation and use allowances.* a. The expenses under this heading are the portion of the costs of the institution's buildings, capital improvements to land and buildings, and equipment which are assigned to current operations in accordance with Section J9.

b. The expenses included in this category shall be allocated in the following manner:

(1) Depreciation or use allowances on equipment or buildings used exclusively in the conduct of a single function shall be allocated to that function.

(2) Depreciation or use allowances on buildings and capital improvements to buildings shall be allocated to the individual functions performed in each building on the basis of usable square feet of space, excluding common areas such as hallways, stairwells, and restrooms.

(3) Depreciation or use allowances on equipment or buildings used jointly shall be allocated to benefiting functions in proportion to the total salaries and wages applicable to those functions. Depreciation or use allowances on equipment and buildings used predominantly for one function and only incidentally for the other(s), shall be assigned to the function in which it is used predominantly. The institution and the Government should agree in advance when use of equipment or space is incidental or predominant to a given function.

(4) Depreciation or use allowances on certain capital improvements to land, such as paved parking areas, fences, sidewalks, and the like, not included in the cost of buildings, shall be allocated on an unweighted headcount basis to user categories of students and employees. The student categories shall consist of all individuals enrolled at the institution as students regardless of whether they do or do not earn credits toward a degree or certificate. The employee category shall consist of all faculty members, other professionals and nonprofessional employees excluding student employees. The amount allocated to the student category shall be assigned to the instruction function of the institution. The amount allocated to the employee category shall be further allocated to the major functions of the institution in proportion to the salaries and wages of all employees applicable to those functions.

2. *Operation and maintenance expenses.* a. The expenses under this heading are those that have been incurred by a central service organization or at the departmental level for the administration, supervision, operation, maintenance, preservation, and protection of the institution's physical plant. They include expenses normally incurred for such items as janitorial and utility services; repairs and ordinary or normal alterations of buildings, furniture and equipment; and care of grounds and maintenance and operation of buildings and other plant facilities. The operation and maintenance expense category should also include the fringe benefit costs applicable to salaries and wages included therein, and depreciation and use allowance.

b. The expenses included in this category shall be allocated on the basis of usable square feet of space assigned to each function, excluding common areas such as hallways, stairwells, and restrooms. Operation and maintenance expenses applicable to space used jointly for two or more functions shall be further allocated to the benefiting functions in proportion to the total salaries and wages applicable to those functions. Operation and maintenance expenses applicable to space used predominantly for one function and only incidentally for the other(s), shall be assigned to the function in which it is used predominantly. The institution and the Government shall agree in advance when use of space is incidental or predominant to a given function.

3. *General administration and general expenses.* a. The expenses under this heading are those that have been incurred for the general executive and admin-

general administration and general expenses, the operation and maintenance expenses, and depreciation and nse allowance. Appropriate adjustments should be made for services provided to otber functions or organiztions.

b. The expenses included in this category shall be allocated to the major functions of the institution under which the sponsored agreements are conducted in proportion to the number of agreements active during the period for which the expenses are allocated.

c. An appropriate adjustment shall be made to eliminate any duplicate charges to sponsored agreements when this category includes similar or identical activities as those included in tbe general administration and general expense category or other indirect cost items, such as accounting, procurement, or personnel administration.

6. *Library expenses.* a. The expenses under this heading are those tbat have been incurred for the operation of the library, including the cost of books and library materials purchased for the library, less any items of library income tbat qualify as applicable credits under Section C5. The library expense category should also include the staff benefit and pension plan costs applicable to the salaries and wages included thereiu, an appropriate share of general administration and general expenses, operation and maintenance expense, and depreciation and use allowances. Costs incurred in the purchases of rare books (museum-type books) with no value to sponsored projects should not be allocated to sponsored agreements.

b. The expenses included in this category shall first be allocated on an unweighted headcount basis to user categories consisting of students, professional employees, and other users.

(1) The student category shall consist of all individuals enrolled at the institution as students regardless of whether they do or do not earn credits toward a degree or certificate.

(2) The professional employee category shall consist of all faculty members and other professional employees of the institution, except student employees.

(3) The other users category shall consist of all other users of library facilities, including the general public.

c. Amounts allocated in b above shall be assigned further as follows:

(1) The amount allocated to the student category shall be assigned to the instruction function of the institution.

(2) The amount allocated to the professional employee category shall be further allocated to the major functions of tbe institution in proportion to the salaries and wages of all faculty members and other professional employees (excluding student employees) applicable to those functions.

(3) The amount allocated to the other users category shall be assigned to the other institutional activities function of the institution.

7. *Student administration and services. a.* The expenses under his heading are those that have been incurred for the administration of student affairs and for services to students, including expenses of such activities as deans of students, admissions, registrar, counseling and placement services, student advisers, student health and infirmary services, catalogs, and commencements and convocations. The salaries of members of the academic staff whose academic appointments or assignments involve the performance of such administrative or service work may also be included to the extent that the portion so charged is supported pursuant to Section J6. This expense category also includes the fringe benefit costs applicable to the salaries and wages included therein, an appropriate share of general administration and general expenses, operation and maintenance, and use allowances and/or depreciation.

b. The expenses in this category are applicable in their entirety to the instruction function. However, to the extent that such expenses reasonably benefit sponsored agreements in the instruction function, they may be included in the common pool of indirect costs for that function for subsequent distribution to the agreements (See Section G1a.). Expenses included in this category that do not benefit sponsored agreements shall be excluded from the common pool. Where the level of benefits varies significantly for different agreements, or different groups of agreements, the expenses sball be allocated only to applicable cost objectives within the instrnction function through separate cost groupings and selective allocations, in accordance with Section E2b.

8. *Offset for indirect expenses otherwise provided for by the Government.* a. The items to be accumulated under this heading are the reimbursements and other payments from the Federal Government which are made to the institution to

tions, to facilitate the preparation of their budgets, and to permit more expeditious closeout of such contracts when the work is completed. In view of the potential advantages offered by this procedure, consideration should be given to the negotiation of predetermined fixed rates for indirect costs in those situations where the cost experience and other pertinent facts available are deemed sufficient to enable the parties involved to reach an informed judgment as to the probable level of indirect costs during the ensuing accounting period.

5. *Negotiated fixed rates and carry-forward provisions.* When a fixed rate is negotiated in advance (or a fiscal year for other time period), the over- or under-recovery for that year may be included as an adjustment to the indirect cost for the next rate negotiation. When the rate is negotiated before the carry-forward adjustment is determiued due to the delay in audit, the carry-forward amount may be applied to the next subsequent rate negotiation. When such adjustmeuts are to be made, each fixed rate negotiated in advance for a given period will be computed by applying the expected indirect costs allocable to sponsored agreements for the forecast period plus or minus the carry-forward adjustment (over- or under-recovery) from the prior period, to the forecast distribution base. Unrecovered amounts under lump-sum agreements or cost-sharing provisions of prior years shall not be carried forward for consideration in the new rate negotiation. There must, however, be an advance understanding in each case between the institution and the Government as to whether these differences will be considered in the rate negotiation rather than making the determination after the differences are known. Further, institutions electiug to use this carry-forward provision may not subsequently change without prior approval of the Government. In the event that an institution returns to a post determined rate, any over- or under-recovery during the period in which negotiated fixed rates and carry-forward provisions were followed will be included in the subsequent post-determined rates. Where multiple rates are used, the same procedure will be applicable for determining each rate. This procedure also applies to rates established for grants and contracts for training and other educational services, but does not apply to cost-type agreements covering work performed iu wholly or partially Government-owned facilities.

H. SIMPLIFIED METHODS FOR SMALL INSTITUTIONS

1. *General.* a. Where the total direct cost of work performed under all sponsored agreements at an institution does not exceed $3,000,000 in a fiscal year, the use of the simplified procedure described in 2. below, may be used in determining allowable indirect costs. Under this simplified procedure, the institutiou's most recent annual financial report and immediately available supporting information with salaries and wages segregated from other costs, will be utilized as a basis for determining the indirect cost rate applicable to all sponsored agreements.

b. The simplified procednre should not be used where it produces results which appear inequitable to the Government or the institution. In any such case, indirect costs should be determined through use of the regular procedure.

2. *Simplified procedure.* a. Establish the total amount of salaries and wages paid to all employees of the institution.

b. Establish an indirect cost pool consisting of the expenditures (exclusive of capital items and other costs specifically ideutified as unallowable) which customarily are classified under the following titles or their equivalents:

(1) General administration and general expenses (exclusive of costs of student administration and services, student activities, student aid, and scholarships).

(2) Operation and maintenance of physical plant.

(3) Library.

(4) Department administration expenses, which will be computed as 20 percent of the salaries and expenses of deans and heads of departments.

In those cases where expenditures classified under (1) and (2) above have previously been allocated to other institutional activities, they may be included in the indirect cost pool. The total amount of salaries and wages included in the indirect cost pool must be separately identified.

c. Establish a salary and wage distribution base, determined by deducting from the total of salaries and wages as established in a above the amount of salaries and wages included uuder b. above.

d. Establish the indirect cost rate, determined by dividing the amount in the indirect cost pool, b. above, by the amount of the distribution base, c. above.

activity reports. The latter must be used for nonprofessional and student employees. Under either alternative, salaries and wages applicable to nonmandatory cost sharing may be incorporated in institutional costs (such as instructional costs) and need not be separated therefrom. In the use of either method, it is recognized that, because of the nature of work involved in academic institutions, the various and often interrelated activities of professorial and professional employees frequently cannot be measured with a high degree of precision, that reliance must be placed on reasonably accurate approximations, and that acceptance of a degree of tolerance in measurements is appropriate.

c. *Monitored workloads.* Under this method the distribution of salaries and wages applicable to sponsored agreements is based on budgeted or assigned workloads, updated as required to reflect any significant changes in workload distributions. A monitored workload system used for salaries and wages charged directly or indirectly to sponsored agreements will meet the following standards.

(1) A system of budgeted or assigned workloads will be incorporated into the official records of the institution or campus, and encompass both sponsored and all other activities on an integrated basis. The system may include the use of subsidiary records.

(2) The system will reasonably reflect workloads of employees, accounting for 100 percent of each employee's total salaried activity for which the employee is compensated and which is required in fulfillment of the employee's obligations to the institution. Because practices vary among institutions and within institutions as to the total activity constituing a full workload—when expressed in measurable units, such as contract hours in teaching—the system will be based on a determination for each individual, reflecting the ratio of each of the activities which comprise the total workload of the individual.

(3) The system will provide for modification of an individual's salary or salary distribution commensurate with any significant change in the employee's workload or the ratio of activities comprising the total workload. A significant change in an employee's workload shall be considered to include the following as a minimum: when work begins or ends on a Government agreement, when a teaching load is materially modified, when additional unanticipated assignments are received or taken away, when an individual begins or ends a sabbatical leave, prolonged sick leave, or leave without pay, etc. Short-term (such as one or two months) fluctuation between workload categories need not be considered as long as the distribution of salaries and wages is reasonable over the longer term such as an academic period. Whenever it is apparent that a significant change in workload will occur or has occurred, the change will be documented over the signature of a responsible official and entered into the system.

(4) The system will utilize workload categories reflecting direct activity which is applicable to and chargeable to each sponsored agreement, activity required to meet mandatory cost sharing, activity applicable to any indirect cost category, and activity applicable to other direct cost categories (see section B1).

(5) At least annually a statement will be signed by an employee, principal investigator, or responsible official, having first hand knowledge of the work stating that salaries and wages charged to Government agreements as direct charges, or that salaries and wages charged to both direct and indirect cost categories, or to more than one indirect cost category are proper.

In the use of this method an institution shall not be required to provide additional support or documentation for the effort actually performed, but is responsible for assuring that the system meets the above standards.

In cases where nonprofessional, student, or other "task oriented" employees are charged to projects based on use of services rather than longer term assignment, systems such as time cards or similar distribution systems or service center costing arrangements may be used (see d below).

d. *Personnel activity reports.* Under this method the distribution of salaries and wages will be supported by personnel activity reports as prescribed below.

(1) Personnel activity reports will reflect the distribution of activity expended by each employee not under the monitored workload system.

(2) The reports will reflect an after-the-fact reporting of the percentage of activity of each employee. Estimates made before the services are performed may be used initially: *Provided*, That such charges are promptly adjusted if significant differences are indicated by activity reports.

(3) Each report will account for 100 percent of each employee's total activity for which the employee is compensated and which is required in fulfillment of his or her obligations to the institution. The report will reasonably reflect (a)

7. *Contingency provisions.* Contributions to a contingency reserve or any similar provisions made for events, the occurrence of which cannot be foretold with certainty as to time, intensity, or with an assurance of their happening, are unallowable.

8. *Deans of faculty and graduate schools.* The salaries and expenses of deans of faculty and graduate schools, or their equivalents, and their staffs, are allowable.

9. *Depreciation and use allowances.* Institutions may be compensated for the use of their buildings, capital improvements, and equipment: *Provided*, That they are used beneficially, needed in the institutions' activities, and properly allocable to sponsored agreements. Such compensation shall be made by computing either depreciation or use allowance. Use allowances are the means of providing such compensation when depreciation or other equivalent costs are not computed. The allocation for depreciation or use allowance shall be made in accordance with section F1. Depreciation and use allowances are computed applying the following rules:

a. The computation of depreciation or use allowances shall be based on the acquisition cost of the assets involved. For this purpose, the acquisition cost will exclude (1) the cost of land; (2) any portion of the cost of buildings and equipment borne by or donated by the Government, irrespective of where title was originally vested or where it is presently located; and (3) any portion of the cost of buildings and equipment contributed by or for the institution in satisfaction of a Federal cost sharing or matching requirement. For an asset donated to the institution by a third party, its fair market value at the time of the donation shall be considered as the acquisition cost.

b. In the use of the depreciation method, the following shall be observed:

(1) The period of useful service or useful life established in each case for usable capital assets must take into consideration such factors as type of construction, nature of the equipment, technological developments in the particular area, and the renewal and replacement policies followed for the individual items or classes of assets involved.

(2) The depreciation method used to charge the cost of an asset (or group of assets) to accounting periods shall reflect the pattern of consumption of the asset during its useful life. In the absence of clear evidence indicating that the expected consumption of the asset will be significantly greater in the early portions than in the later portions of its useful life, the straight-line method shall be presumed to be the appropriate method. Depreciation methods once used shall not be changed unless approved in advance by the Government.

(3) Where the depreciation method is introduced for application to assets for which use allowance was previously charged, the aggregate amount of use allowances and depreciation applicable to such assets must not exceed the total acquisition cost of the assets.

(4) When the depreciation method is used for buildings, a building "shell" may be treated separately from other building components, such as plumbing system and heating and air conditioning system. Each component item may then be depreciated over its estimated useful life. On the other hand, the entire building, including the shell and all components, may be treated as a single asset and depreciated over a single useful life.

(5) Where the depreciation method is used for a particular class of assets, no depreciation may be allowed on any such assets that should be viewed as fully depreciated.

c. Under the use allowauce method, the following shall be observed:

(1) The use allowance for buildings and improvements (including improvements such as paved parking areas, fences, and sidewalks) wil be computed at an annual rate not exceeding two perecut of acquisition cost. The use allowance for equipment will be computed at an annual rate not exceeding six and two-thirds percent of acquisition cost.

(2) In contrast to the depreciation method, the entire building must be treated as a single asset without separating its "shell" from other building components under the use allowance method. The entire building must be treated as a single asset, and the two-percent use allowance limitation must be applied to all parts of the building. The two-percent limitation, however, need not be applied to equipment or other assets that are merely attached or fastened to the building but not permanently fixed and are used as furnishings, decorations or for specialized purposes (e.g., dentist chairs and dental treatment units, counters, laboratory benches bolted to the floor, dishwashers, and carpeting). Such equipment and assets will be considered as not being permanently fixed to the build-

where such expenditures are specifically approved in advance by the sponsoring agency.

(4) Equipment and other capital expenditures are unallowable as indirect costs.

(5) See Section J9 for allowability of depreciation or use allowance on buildings, capital improvements, and equipment. Also see Section J33 for allowability of rental costs on land, buildings, and equipment.

14. *Fines and penalties.* Costs resulting from violations of, or failure of the institution to comply with, Federal, State, and local laws and regulations are unallowable, except when incurred as a result of compliance with specific provisions of the sponsored agreement, or instruction in writing from the contracting officer.

15. *Fringe benefits.* a. Fringe benefits in the form of regular compensation paid to employees during periods of authorized absences from the job, such as for annual leave, sick leave, military leave, and the like, are allowable. *Provided,* Such costs are distributed to all institutional activities in proportion to the relative amount of time or effort actually devoted by the employees. See Section J35 for treatment of sabbatical leave.

b. Fringe benefits in the form of employer contributions or expenses for social security, employee insurance, workmen's compensation insurance, tuition or remission of tuition for individual employees or their families and the like are allowable: *Provided,* Such benefits are granted in accordance with established institutional policies, and are distributed to all institutional activities on an equitable basis. See Section J36b for treatment of tuition remission provided to students.

c. Rules for pension plan costs are as follows:

(1) Costs of the institution's pension plan which are incurred in accordance with the established policies of the institution are allowable: *Provided,* (a) Such policies meet the test of reasonableness; (b) the methods of cost allocation are equitable for all activities; (c) the amount of pension cost assigned to each fiscal year is determined in accordance with (2) below; and (d) the cost assigned to a given fiscal year is funded for all plan participants wtihin six months after the end of the year.

(2) The amount of pension cost assigned to each fiscal year shall be determined in accordance with generally accepted accounting principles as prescribed in Accounting Principles Board Opinion Number 8, "Accounting for the Cost of Pension Plans," issued by the American Institute of Certified Public Accountants. However, institutions may elect to follow the "Cost Accounting Standard for Composition and Measurement of Pension Cost" (4 CFR Part 412). Where these standards are followed, actuarial gains and losses shall be accounted for in accordance with Accounting Principles Board Opinion No. 8.

(3) Premiums paid for pension plan termination insurance pursuant to the Employee Reirement Income Security Act of 1974 (Pub. L. 93-406) are allowable. Late payment charges on such premiums are unallowable. Excise taxes on accumulated funding deficiencies and prohibited transactions of pension plan fiduciaries imposed under the Employee Retirement Income Security Act are also unallowable.

d. Fringe benefits may be assigned to cost objectives by identifying specific benefits to specific individual employees or by allocating on the basis of the salaries and wages of the employees receiving the benefits. When the allocation method is used, separate allocations must be made to selective groupings of employees, if the costs in relationship to salaries and wages differ significantly for different groups of employees. Also, fringe benefits related to institutional salaries and wages treated as direct costs shall also be treated as direct costs.

16. *Insurance and indemnification.* a. Costs of insurance required or approved, and maintained, pursuant to the sponsored agreement, are allowable.

b. Costs of other insurance maintained by the institution in connection with the general conduct of its activities, are allowable subject to the following limitations: (1) Types and extent and cost of coverage must be in accordance with sound institutional practice; (2) costs of insurance or any contributions to any reserve covering the risk of loss of or damage to Government-owned property are unallowable, except to the extent that the Government has specifically required or approved such costs; and (3) costs of insurance on the lives of officers or trustees are unallowable except where such insurance is part of an employee plan which is not unduly restricted.

c. Contributions to a reserve for an approved self-insurance program are allowable, to the extent that the types of coverage, extent of coverage, and the

24. *Plant security costs.* Necessary expenses incurred to comply with Government security requirements, including wages, uniforms and equipment of personnel engaged, in plant protection, are allowable.

25. *Preagreement costs.* Costs incurred prior to the effective date of the sponsored agreement, whether or not they would have been allowable thereunder if incurred after such date, are unallowable unless specifically set forth and identified in the sponsored agreement.

26. *Professional services costs.* a. Costs of professional services rendered by the members of a particular profession who are not employees of the institution are allowable, subject to b and c below, when reasonable in relation to the services rendered and when not contingent upon recovery of the costs from the Government. Retainer fees to be allowable must be reasonably supported by evidence of services rendered.

b. Factors to be considered in determining the allowability of costs in a particular case include (1) the past pattern of such costs, particularly in the years prior to the award of sponsored agreements; (2) the impact of sponsored agreements on the institution's total activity; (3) the nature and scope of managerial services expected of the institution's own organizations; and (4) whether the proportion of Government work to the institution's total activity is such as to influence the institution in favor of incurring the cost, particularly where the services rendered are not a continuing nature and have little relationship to work under sponsored agreements.

c. Costs of legal, accounting, and consulting services, and related costs, incurred in connection with the prosecution of claims against the Government, are unallowable. Costs of legal, accounting and consulting services, and related costs, incurred in connection with patent infringement litigation, are unallowable unless otherwise provided for in the sponsored agreements.

27. *Profits and losses on disposition of plant equipment or other capital assets.* Profits or losses arising from the sale or exchange of plant, facilities, equipment or other capital assets, including sale or exchange of either short-term or long-term investments, shall not be considered in computing the costs of sponsored agreements except for pension plans as provided in Section J15c. When assets acquired with Federal funds, in part or wholly, are disposed of, the distribution of the proceeds shall be made in accordance with Attachment N, OMB Circular No. A-110.

28. *Proposal costs.* Proposal costs are the cost of preparing bids or proposals on potential Government and nongovernment sponsored agreements or projects, including the development of engineering data and cost data necessary to support the institution's bids or proposals. Proposal costs of the current accounting period of both successful and unsuccessful bids and proposals normally should be treated as indirect costs and allocated currently to all activities of the institution and no proposal costs of past accounting periods will be allocable to the current period. However, the institution's established practices may be to treat proposal costs by some other recognized method. Regardless of the method used, the results obtained may be accepted only if found to be reasonable and equitable.

29. *Public information services costs.* Cost of news releases pertaining to specific research or scientific accomplishment are allowable.

30. *Rearrangement and alteration costs.* Cost incurred for ordinary or normal rearrangement and alteration of facilities are allowable. Special arrangement and alteration costs incurred specifically for the project are allowable when such work has been approved in advance by the sponsoring agency concerned.

31. *Reconversion costs.* Costs incurred in the restoration or rehabilitation of the institution's facilities to approximately the same condition existing immediately prior to commencement of a sponsored agreement, fair wear and tear excepted, are allowable.

32. *Recruiting costs.* a. Subject to b, c, and d below, and provided that the size of the staff recruited and maintained is in keeping with workload requirements, costs of "help wanted" advertising, operating costs of an employment office necessary to secure and maintain an adequate staff, costs of operating an aptitude and educational testing program, travel costs of employees while engaged in recruiting personnel, travel costs of applicants for interviews for prospective employment, and relocation costs incurred incident to recruitment of new employees, are allowable to the extent that such costs are incurred pursuant to a well managed recruitment program. Where the institution uses employment agencies, costs not in excess of standard commercial rates for such services are allowable.

b. In publications, costs of help wanted advertising that includes color, includes advertising material for other than recruitment purposes, or is excessive in size

on an equitable basis among all related activities of the institution. Where sabbatical leave is included in fringe benefits for which a cost is determined for assessment as a direct charge, the aggregate amount of such assessments applicable to all work of the institution during the base period must be reasonable in relation to the institution's actual experience under its sabbatical leave policy.

36. *Scholarships and student aid costs.* a. Scholarships, fellowships, and other forms of student aid and the costs of administering such aid are allowable only when the purpose of the sponsored agreement is to provide training to selected participants and the charge is approved by the sponsoring agency. However, tuition remission and other forms of compensation paid as, or in lieu of, wages to students performing necessary work are allowable: *Provided*, That (1) there is a bonafide employer-employee relationship between the student and the institution for the work performed, (2) the tuition or other payments are reasonable compensation for the work performed and are conditioned explicitly upon the performance of necessary work, and (3) it is the institution's practice to similarly compensate students in nonsponsored as well as sponsored activities.

b. Charges for tuition remission and other forms of compensation paid to students as, or in lieu of, wages shall be subject to the reporting requirements stipulated in section J6, and shall be treated as direct or indirect cost in accordance with the actual work being performed. Such compensation shall not be classified as a fringe benefit.

37. *Severance pay.* a. Severance pay is compensation in addition to regular salary and wages which is paid by an institution to employees whose services are being terminated. Costs of severance pay are allowable only to the extent that such payments are required by law, by employer-employee agreement, by established policy that constitutes in effect an implied agreement on the institution's part, or by circumstances of the particular employment.

b. Severance payments that are due to normal recurring turnover and which otherwise meet the conditions of a. above may be allowed: *Provided*, The actual costs of such severance payments are regarded as expenses applicable to the current fiscal year and are equitably distributed among the institution's activities during that period.

c. Severance payments that are due to abnormal or mass terminations are of such conjectural nature that allowability must be determined on a case-by-case basis. However, the Government recognizes its obligation to participate, to the extent of its fair share, in any specific payment.

38. *Specialized service facilities.* a. The costs of institutional services involving the use of highly complex or specialized facilities such as electronic computers, wind tunnels, reactors, and animal resource centers are allowable: *Provided*, The charge for the service meets the conditions of b through d below.

b. The cost of each service shall consist of both its direct costs and its allocable share of indirect costs with deductions for appropriate income or Federal financing as described in section C5.

c. The cost of such institutional services when material in amount must be charged directly to applicable sponsored agreements based on actual use of the services on the basis of a schedule of rates that: (1) does not discriminate between federally and non-federally supported activities of the institution, including usage by the institution for internal purposes; and (2) is designed to cover not more than the aggregate cost of the services over a long-term period agreed upon in advance by the Government on a case-by-case basis. Accordingly, it is not necessary that the rates charged for services be exactly equal to the cost of providing those services during any one fiscal year as long as rates are adjusted to offset overcharges or undercharges at least annually.

d. Where the costs incurred for such institutional services are not material, they may be assigned as indirect costs to those activities which they benefit on a basis representative of benefits received. Such arrangements must be worked out in advance with the Governmeut in order to assure an equitable distribution of the costs.

39. *Special services costs.* Costs incurred for general public relations activities, catalogs, alumni activities, and similar services, are unallowable.

40. *Student activity costs.* Costs incurred for intramural activities, student publications, student clubs, and other student activities, are unallowable, unless specifically provided for in the sponsored agreements.

41. *Student services costs.* Costs of the deans of students, administration of student affairs, registrar, placement offices, student advisers, student health and infirmary services, and such other activities as are identifiable with student

b. The cost of common items of material reasonably unable on the institution's other work will not be allowable unless the institution submits evidence that it could not retain such items at cost without sustaining a loss. In deciding whether such items are reasonably usable on other work of the institution, consideration should be given to the institution's plans and orders for current and scheduled work. Contemporaneous purchases of common items by the institution will be regarded as evidence that such items are reasonably usable on the institution's other work. Any acceptance of common items as allowable to the terminated portion of the agreement should be limited to the extent that the quantities of such items on hand, in transit, and on order are in excess of the reasonable quantitative requirements of other work.

c. If in a particular case, despite all reasonable efforts by the institntion, certain costs cannot be discontinued immediately after the effective date of termination, such costs are generally allowable within the limitations set forth in this Circular, except that any such costs continuing after termination due to the negligent or willful failure of the institution to discontinue such costs will be considered nnacceptable.

d. Loss of useful value of special tooling, and special machinery and equipment is generally allowable, *Provided*, (1) Such special tooling, machinery, or equipment is not reasonably capable of nse in the other work of the institution; (2) the interest of the Government is protected by transfer of title or by other means deemed appropriate by the contracting officer or equivalent; and (3) the loss of useful value as to any one terminated agreement is limited to that portion of the acquisition cost which bears the same ratio to the total acquisition cost as the terminated portion of the agreement bears to the entire terminated agreement and other Government agreements for which the special tooling, special machinery, or equipment was acquired.

e. Rental costs under unexpired leases are generally allowable where clearly shown to have been reasonably necessary for the performance of the terminated agreement, less the residual value of such leases, if (1) the amount of such rental claimed does not exceed the reasonable use value of the property leased for the period of the agreement and such further period as may be reasonable; and (2) the institution makes all reasonable efforts to terminate, assign, settle, or otherwise reduce the cost of such lease. There also may be included the cost of alterations of such leased property: *Provided*, Such alterations were necessary for the performance of the agreement, and of reasonable restoration required by the provisions of the lease.

f. Settlement expenses including the following are generally allowable: (1) Accounting, legal, clerical, and similar costs reasonably necessary for the preparation and presentation to contracting officers or equivalent of settlement claims and supporting data with respect to the terminated portion of the agreement, and the termination and settlement of subagreements; and (2) reasonable costs for the storage, transportation, protection, and disposition of property provided by the Government or acquired or produced by the institution for the agreement.

g. Claims under subagreements, including the allocable portion of claims which are common to the agreement and to other work of the institution, are generally allowable.

K. *Certification of charges.* To assure that expenditures for sponsored agreements are proper and in accordance with the agreement documents and approved project budgets, the annual and/or final fiscal reports or vouchers requesting payment under the agreements will include a certification, signed by an authorized official of the university, which reads essentially as follows: "I certify that all expenditures reported (or payment requested) are for appropriate purposes and in accordance with the provisions of the application and award documents."

[FR Doc. 78–6275 Filed 3–9–78; 8:45 a.m.]

[3110–01]

PRIVACY ACT OF 1974

REPORTS ON NEW SYSTEM

The purpose of this notice is to list reports on new systems filed with the Office of Management and Budget to give members of the public the opportunity to make inqniries about them and to comment on them.

System name. Cancer patients on laetrile and physicians.
Report date. February 10, 1978.
Point of contact. Mr. John D. Young, Department of Health, Education, and Welfare, Washington, D.C. 20201.

DEPARTMENT OF AGRICULTURE

System name. Food service management company registration system for the summer food service program for children.
Report date. February 6, 1978.
Point of contact. John Hesliu, Special Feeding Programs Branch, U.S. Department of Agriculture, 201 14th Street NW., Washington, D.C. 20250.
Summary. This system, to be operated by the Food and Nutrition Service, will consist of records of registered food service management companies and their program records, and will be used to certify the qualifications of those companies.

SMALL BUSINESS ADMINISTRATION

System name. Official travel file.
Report date. February 13, 1978.
Point of contact. Mr. Nicholas Kalcounos, FOIA and Privacy Officer, Small Business Administration, Washington, D.C. 20416.
Summary. SBA proposes to change this system of records to reflect the inclusion of applications for advance of funds and the use of the social security number.

VELMA N. BALDWIN,
Assistant to the Director for Administration.

[FR Doc. 78-6274 Filed, 3-9-78; 8:45 a.m.]

JUSTIFICATION

The report form requests information essential for record-keeping on NSF-funded inventions to which the Government has waived principal rights, and will provide more accurate data for the required annual report to the Federal Council for Science and Technology. NSF Institutional Patent Agreements and individual waivers to grantee institutions require annual reports; the proposed form will simplify the task of these institutions. The form is to be filled out for each waived invention at the end of each fiscal year. NSF will, in its initial mailing of the form, fill in all data currently in our possession, and will ask only for data we do not have. The form will be mailed out annually thereafter for updating purposes only.

Justification for Confidentiality

Information obtained by form retained as confidential under 4, 5 USC Section 552 (b)(4) covering trade secrets and privileged or confidential commercial or financial information.

RESEARCH

The federal squeeze on university research

A cut in allowable expenses and threats to existing patent and licensing rights

A springtime of distress for university researchers is turning into open confrontation with the federal government. At issue has been a recent proposal from the White House Office of Management & Budget to restrict severely the types of overhead expense that universities may charge for government-sponsored research.

But even more ominous for the flow of new ideas and inventions from basic research—the segment of the nation's research and development that now is conducted in overwhelming proportion by universities—has been a move within Congress and among consumer advocates to restructure the terms under which universities may patent and then license the ideas developed through federally financed research. "Both of these actions," says Robert M. Johnson, dean of graduate studies and research at Florida State University, "will make it difficult for us to do business with the federal government."

Most universities complain that it is already hard enough to deal with the government, and some go so far as to predict a day when their institutions may refuse money rather than wrestle with the maze of paperwork and conflicting regulations. The situation is all the more confusing because President Carter and his science adviser, Frank Press, have made it clear that the health of university research is a top-priority item within the Administration.

Loss of millions. What the OMB budget hawks are now proposing—and would make effective on Jan. 1 of next year—is the curtailment of such overhead expenses as library use and pay for graduate assistants and other students from costs billable to the government for research it supports. "For the Massachusetts Institute of Technology," Thomas F. Jones, vice-president for research, says, "the regulations represent a loss of more than $1 million a year." At Stanford University, officials estimate a potential loss of $7.5 million.

Although their direct effect on the pace of academic research is difficult to gauge now, the regulations could have a serious impact on the training of future scientists. Today "the federal government is supporting the graduate programs," says Dennis W. Barnes, associate provost for research at the University of Virginia. But while the White House has noted that the average age of university researchers is going up—and has plans to help lure more young minds to science—Gerald J. Lieberman, Stanford's dean of research, says that the OMB rules would eliminate 75 to 100 graduate research slots at his school. And that means a contracting talent pool for industry. "These are the future scientists that will make up the labor force," says Lieberman.



Senator Nelson: He is conducting hearings on possible "government giveaways" to universities and industry.

While the universities continue to lobby against the OMB regulations, they must also contend with the patent issue. Four months ago, the General Services Administration published regulations that would have allowed the so-called Institutional Patent Agreement (IPA) used by the Health, Education & Welfare Dept. and the National Science Foundation to be substituted for the 22 different arrangements universities now make with government funders. Under an IPA, the school has exclusive patent and licensing rights to its government-funded research for up to five years.

Giveaway? At the request of Senator Gaylord Nelson (D-Wis.), the OMB delayed the regulations, and Nelson's subcommittee on monopoly and anticompetitive activities recently began hearings on the whole issue of university patents. Nelson has said that he is particularly concerned about possible "government giveaways" of the millions of dollars that industry and universities might realize from the commercialization of research that was originally supported by Washington. Ralph Nader, too, has joined the fray, suggesting that IPAs might be unconstitutional. While Nelson now says that the universities "made a good presentation" at the hearings, he told BUSINESS WEEK that "other issues could come up in the next set of hearings," scheduled for later this month.

Exclusivity. The critics say that the government has been denied income from such famous university innovations as the computer magnetic-core memory, developed under federal grants in 1948 by Jay Forrester at MIT. That technology alone has earned MIT more than $20 million. Another favored example is Gatorade, the thirst-quencher formulated by Robert Cade at the University of Florida.

But university spokesmen argue that federally controlled patents available to everyone end up being exploited by no one. "Industry is not going to touch inventions held by the government, without exclusive licensing," says William D. Carey, executive officer of the American Association for the Advancement of Science.

Statistics developed by the Commerce Dept.'s National Technical Information Service (NTIS), which is charged with trying to license federal patents, dramatically illustrate Cary's point. Of 28,000 government-owned patents, says the NTIS, companies have taken licenses for a scant 15%. "The government," notes Jones of MIT, "has never distinguished itself at running a business." And the government's overall success with selling new ideas compares badly with the experience at HEW, where IPAs have been used since 1968. "Before 1968, no inventions reached the marketplace," says Norman Latker, patent counsel for HEW. "Since that date, 60 inventions were delivered."

Unexploited. At the University of Wisconsin, where numerous patents have been negotiated over the years, officials cite an example of a good idea now insufficiently protected by a federal patent. With funding from the Interior Dept., Roger W. Boom, a metallurgical engineering professor, has developed a process by which superconductive mag-

[From Science, March 17, 1978]

Patent Policy Changes Stir Concern

Acting on recommendations that date as far back as 1971, the General Services Administration (GSA) has amended federal procurement regulations to permit universities to get a larger share of the commercial benefits of federally financed research.

The new regulations were based primarily on suggestions by a subcommittee of the Federal Council for Science and Technology that greater incentives are needed for universities to pursue commercialization of their research. The GSA regulations would provide this incentive by encouraging federal agencies to allow universities to retain possession and control of their federally financed discoveries; universities, in turn, would be encouraged to license these discoveries to private industry.

Specifically, the regulations provide for a standard agreement between federal agencies and universities, known as an Institutional Patent Agreement (IPA). "The agreements permit . . . institutions, subject to certain conditions, to retain the entire right, title, and interest in inventions made in the course of their contracts" with the federal government.

Such agreements are in common use by federal agencies now, but each may have a slightly different form. The GSA regulations require that all new IPA's, meaning any written or rewritten after the effective date of 20 March, must follow a single standard.

Moreover, the standard specified in the regulations is different from the IPA's being used now in several respects, according to several federal patent officials.

1) The new IPA can be used to cover research funded through contracts as well as grants.

2) The new IPA increases the period of exclusive control that a university can give to a licensee from 3 years after the initial marketing of a product to 5 years after the initial marketing.

3) The time that a licensee spends trying to get a federal regulatory agency to approve the product will be exempted from the time limits on exclusive marketing.

4) It permits universities to affiliate with for-profit patent management companies, which are organized to promote the licensing of university discoveries to private industry.

5) It removes the ceiling on the amount of royalties from a discovery that can be returned to the researcher who invented it, essentially allowing each university to set its own policy on the amounts.

Although this patent policy is intended to facilitate the transfer of research results from laboratory to marketplace, there is some concern on Capitol Hill that it goes too far in the direction of allowing profit-making firms to benefit from federally funded research. Also of concern is a provision that could pressure researchers to withhold publication pending patent filings. Senator Gaylord Nelson (D–Wis.), chairman of the Small Business Committee, hopes to hold hearings before the policy goes into effect next week. If that cannot be done, he intends to ask the Office of Management and Budget to delay implementation until hearings can be scheduled.—R. JEFFREY SMITH

He said that on balance, Federal support of private scientific research would increase, although "accounting options available to universities will be narrowed."

While some aspects of the regulations may change, he said he expected them to be put in final form this summer and implemented Oct. 1. He added that money uow wasted by university and Government accountants and auditors arguing over financial points would be saved by a more exact set of rules.

One Stanford University official, who asked not to be quoted by name, replied: "Well, it's a clearcut fight between the accountants and the scientists. It has been dumped squarely in the lap of Frank Press," Mr. Carter's science adviser. The official added that a number of large universities, including most of the major California institutions, were cousidering hiring a professional Washington lobbyist to work for their interests on this issue, the patent rights case and others.

The Stanford official also said that the charges of a Government "give-away" of patent rights were false and distorted.

"The Government objective is that the results of research be absorbed as rapidly as possible by American technology," he said. "University research is conveyed to private industry, and thus into the American economy, through the patent licensing system.

"We have patent rights for only three years as it is, often inadequate for educasting industry in the benefits of a new process and persuading it to take some development and marketing risks. Any time a patent is not heing properly exploited by a uuiversity license, the Governmeut retains 'march-in' rights, to take the patent back."

"The Government should be helping American industry, not hurtiug it," he said.

[From Nature, vol. 273, June 8, 1978, pp. 420, 421]

Patent Rights: Once More Around the Block

(David Dickson reports on the latest skirmishing in the U.S. over who should get rich out of moneys spinning inventions.)

Who is entitled to the rewards of a scientific experiment that results in a technological moneyspinuer? The research worker involved? His or her supporting institution? The entrepreneur who provides capital to bring the product to the market place? Or the government agency who supported the research? The debate is not new—indeed it has been going on for at least 30 years, ever since the rapid post-war expansion of federally sponsored research in universities which is now estimated to be worth over $3.5 billion a year.

The latest round of skirmishing has been sparked off by the recent publication of a planned change in federal regulations. It proposes that universities should, uuder certain defined circumstances, be automatically grauted the patent rights to the results of research carried out on government funds.

At present, different government agencies have different policies on patent rights. The Department of Energy, for example, has inherited from the Atomic Energy Commission a statutory "title" to the rights on research that it was paid for, although it can decide to waive this right and give it to the university which has carried out the research.

In contrast, the Department of Health, Education and Welfare has no statutory responsibilities, but as a matter of policy is prepared to waive rights if a petition to do so is received. Partly as a result of administrative problems in pursuing this policy (last summer, as part of a review of patent policy, a block was put on fnrther waivers holding up about 30 patents which universities had applier for) the department also has a scheme of institutional patent agreements (IPAS). Any institution which receives new research funds can apply for such an agreement. To qualify, the institution has to demonstrate that it operates an effective technology transfer programme. The IPA, if granted, provides that the institution will automatically receive the patent rights on the research it carries out.

At present the only other agency to use IPAS is the National Science Foundation which has agreed them with 19 universities since 1974. Under the uew proposals, a revised form of IPA would be extended to all government agencies sponsoring university research, and would become the standard mechanism for dealing with patent rights.

Subcommittee staff members are also looking at the possible appropriateness of a government agency such as the UK's National Research Development Corporation, which has a statutory responsibility to handle the patenting and licencing aspects of research carried out on government money including that funded in universities by the UK's research councils.

But at present any major innovation in patent policy, apart from the introduction of the new regulations, seems unlikely. Recognising the complexity of the issues—economic, political and legal—and the intensity of the motions that they raise the White House, for example, has steered clear of the area and it will not be part of a multiagency study of innovation announced recently. "The debate over government patent policy is a thicket a prudent man hesitates to enter," Mr. Charles H. Herz, general counsel of the NSF, told the Senate Snbcommittee. So it has been and so it promises to remain.

—David Dickson.

[From the New York Times, June 13, 1978, p. A16]

COMMERCE OFFICIALS LIFT SECRECY ORDER—DECREE ON COMPUTER RESEARCH AT WISCONSIN U. IS RESCINDED AFTER ACADEMIC FREEDOM PROTEST

(By Judith Miller)

Washington, June 12—The Commerce Department has lifted the controversial secrecy order that its Patent and Trademark Office had imposed on publicly funded research on computer security conducted at the University of Wisconsin-Milwaukee, Government officials confirmed today.

A spokesman for the department said that the order was imposed on April 21 at the request of the Department of Defense. It was lifted late last week, the spokesman said, when the Defense Department withdrew its request after an inquiry by Commerce Department officials.

Frank A. Cassell, assistant chancellor for university relations, said in a telephone interview that the university had not yet been informed of the decision but added, "If it's true, we are naturally very pleased and relieved by the decision. We remain concerned, however, abont the principle of the integrity of scientific research raised by this affair."

AGENCY HAS NO COMMENT

The secrecy order was imposed on unclassified research funded by the National Science Foundation. The research study, which focused on ways to safeguard computer data, was performed by George I. Davida, associate professor of electrical engineering and computer sciences. The order was issued by the security unit of the Commerce Department's Patent and Trademark Office, which refused to comment today on the recision.

Warner A. Baum, chancellor at the Milwaukee campus, had challenged the order, arguing in a letter to Richard C. Atkinson, director of the National Science Foundation, that the action "established a precedent which has a chilling effect on academic freedom."

In a visit to Milwaukee last week Juanita M. Kreps, the Secretary of the Commerce Department, discussed the order with Mr. Baum and promised to look into the circumstances surrounding it. In addition, informal inquiries were made by officials of the National Science Foundation.

Charles Herz, general counsel of the foundation, said that it was his understanding that the Patent and Trademark Office was not aware when it issued the order that the research had been sponsored by the foundation or had been conducted at a university.

The order sparked a controversy within the academic community, which has for some time been uncomfortable with the desire of several Government intelligence agencies to keep a close watch and, in some cases, a lid on research relating to the protection of computer data.

[From Business Week, January 17, 1977]

SET FOR BIOLOGY'S NEW REVOLUTION

Turning a hot science into a going industrial venture has proved to be tougher than expected for Cetus Corp., a new kind of biological and genetics engineering

the company's early customers. "We were naive about the problems of scale-up," Farley concedes. "We didn't realize that finding mutants was only half the game."

Loath to patent its systems and reveal its know-how, moreover, Cetus decided to keep its methods in tightly guarded secrecy. That put off many prospective customers who wanted to know exactly what they were paying for in dealing with a company with no track record.

However, Cetus was convinced it had something no one else could duplicate. It demanded not only heavy front-end payments—over $500,000 for all projects—but also royalty payments from work that proved successful. Now such stubborness may pay off: Cetus expects to start collecting about $1 million a year very soon from a customer that is using a Cetus-bred microorganism to increase production of an unpateuted—and thus cost-sensitive—antibiotic by 15%. That and other successes have bolstered the company's credibility in the pharmacentical industry. "This is a numbers game, and apparently Cetus plays it very well," says Raymond P. Lanzillotta, a senior microbiology researcher at Syntex Corp.

When it comes to the services that Cetus has performed for them, customers are generally even more tightlipped than Cetus itself is about its own know-how. Most customers demand a strict nondisclosure clause in their contracts. Says a senior executive of a major drug company that negotiated one of Cetus' first contracts, but still does not want to be identified: "With their scientists and 'black-box' technology, they've been able to build a bridge between fundamental and applied science and automate certain processes for the first time. They can do in hours what it takes the pharmaceutical industry days or weeks to do." Another pharmaceutical executive takes a different perspective, crediting Cetus' ability to process microorganisms as "the kind of competition you have to be concerned with."

NEW VENTURES

Even with its small revenues, Cetus has been able to bank about half of its seed money and break even on operations, while recycling 10% of its revenues into its own research and development. Now that their company has started to gain a reputation in the pharmaceutical industry, where customers are familiar with the technology, Farley and Cape hope to branch out in three new directions: spreading to other industries that can use biochemical processes, developing proprietary products of their own, and devoting at least a quarter of the company's energies to the leading-e ge technologies of molecular biology and gene manipulation.

Cape and Farley believe that in 2 to 10 years, microorganisms will play a far greater role in industrial chemistry than the kinds of fermentation techniques now in use. The more productive bugs could be either natural mutants or specially tailored bacteria developed from an understanding of the intricacies of the genetic code. And the prospects for their use cover a wide range: They may produce chemicals from renewable resources at low temperatures and pressures, such as acetic acid from starches; make vitamins and proteins from agricultural waste; and help develop new energy sources, such as methane from organic refuse, alcohol from cellulose, and oil from depleted wells. It may also be possible to develop microorganisms that will concentrate metals from tailings and low-grade ores that are now uneconomic to exploit.

A RISKY FUTURE

The Cetus staff sees its most exciting future possibilities in the controversial field of direct gene manipulation—experimenting with recombinant DNA, the carrier of the genetic code. The promise of major breakthroughs is bright, and progress in basic research in gene stitching and synthesis has been remarkably rapid in the last few years. But the company faces considerable risks. "There is no way to pursue recombinant DNA programs on a shoestring," Cape cautions. "We can't afford to be scientific heroes but business flops." A suitable containment facility alone for that kind of work costs more than $1 million.

Beyond the funding problem, there is a raging public controversy about the hazards in research that is aimed at producing new and perhaps lethal mutant microorganisms. Although not yet required to do so, Cetus plans to follow the same rigorous research guidelines that the National Institutes of Health requires for all government sponsored work involving recombinant DNA. But more stringent rules may come. Late last year a Congressional symposium in Washington heard some scientists go so far as to recommend a total ban on recombinant DNA work. And federal agencies and Congress alike are exploring whether the gov-

Across the bay in Berkeley, six-year-old Cetus Corp. is also opening a recombinant-DNA facility to complement its work in conventional chemical and radiological means for mutating bacteria. "This is the hottest area in biology today," says Peter J. Farley, Cetus' executive vice-president. Two months ago, Standard Oil Co. (Indiana) bought one-fifth of Cetus for about $10 million.

Elsewhere, Upjohn Co. will soon open its own recombinant DNA lab. According to Joseph E. Grady, head of Upjohn's infectious disease research, the company expects to develop marketable applications within five years. Abbott Laboratories is just now beginning work on recombinant DNA, while Miles Laboratories Inc. is becoming the major supplier of the so-called restriction enzymes that scientists use to cut strands of DNA for recombination. Altogether, between 10 and 15 industrial labs are now pursuing recombinant-DNA experiments.

TRYING FOR INSULIN

The Genentech research began with the construction of an artificial gene by the team at the City of Hope under the leadership of molecular biologist Arthur D. Riggs. The scientists chose to construct the gene from somatostatin because the hormone's chemistry, worked out at the Salk Institute, is reasonably well-known, and because sensitive tests are available to measure whether it is actively working within a cell. More important, somatostatin seems to play an important role in regulating body growth and inhibiting the production of insulin in the pancreas. Thus, it and otber hormones now under stndy seem to have wide possible application in treating diseases such as diabetes. Today, somatostatin costs around $30,000 per gram to synthesize chemically, but Genentech believes it can bring the cost down to $300 or less.

Once it had an artificial gene, Boyer's team at UC-San Francisco used restriction enzymes to cut open a ring of DNA known as a plasmid in the cells of a special strain of *Escherichia coli*, the human gut bacteria most commonly used in recombinant-DNA work. The strain the team used, called K-12 bacteria, had been specially mutated so that is could not survive outside laboratory conditions. The gene was then stitched into the plasmid, and the combination was introduced into another K-12 bacterium, which accepted the foreigu genetic material as its own. Then, for the first time anywhere, the artificial gene not only replicated itself but also instructed the bacteria to produce somatostatin.

The experiment is the third "first" registered by UC-San Francisco scientists this year. Earlier, they snccessfully inserted into *E. coli* a rat gene responsible for the production of insulin. But while the work was hailed as an early proof of recombinant-DNA's potential value to man, one early phase of the experiment had also involved the first violation, albeit accidental, of NIH safety guidelines. The scientists had to destroy the earlier experiment.

$100 MILLION MARKET

Such miscues only heighten fears tbat recombinant-DNA research might lead to the production of lethal organisms. Scientists who discount the danger have launched an effective campaign to calm the worriers, and this summer they successfully headed off congressional control of their work. Now the Carter Administration is urging industrial labs to comply voluntarily with the NIH guidelines. But an even more effective means of review may emerge from a recent court decision in favor of Upjohn that allows man-made organisms to be patented. Thns, the companies would have legal protection for their discoveries while their lab procedures could be scanned throngh the patent application process. Yet another check would be possihle through the Food & Drug Administration, which would pass on the introdnction of any new medicines.

Genentech has already filed for patent protection for its somatostatin technology and will similarly cover the expected breakthrough for insulin—an eventually made more likely by the new research. Says Irving Johnson, vice president of research at Eli Lilly & Co., currently the largest producer of insulin: "Commercial results are more imminent than tbought," Swanson aud Boyer expect their company to compete effectively for the $100 million insulin market, and they see all sorts of fnture applications for hormones to antibiotics and even enzymes.

For now, though, they will have plenty of business producing products already in demand. Swanson points out that "missionary marketing" of new substances is not in Genentech's development plans. "The field is opening up rapidly," adds Boyer, "and we have the flexibility to move."

[From the Washington Post, June 27, 1978]

LIVING THINGS PATENT CASE IS SENT BACK

(By Morton Mintz)

The Supreme Court passed up yesterday an opportunity to review an unprecedented ruling that a person can patent living things, choosing instead to return the case to a divided appeals tribunal.

The justices nullified the ruling and sent the case back to the U.S. Court of Customs and Patent Appeals "for further consideration in light of" a decision they announced in another patent case last Thursday.

In that decision the court ruled an inventor can not patent a method for identifying a limited category of useful but conventional applications when a mathematical formula is the only novel feature.

Sources said they were uncertain how the appeals tribunal will interpret the phrase "in light of," but speculated that it may reverse its 3 to 2 holding last Oct. 6 in a case principally affecting the chemical and pharmaceutical industries.

The October case involved a strain of bacteria found in certain Arizona soil. Upjohn Co. scientists isolated and purified the micro-organisms under carefully controlled laboratory conditions and then used them to prepare an antibiotic tradenamed Lincocin (lincomycin).

The scientists applied for a patent on the tiny forms of life, intending to assign their rights to the pharmaceutical manufacturer.

The U.S. Patent and Trademark Office rejected the application. It ruled that in allowing patent monopolies for new and useful discoveries, inventions, and improvements of machines, processes and compositions of matter, Congress did not intend to permit patents on living organisms.

The government asked the Supreme Court to reverse the ruling. If allowed to stand, the Justice Department argued, it would open "an enormous range" of living things to patent monopolies.

Other court actions.

LOW-COST LIFE INSURANCE

In New York State, savings banks sell life insurance that is inexpensive, partly because it is merchandised over the counter, by mail and by phone rather than by salesmen who earn commissions, and also because the termination rate is low. But a state law prohibits sales of Savings Bank Life Insurance (SBLI) to persons who neither reside nor regularly work in the state.

After a bank refused to sell a $30,000 SBLI policy to a New Jersey man, Consumers Union, the nonprofit testing organization, filed a suit charging that the law violated the provision of the Constitution barring a state from abridging "the privileges of immunities" of citizens of other states.

A panel of three federal judges disagreed.

The Supreme Court, in a 9-to-0 decision last Thursday, invoked the "privileges and immunities" clause to invalidate an Alaska law that tried to get jobs for Alaskans by requiring private firms involved in oil and gas development to favor them over nonresidents. Yesterday, the court nullified the panel's ruling in the SBLI case and sent it back "in light of" the Alaska decision.

COMMODITY TRADING

Acting in a case involving the now defunct British American Commodity Options Corp., the court let stand a decision upholding the power of the Commodity Futures Trading Commission to halt trading by a dealer while it investigated a registration application.

[From the Wall Street Journal, June 23, 1978, p. 6]

COMPUTER PROGRAM IS DENIED A PATENT IN HIGH COURT CASE—ALGORITHM USED IN SOFTWARE IS LAW OF NATURE, JUSTICES SAY, AND NOT PATENTABLE

WASHINGTON.—The Supreme Court indicated that developers of compnter programs, or software, had better appeal to Congress if they want to be able to patent novel programs.

LEGAL AFFAIRS

A new federal threat to the value of patents

The International Trade Commission is now examining their validity

A collision between two marketers of toy trucks has signaled an important new course for the International Trade Commission. The agency, which has been concerned with protecting U. S. companies from imports, is now a place where American companies may lose patents that they have won from the Commerce Dept.'s Patent & Trademark Office.

This development is the latest in a long string of judicial and administrative actions that have eroded the value of patents. Before World War II, most circuit court rulings on patent validity favored the patent holder. But in recent decades, patent holders have been winning no more than one-third of such cases. Supreme Court decisions have opened the way for more challenges to the validity of patents. At the same time, these decisions have given owners less chance to defend their patents. And, for the past eight years, the Justice Dept.'s Antitrust Div. has had a section that specializes in launching cases charging companies with unlawfully extending the legal monopolies granted by patents.

Flexing unused muscles. The new policy at the ITC means "it's one more place where patents can get knocked down," says Washington lawyer James H. Wallace Jr., "and once they are down, they are down forever." The agency has looked at questions of patent law even before 1974, when it was called the U. S. Tariff Commission. Under section 337 of the 1930 Tariff Act, it has the power to keep products that infringe on U. S. patents out of the country. But until recently, it examined only whether the foreign goods did, in fact, copy patented features, not whether the patent should have been granted in the first place.

When the agency got its new name and new powers from Congress, the lawmakers said that the commissioners could look at patent validity in deciding whether to bar particular imports. That authority has been used only sparingly until now: The commission found that a chain door lock patent was valid, and that the patent on a device for removing solder was invalid. But it had generally assumed that if it found no infringement, it had no reason to probe the basic strength of the patent.

In early April, however, the Court of Customs & Patent Appeals (CCPA) asked the commission to rule on all questions at the same time, in order to prevent the possibility of future appeals. The toy truck case is the first evidence that the commission will now follow that procedure. Therefore, questions of patent validity are likely to be at issue in upcoming bids for import curbs involving such U. S. manufacturers as Walter Kidde, Samsonite, Ferro, Rival Mfg., and Dennison Mfg.

Remarkable insight. In the landmark case, Tonka Corp. asked the commission to exclude from the country toy trucks made by eight different Japanese and Hong Kong manufacturers and sold in the U. S. under the Buddy L trademark. Tonka insisted that the imports infringed on two of its patents: one on a cab hinge and the other on a design to keep the tires from falling off the truck wheels. The commissioners ruled that the imports did not infringe on Tonka's patents. They went on to say: "Assuming for the sake of argument that the patents were infringed by the imported articles, we find that the subject patents are invalid as obvious." In other words, only inventions that show some remarkable insight are patentable.

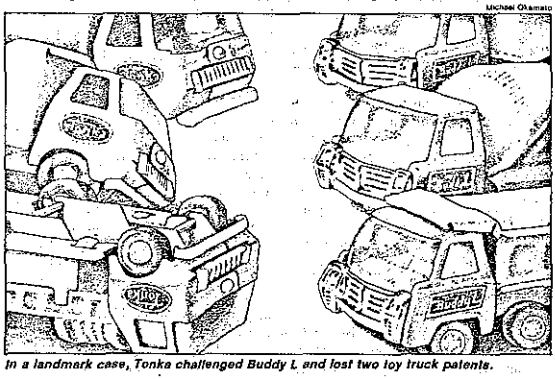
Tonka is still considering whether to appeal the decision to the CCPA. But the question that worries lawyers is not whether Tonka's two patents are valid, but what the impact of similar decisions in future cases will be.

Under a 1971 Supreme Court ruling, a court finding that a patent is valid does not stop a company that is not a party to that suit from challenging the patent in a new action. But a finding that a patent is invalid is the final word, and the patent owner can never again try to enforce the lost privilege. A finding by the ITC that a patent is invalid does not have that legal effect, because the commission is not a court. But a CCPA ruling affirming the commission may be a death knell.

Part of the game. The ITC decision, many experts predict, will also carry a lot of weight in district courts. Under the statute, all the ITC can find is that the patent is invalid as far as trade law goes. But, says Maurice H. Klitzman, patent expert at International Business Machines Corp.: "I don't see how you can have two sets of standards. If it's invalid for one purpose, it's invalid for another." John Calimafde, Buddy L's lawyer in the truck case, thinks it would be "folly" to try to continue to enforce a patent found invalid by the ITC because a defendant would have good cause to stick the patent holder with his legal bills for fighting a purposeless case.

That "may give people some concern before they file before the commission," says Nelson Shapiro, who is representing Kidde in two patent cases at the agency now. Lawyers say that they now warn clients thinking about bringing complaints before the ITC that they may lose their patent in the process. Shapiro insists that is just part of the game. "Whenever you litigate to enforce a claim," he says, "you always run the risk of putting the validity of your patent on the line." ■

Michael Okamato



In a landmark case, Tonka challenged Buddy L and lost two toy truck patents.

[From the Wall Street Journal, July 28, 1977]

FIRM FIGHTS CANCELLATION OF RIGHTS ON CT SCANNER

CAMBRIDGE, MASS.—American Science & Engineering Inc. said it will fight what it called "unwarranted and arbitrary" cancellation of a federal government grant to the company of exclusive commercial rights related to the company's computerized axial tomography or, CT, scanner.

American Science developed the scanner, used in making cross-section X-rays of the body, for the Health, Education and Welfare Department's National Institutes of Health.

Last June after six months of study, HEW granted American Science a three-year exclusive license in the U.S. aud unlimited exclusive commercial rights abroad on key inventions in the CT scanner, American Science said.

But on Monday, American Science said it received a letter from HEW stating that its license had been changed to "world-wide nonexclusive." That could allow other companies with a license to market the scanner.

HEW said it canceled the exclusive rights when it realized that in this case it "didn't have the authority to graut an exclusive license."

[From the Wall Street Journal, July 29, 1977]

TECHNICARE UNIT GETS LICENSE FROM HEW FOR USE OF INVENTIONS

SOLON, OHIO.—Technicare Corp. said its Ohio-Nuclear Inc. subsidiary was granted a nonexclusive, royalty-free license to use inventions covered by two patent applications owned by the federal government.

The inventions claimed under the patent applications pertain to computerized tomographic scanning, a method of making cross-section X rays of the body. They were developed under a National Cancer Institute contract, Technicare said.

American Science & Engineering Inc., Cambridge, Mass, filed suit against Technicare earlier this month in a dispute over the technology covered by the patent applications.

American Science also had said it would fight the "nnwarranted and arbitrary" cancellation by the U.S. of exclusive commercial rights related to the company's CT scanner. The Health, Education and Welfare Department changed the company's license to "world-wide nonexclusive" because it said it lacked authority to grant exclusive rights.

[From the Washington Star, July 1, 1978]

GOVERNMENT FAVORS THE GIANTS IN HANDING OUT R&D FUNDS

(By John Holusha)

The federal government overwhelmiugly favors corporate giants when it hands out research funds, despite its admission that smaller firms tend to be more innovative.

This assessment is contained in an internal Office of Management and Budget study of the impact of federal research and development funds.

The study has surfaced at a time of growing concern at the slowdown of productivity in this country and complaints by some members of Congress that the government is at least partially to blame because of its favoring of big business.

The OMB study is the product of an interagency task force that looked into lagging technology. Although it contains recommendations to increase the share of federal R&D dollars going to smaller firms, it was never released or implemented.

The study found:

Small businesses accounted for almost half of all major innovations in the 1953–1973 period.

Small businesses produce four times as many innovations per researcher as big business.

The total cost of each scieutist or engineer is twice as great in big business as it is in small business.

tematically at keeping in touch with the ontput of American laboratories. And we make it extremely easy for them to do so. Bnt in the meantime, there is scarcely an organized American effort to keep abreast of foreign research, which, despite our ethnocentric notions of American scientific snpremacy, actually accounts for well over half of the world's scientific and technological output. Furthermore, when it comes to research of industrial value, our seemingly huge budgets are misleading. Half of the government's funds go into military projects, whereas Japan, for instance, devotes no more than 10 percent to that purpose.

In evalnating the calls for protectiouism, however, the relevant point isn't who's doing more or less research, since great quantities of it are going on here and abroad. Rather, it's our indolence in matching the organized, serious efforts that many nations make to exploit—as the protectionists correctly contend—American-financed research.

For example, the semigovernmental Japan Trade Center has technically trained representives posted in New York, Los Angeles, San Francisco, Honston and Chicago. Their duties, according to a spokesman, "are to watch everything in American indnstry and gather information." The same monitoring role is carried on by representives of many Japanese firms.

France, which follows a determined policy of keeping in touch with research in the major industrialized nations, keeps six science attaches in Washington, plus one each in Boston, Houston and San Francisco. Principal among their dnties is following American science and technology at the laboratory level. The object is to know what's going on long before the rest of the world finds out through the traditionally slow process of scientific publishing.

The embassies of almost all the other industrialized nations are staffed for that purpose, though the intensity of the efforts varies. A staff member of the State Department science office points out, "Most of these people work for their ministries of commerce and industry, not for the foreign ministry, and their joh is to watch the industrial area."

It's all open and aboveboard and, in fact, is greatly assisted by the U.S. government National Technical Information Service (NTIS), which offers for sale about 75 percent of all scientific and technical papers produced in the United States. Foreign sales are such a booming business—with Japan the biggest customer—that NTIS has contracted for foreign dealers to handle its publications in Japan, Britain, France and the Netherlands. Foreigners take 10 percent of NTIS sales. It is a unique window on a national research enterprise—immensely valuable, of course, to American researchers, bnt equally so to foreign competitors. Except for small organization in the Netherlands, no other conntry has anything resembling NTIS.

The United States does maintain science attaches at 23 of our embassies. But unlike most of their foreign counterparts here, they're not in the business of collecting scientific and technical data for shipment back home. Rather, they're concerned with "policy matters"—whatever that means.

The military services, led by a longstanding Navy operation based in London, try to keep in touch with leading scientific centers broad, but their interests are narrowly defined and are not geared to industrial purposes.

The imbalance in scieutific and technological voyeurism is something that American indnstry is aware of. Bnt with the government indifferent to the problem and pooled monitoring efforts barred by antitrust regulations, few companies do anything about it.

One major exception is General Electric, perhaps the most shrewdly and tightly managed of our big high-technology corporations. Monitoring of foreign science and technology is handled by two GE representatives in Zurich, two in London and one in Tokyo. According to Charles M. Huggins, GE's manager of international programs for corporate research and development, "We assnme that 60 percent of all new science and technology is developed outside the United States."

American campaigners for technological protectionism should think about that.

As federal research has increased and private research diminished "small companies, at least in high technology, are finding the government can be their greates competitor," Reimers says

"Market dominating companies, with the nonexclusive patent policy favored by the Justice Department, can treat government technology as a large patent pool, with no threat to their market dominance.

"If only nonnexclusive licenses are available, then foreign industry has equal access in using the results of government-funded research."

The National Technical Information Service, a Commerce Department agency which provides low-cost summaries of federally funded research, is opening an office in Japan to meet soaring demand for there data there. Caneda recently surpassed Japan as the top customer for NTIS summaries.

In a recent letter to Attorney General Griffin Bell, Reimers noted that after Stanford issued an exclusive license for a variation of an existing instrument to a U.S. company "we were challenged by a foreign manufacturer who demanded to know how we could give exclusive rights to an invention from U.S.-public funded research.

"For the same invention, another foreign firm—the market leader—obtained Stanford's research files through the National Science Foundation, using the Freedom of Information Act. The foreign firm charged patent interference, and the invention has yet to be developed."

Foreign firms aren't the only source of delay in getting inventions to the commercial marketplace, he adds. The Department of Energy now has a nonexclusive patent policy which requires a lengthy waiting period—often 18 months to two years—to obtain any waiver of patent rights.

"Many allege that the Atomic Energy Commission-Energy Research and Development Administration-DOE policies have acted to inhibit innovation in energy technology and also have limited participation in DOE research primarily to large companies. For these firms, proprietary rights are less significant in innovation than small companies."

At ERDA patent policy hearings in 1976, all universities and all small companies testifying opposed the ERDA policy. Support came only from General Electric, Westinghouse, and a major oil firm.

Even with exclusive licenses, it is difficult to get companies to bring university discoveries to the marketplace, Reimers notes. Any example where an exclusive license based on government research has in fact achieved a "monopolistic" or "dominating market position" would be helpful—but Reimers has yet to find one.

Most inventions are relatively minor improvements in an existing art, which have to compete with alternative ways of accomplishing the same function and with the likelihood of being surpassed by newer inventions in time.

Reimers says the Justice Department position can be traced back to a 1947 report which contained no operational data. He has asked Bell, in vain, for even a single example where patent rights from government research "have set the price of goods to the public, rather than competition, and where the profit was disproportionate to the risk capital contribution of the company making the technology available."

4-4-4

In a speech last month to the Society of University Patent Administrators, HEW Patent Counsel Norma J. Latker took sharp issue with Assistant Attorney General Shenenfield's claim that exclusive licensing may actually hurt the commercialization of inventions.

"A strong argument can be made that allowing (federal) contractors and grantees to retain patent rights will tend to promote competition, whereas if government adopts a policy of normally dedicating the invention to the public or licensing on a nonexclusive basis, concentration and monopoly will be enhanced."

Where industries are oligarchical in structure, he added, "a policy of nonexclusive dedication or licensing tends to serve the interests of the dominant firms, for whom patent rights are not normally a factor in maintaining dominance.

"Rather, control of resources, extensive marketing and distribution systems, and superior financial resources are more important factors in maintaining dominance and preventing entry of new firms and ideas. . . .

"Dominant firms may well be foreign-based, and dominate due to subsidization by their governments, making the inadequancies of a policy of normally licensing on a nonexclusive basis. . .even more pronounced. . . .

"On the other hand, smaller firms in an industry and firms requiring premarket clearance by the government must necessarily rely on a proprietary position in innovations and products in order to protect their investment in foreign and domestic markets. Thus, patent rights tend to be a much more significant factor affecting their investment decisions.

"They may need the exclusivity of patent rights to offset the probability that a successful innovation will lead to copying by a dominant firm which would soon undercut their position by marketing, financing, and other commercial techniques.

"Accordingly, nonexclusive licensing. . .may in fact be anticompetitive, since it encourages the status quo by discouraging promotion of innovations which displace old technology. Also, it is clear that the government can determine with whom it wishes to contract and rule out firms it deems to be dominant if deemed appropriate."

If the share of government funding of research were to approach 100% nationally and if patent rights were a primary factor in obtaining private resources for developing government funded inventions, he asked, "Does not the government then control whether most new ideas are developed or not?

"Is not the control of development of all ideas the ultimate regulation, and support Henry Ford II's recent admonition that the government's growing web of industrial regulations is fast bringing us to a point where only the largest companies can survive?"

If Senator Nelson's policy were to be adopted, through legislation or administrative action, he concluded "it seems clear that the industrial sector's effectiveness in sensing the needs of our society in introducing new technology to meet such needs would be severely impacted, starting our country down a long road to mediocrity."

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groups such as the Industrial Research Institute (IRI), the Business Roundtable, and the Conference Board. "We want both CEOs and R&D vice-presidents," says a White House official. Labor groups have been asked to participate, too, along with public-interest groups. Congressional leaders such as Senator Adlai E. Stevenson (D-Ill.), chairman of the Senate subcommittee on science, technology, and space, have been brought into the early planning. And the 28 agencies involved extend beyond obvious candidates, such as the Environmental Protection Agency, to the Justice Dept. and even the Small Business Administration.

The study's scope is so sweeping, in fact, that some federal officials are talking about a "thundering herd" approach to policymaking. But one government science manager demurs. "It beats having one guy write a national energy program in three months," he sniffs.

Philip M. Smith, an assistant to Presidential science adviser Frank Press and an early organizer of the study, concedes that "a lot of people have told us that we are likely to fail." But such skepticism, he believes, does not take into account the considerable clout of those involved in the effort. Commerce Secretary Juanita M. Kreps, for example, is chairing the study, and she heads a coordinating committee whose members include Charels L. Schultze, chairman of the Council of Economic Advisers; Administration inflation fighter and chief trade negotiator Robert S. Strauss, and Zbigniew Brzezinski, Carter's national security adviser. Even more important is the support of Eizenstat, who, says Smith, "is very interested in this particular review."

FINDING "NEW DIRECTIONS"

On the other hand, there is already grumbling within the Agriculture Dept., which was left off Krep's committee. "We are red-faced," says a high-ranking Agriculture official. "We are out of the project because this Administration and those before it do not place any priority on agricultural research." However, Jordan Baruch insists that the department will play a role in the study. Agriculture experts point out that farm commodity exports of over $24 billion play a key role in the U.S. balance of payments. They note also that superior technology is the basis of the commanding American position among world food exporters.

Whatever its outcome, the White House policy review is being undertaken at a time when, as Frank Press puts it, "we badly need some new directions." Many experts review with alarm the declining federal dollar commitment to R&D, which has dropped from 3 percent of gross national product in 1963 to just 2.2 percent this year. For its part, industry as a whole has more or less matched the inflation rate and then some with its own spending. But such macroscale indicators do not tell all. "We've got to find out what the story is sector by sector, because each industry is going to be different," says Press. "We also have to find out what's going on abroad."

Better data on the relationship between industrial innovation and the health of the economy are becoming available. According to a 1977 Commerce Dept. report, for instance, technological innovation was responsible for 45 percent of the nation's economic growth from 1929 to 1969. The study went on to compare the performance of technology-intensive manufacturers with that of other industries from 1957 to 1973, and found that the high-technology companies created jobs 88 percent faster than other businesses, while their productivity grew 38 percent faster.

The numbers help to establish the central role of industrial innovation in stimulating economic development, but they also are beginning to reveal the changing character of industrial research. The amount of basic research that industry performs, for instance, has dropped to just 16 percent two years ago from 28 percent of the national total in 1956.

And a new IRI survey of member companies for the National Science Foundation demonstrates how federal policy has directly altered the nature of the research effort in another way, making it more and more defensive. The study shows that surveyed companies increased R&D spending devoted to proposed legislation by a striking 19.3 percent, compounded annually, from 1974 to 1977. And the rate was 16 percent a year for R&D devoted to Occupational Safety and Health Administration (OSHA) requirements. "When overall R&D spending is not growing nearly this fast," note the survey's authors, George E. Manners, Jr., and Howard K. Nason, "other categories of effort—especially research—must be suffering."

Other observers compare the viability of industrial innovations in the U.S. with that of foreign countries. One expert is J. Herbert Hollomon, director of the Center for Policy Alternatives at Massachusetts Institute of Technology. According to Hollomon, a reason the U.S. is losing its leadership is that "we're arrogant—we have an NIH [not invented here] complex at the very time a majority of technological advances is bound to come from outside the U.S." Consequently, he argues, the U.S. has not organized itself to capitalize on these advances, as foreign countries have done for years with American knowhow. Since as much as two-thirds of all R&D is now conducted by foreign laboratories, Hollomon says, it should be no surprise that they have taken the lead in such technologies as textile machinery and steel production.

"We essentially prohibited West Germany and Japan from defense and space research," says Hollomon. "So it's no accident they concentrated on commercial fields." He adds: "I believe other nations better understand that the innovation process is important."

Says a research director for one high-technology company: "For a country like ours, the technology leader of the world, what has been happening is downright embarrassing." Indeed, even the presumed sources of strength in a consumer-oriented society are today under intense pressure. "Our experience with Japan in the consumer electronics industry—namely televisions, radios, audio, and transceiver equipment—shows some of our weaknesses," testified Gary C. Hufbauer, a Deputy Assistant Treasury Secretary, before a congressional subcommittee. In 1977, he said, "we had a $23.6 billion trade deficit with Japan in high-technology goods, and about two-thirds of this was accounted for by imports of consumer electronic goods."

THE ROLE OF REGULATION

The cumulative response to these developments has been alarm. "The system has now sharpened its pencils in a way that discourages changes that are major," worries Robert A. Frosch, head of the National Aeronautics & Space Administration. "We have been so busy with other things that we may have inadvertently told the people who think up ideas to go away."

Even labor unions, which historically have left R. & D. decision-making up to corporate board rooms, now are complaining about lack of innovation. "Having helped to develop and pay for this technology," says Benjamin A. Sharman, international affairs director of the International Association of Machinists, "American workers have a right to demand government responsibility for using it to create new products, more jobs, better working conditions, and general prosperity." And Charles C. Kimble, research director of the Electrical, Radio & Machine Workers union, goes so far as to suggest that labor should now have a say in how industrial research money is spent.

Among research managers themselves, excessive or contradictory federal regulatory policy is the single greatest complaint. Hannay of Bell Labs points to Food & Drug Administration requirements as a case in point. According to one study, says Hannay, a 1938 application for adrenaline in oil was presented to the FDA in 27 pages. In 1958, a treatment for pinworms took 439 pages to describe. "By 1972," he says, "a skeletal muscle relaxant involved 455 volumes, each 2 in. thick—76 ft. in total thickness and weighing one ton."

Regulation, says Tinsley of Union Carbide, has put a bottleneck on new-product development in the chemical industry and has so added to the cost of getting any new chemical approved that only those targeted at a vast, assured market are attempted today. Food and drug industry researchers echo that complaint. "Today," says Al S. Clausi, director of technical research at General Foods Corp., "our industry does work that is fostered by unreal and invalid public concerns."

But regulation can have less obvious impacts, such as forcing an industry to stick with old technology rather than to experiment with new approaches to problems. "The overall effect of regulations on the auto industry has been to build an envelope around the internal-combustion engine and the whole car structure," says Harvard Business School Professor William J. Abernathy, who specializes in technology management. "Don't do anything really new, don't change." That's what these regulations say." Paul F. Chenea, vice-president for research at General Motors Corp., agrees. "You just don't have time to explore wild new ideas when a new rule is so closely coupled to your current business," he says.

"THE SCIENCE OF THE MATTER"

In Congress, where the regulatory laws are written, such thinking has so far found a small audience. "A great number of the regulations that we would call environmental . . . may actually be self-defeating," muses Harrison H. Schmitt, the former astronaut from New Mexico who is the ranking Republican on Stevenson's Senate subcommittee. "Instead of looking at pollution controls, if we were looking at building a more efficient and therefore less-polluting engine, we would not only be solving our environmental problems, but we would be producing a new thing for export."

Schmitt is one of only three federal legislators with the semblance of a science background. "We probably have exercised very poor judgment in the past," he says, "because the Congress overall—members as well as staff—have not been able to understand what is possible technologically and what is not, and therefore not been able to relate the costs [of legislation]."

Jason M. Salsbury, director of the chemical research division at American Cyanamid Co., pleads, "Before the laws were written the legislation, let them know the science of the matter." Not only may some mandates be beyond what industry can legitimately perform, he says, but the rules force a conservative approach to science. One key indicator of this trend is the increasing number of toxicologists now employed in chemical company research labs. "Toxicologists don't innovate," notes Frank H. Healey, vice-president for research and engineering at Lever Bros. Co.

Then there is the regulatory bias against new ideas. In the EPA's grant programs for waste-water treatment at the municipal level, for instance, equipment specifications must be written so that gear can be procured from more than one source. That means a company with a unique process is

business considerations." Another criticism has been of the haphazard way in which companies have launched new R&D programs. In essence, industry should try to learn how to weed out bad ideas early on, say the detractors. To that end, Dexter Corp. has instituted an eight-factor "innovation index" approach to research management that weighs questions such as effectiveness of communications, competitive factors, and timing, and comes up with an "innovation potential" for new ideas. At Continental Group Inc., D. Bruce Merrifield, vice-president of technology, says that "constraint analysis" of new ideas now means that eight of 10 projects that survive the review will generate cash flow within two to four years. That contrasts with accepted estimates that only one in 50 ideas that come out of research labs ever generates cash flow, and not for seven to 10 years.

Large companies often fail to exploit their own resources effectively. In the 1950s and 1960s, some companies set up centralized research facilities, but many of these did not yield the hoped-for synergism—in many cases, apparently, because the different parts of the company were in businesses too unrelated to one another.

On the other hand, Raytheon Co. was highly successful in transferring its microwave expertise to its newly acquired Amana appliance subsidiary in 1967, resulting in the counter-top microwave oven. That was done through a new-products business group set up specifically for such purposes. And more recently, this group, headed by Vice-President Palmer Derby, brought the company's microwave talent to bear on its Caloric subsidiary's product line, resulting in a new combination microwave-electric range.

In such ways, industry can maximize its potential for innovation in the most adverse environment. But the future health of the nation's economy, many experts believe, requires a much more benign environment for industrial R&D than has existed over the past decade. And Jordan Baruch, the enthusiastic leader of the multi-agency federal study, believes that such an environment is likely to emerge as a result of the Administration's concern.

"We may have bitten off more than we can chew," notes Frank Press, "and it may be that we can't get much done in a year. But even if it takes three or five or 10 years, I think it is historically very important."●

be "overly broad," according to a Library of Congress analysis prepared for a Senate subcommittee.

Gerald Sturges, a staff attorney with the Senate Select Small Business Committee's Subcommittee on Monopoly and Anticompetitive Activities, said he feared that Exemption 4 of the Freedom of Information Act and the similar exemption in the Government-in-the-Sunshine Act are being stretched to include patentable material. The exemptions protect trade secrets and confidential business information.

Sturges said the concern was that universities or nonprofit institutions could assert, as grounds for denying public access, that their proposals for research and development grants or contracts contain information about potentially patentable material. Peer review panels, which review grant applications for scientific and technical merit, might rely upon such assertions to close their meetings or deny access to documents.

The problem with such an approach, Sturges explained, is that grant and contract proposals rarely, if ever, contain pre-invention information of a patentable nature. Because most such information comes about only as an unplanned by-product of research and development, it cannot be identified in a simple proposal for funding for scientific research.

Last year, the NIH began to claim that meetings to discuss proposals concerning contract proposals or grant applications could be closed to protect "confidential trade secrets or commercial property such as patentable materials . . . ."

However, the Congressional Research Service of the Library of Congress concluded that patentable information does not automatically justify a closed meeting. In a memorandum to the subcommittee, the research service said: "Patentable material must satisfy the requirements of either a trade secret or confidentiality or commercial use before it is subject to withholding. It is not *per se* exempt nor is it necessarily synonymous with commercial property, as the language in NIH notices seems to indicate. In that regard, the closure notices would seem to be overly broad since any 'patentable material' which may be involved must also meet the specific criteria of Exemption 4 in order to justify closure."

However, Sen. Gaylord Nelson, D-Wis., chairman of the subcommittee, said in the May 19 Congressional Record that universities might use their institutional patent agreements with the Department of Health, Education and Welfare as "official recognition of the commercial potential of the proposed research." Institutional patent agreements give certain approved universities and nonprofit institutions first option to own the rights to inventions resulting from government-sponsored research and development.

Sturges also expressed concern that Exemption 4 could be stretched -- before a patent application is filed -- to cover an institution's disclosures of inventions conceived as a result of such research.

In response to the subcommittee's expressed concerns, the Congressional Research Service said institutions have no right to expect that invention disclosures will be kept confidential if they do not intend to file a patent application. However, the memo continued: "It is those invention disclosures which the institution intends to patent but has not yet filed an application to which Exemption 4 would be applied in determining closure."

the "potential chilling effect [of the Patent Office's action] on freedom of scientific inquiry." He added that "we are strongly of the view that in this context secrecy orders should not be issued lightly or on the basis of any but serious national security implications."

"On the other hand," Atkinson continued, "I think you and I would both recognize that there can be cases when freedom of scientific inquiry must bow to serious national security concerns. Whether this is one of those cases we do not yet know enough to tell . . . . . Again, NSF is continuing to look into it both legally and substantively." -- E.H.



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SOUNDING BOARDS

PROFITABLE AND NONPROFITABLE DRUGS

IN reaction to the thalidomide tragedy, Congress enacted the Kefauver–Harris amendments to the Food, Drug and Cosmetics Act in 1962 that considerably increased the number of preclinical and clinical tests required by the Food and Drug Administration (FDA) before release of a drug for marketing. The Kefauver–Harris amendments have had profound effects on the development of new drugs. Over the years since 1962, the consumer has been protected from potentially dangerous drugs that might have reached the marketplace under the FDA legislative acts of 1906 and 1938. However, the consumer protection has not been gained without adverse consequences. A major complaint of physicians as well as the pharmaceutical industry is FDA overregulation, which has led to an unnecessary delay in the introduction of new drugs in this country. This drug lag, in addition to recent controversial decisions by the FDA on issues such as saccharin and phenformin, has led both Joseph A. Califano, Jr., Secretary of Health, Education, and Welfare, and Senator Edward M. Kennedy (D.–Mass.), chairman of the Health and Scientific Research Subcommittee, to call for further legislation to improve the decision-making processes of the FDA. The main objective of current legislative proposals is to ensure that new safe drugs reach the market sooner and dangerous ones are withdrawn more quickly.

Another major problem, aggravated by the FDA amendments of 1962, has received insufficient attention and should be given a high priority in the formulation of new legislative proposals. The increased cost of documenting drug efficacy and safety under present FDA regulations has progressively diminished the number of diseases that the pharmaceutical companies are willing to provide drugs for. The decision by a pharmaceutical company to develop a new drug is based on several economic and scientific factors, including the basic scientific discoveries that justify preliminary synthesis and testing of a new compound, the need for a drug in a particular disease, the scientific aptitude of the company's research staff and, of crucial importance, the anticipated potential market for the drug. Pharmaceutical companies must choose projects on the basis of the net profit that might reasonably be expected if the drug research is successful. A safe and efficacious drug may not be financially rewarding for several reasons: the time and expense of fulfilling the requirements of the FDA to obtain marketing rights — i.e., approval of a New Drug Application (NDA) — may be prohibitive; the costs of legal liability for clinical drug testing may be excessive; the number of potential patients who would benefit might be small, or the drug might be useful only in limited doses for unusual acute emergency situations; and the inability to patent a drug or the anticipated time for its development may be too long

tion arises as to what will happen to these patients should I retire from the scene or should a product license not be issued. Are they to be allowed to die of a readily treatable disease because no one is prepared to supply, or worse still is permitted to produce, the necessary medication?"[8]

How can the development of new drugs in nonprofitable diseases be encouraged without sacrifice of the medical profession's commitment to the demonstration of both safety and efficacy before approval for marketing? If one examines the position of the three parties involved, the obvious conclusions are that new legislation is needed.

NIH. Most of the resources of NIH are directed toward research-oriented projects that would generally exclude the manufacture and development of new drugs. During the past few years, coincident with increased funding, the National Cancer Institute has supported the costs of manufacture, demonstration of safety and effectivenss and supplying of new anticancer drugs that are not developed by industry because the type of cancer afflicts only a small number of people. Usually, toward the end of development, when many or all of the studies necessary to achieve marketing approval have been accomplished at NIH expense, the particular drug is made available to the highest bidder for marketing. Unfortunately, at present, only the National Cancer Institute has sufficient funds to perform this service.

Pharmaceutical companies. The pharmaceutical industry is a competitive business, and profits are essential for survival. One cannot expect the pharmaceutical companies to jeopardize their business or to be irresponsible to stockholders by spending large sums of money on unprofitable drugs. Before 1962 drugs of little commercial value were more frequently developed and marketed as public-service drugs because the financial costs were much less. The incentives were improvements of corporate and public image. The present cost of drug development has greatly reduced the appeal of these incentives.

FDA. The FDA is a regulatory agency and has no control over the types of drugs developed. There is no legislative mandate or financial resources to initiate, foster or shape the course of drug research.

Since private and governmental institutions are no longer responsive to the needs of all patients, federal legislation is needed to correct this situation. It is to be hoped that new FDA legislative proposals currently being considered in Congress will examine this problem. One of a number of legislative solutions could be enacted to make drug research and development more responsive to scientific advances in uncommon as well as common diseases.

For one thing, the federal government could subsidize appropriate pharmaceutical companies to develop drugs of limited commercial value. This support is analogous to the use of government contracts for research in the space field, drug abuse and cancer research.

Secondly, the National Cancer Institute has recently been able to develop anticancer drugs of limited commercial value. With adequate funding other NIH institutes could carry out a similar function in their areas of interest. However, it might be argued that NIH lacks the necessary experience and expertise required for the most efficient development of new drugs. The proposed New Drug Regulation Reform Act recently introduced by the Administration[9] provides for a National Center for Clinical Pharmacology, which would be empowered to carry out the development and testing of certain drugs. This proposal assumes that once developed and tested, nonprofitable drugs could be manufactured and marketed by private industry.

Thirdly, pharmaceutical companies developing drugs of limited commercial value could be given a tax advantage.

Fourthly, the patent laws might be changed to provide longer patent protection and exclusive licensing for drugs of limited commercial value. This type of incentive would probably be adequate for only a small fraction of these drugs.

Fifthly, a pool of resources could be organized and administered by the Pharmaceutical Manufacturers Association — analogous to the assigned risk pool of automobile insurance. All pharmaceutical companies would agree that important scientific advances with major therapeutic implications for the less common diseases should be developed for the public good, and the cost of this development could be equitably distributed amont the member pharmaceutical companies.

Sixthly, a national pharmaceutical company could be set up as part of NIH to consolidate the present governmental drug-development activities in cancer, vaccines and tropical-parasitic-disease drugs, as well as other drugs of limited commercial value.

Finally, an interagency organization consisting of representatives from the FDA and NIH could take on the responsibility of resolving the peculiar problems involved in the development of drugs of limited commercial value. Such an interagency organization could be a central source of information on drugs of limited commercial value, identify specific areas in which new drugs are needed and encourage research in these areas, encourage pharmaceutical companies to develop certain drugs by government contract or easing of clearance requirements for NDA approval, coordinate clinical trials, gather data on safety and effectiveness for submission of NDA and make available expensive drugs of limited use.

The pharmaceutical industry is well equipped to develop and market new medicines. However, legislative reforms are desperately needed to afford all patients the benefits of their expertise.

Note added in proof: Since this article was written, Cambrian Chemical, Ltd., Croydan, England, has started synthesizing triethylene tetramine.

Mount Sinai School
of Medicine
New York, NY 10029 MELVIN H. VAN WOERT, M.D.

[4110-08]

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Notice of Conference on the Role of the NIGMS/NIH in the Development of New Therapeutic Agents

Notice is hereby given of the Conference on the Role of the NIGMS/NIH in the Development of New Therapeutic Agents to be sponsored by the National Institute of General Medical Sciences on May 31 and June 1, 1978, National Institutes of Health, Billings Auditorium, National Library of Medicine, Bethesda, Md. at 9 a.m. The Conference will be opened to the public.

Substantive program information may be obtained from Dr. Anthony P. Zavadil III, Program Administrator, Pharmacology-Toxicology Program, National Institute of General Medical Sciences, Westwood Building, Room 919, Bethesda, Md. 20014, telephone 301-496-7707.

(Catalog of Federal Domestic Assistance Program 13-859, Pharmacology-Toxicology Program, National Institute of General Medical Sciences, National Institutes of Health.)

Dated: March 14, 1978.

SUZANNE L. FREMEAU,
Committee Management Officer, NIH.

[FR Doc. 78-7885 Filed 3-23-78; 8:45 am]

June 1, 1978

Experiences of Other Institutes with Development of Therapeutic Agents (Continued)

9:00 a.m.	Dr. George Galasso
9:30 a.m.	Dr. Clarice Reid
10:00 a.m.	Discussion
10:20 a.m.	Coffee

Collaboration Among the Pharmaceutical Industry, Federal Agencies, and Federally-Sponsored Programs in the Development of Therapeutic Agents

10:35 a.m.	Case histories of successful collaboration between government and industry - Dr. Maxwell Gordon
11:15 a.m.	Collaborative arrangements among government, industry, and universities that would foster drug development - Dr. John Burns
11:45 a.m.	Implications of the new drug law for drug development - Dr. Barry Bloom
12:15 p.m.	Discussion and Summary
1:00 p.m.	Adjourn

Dr. Thomas Gaffney
Professor and Chairman of Pharmacology
Medical University of South Carolina
80 Barre Street
Charleston, South Carolina 29401

Dr. George J. Galasso
Chief, Development and Applications Branch
Microbiology and Infectious Diseases Program
National Institute of Allergy and Infectious Diseases
Westwood Building, Room 750
Bethesda, Maryland 20014

Dr. Leon Goldberg
Professor and Chairman
Committee on Clinical Pharmacology
Department of Pharmacological and Physiological Sciences
University of Chicago
Chicago, Illinois 60637

Dr. Maxwell Gordon
Vice President
Research Planning and Licensing
Bristol Laboratories
Syracuse, New York 13201

Dr. Ruth L. Kirschstein
Director
National Institute of General Medical Sciences
Building 31, Room 4A-52
Bethesda, Maryland 20014

Dr. Daniel L. Knapp
Assistant Professor of Pharmacology
Medical University of South Carolina
80 Barre Street
Charleston, South Carolina 29401

Mr. Norman J. Latker
Patent Counsel of HEW
5333 Westbard Avenue
Westwood Building, Room 5A-03A
Bethesda, Maryland 20014

Dr. John A. Oates
Professor
Department of Pharmacology
School of Medicine
Vanderbilt University
Nashville, Tennessee 37232

SCIENTISTS DESCRIBE JOINT NIH-INDUSTRY DRUG DEVELOPMENT EFFORTS

Successful collaboration between government and private industry demands as much ingenuity as expertise, researcher told a National Institute of General Medical Science session last week. They emphasized that every agent is different, with delays and frustrations appearing at different stages.

Speaking at the two-day session on "Development of Therapeutic Agents Found with Government Support," Dr. Maxwell Gordon, Bristol Laboratories' vice president for research and planning, called the National Cancer Institute approach to development of one brain-tumor drug, CCNU, "novel." Traditionally, he said, the government publishes its findings, and anyone who wishes can pick them up. But NCI put this drug up for bid. Competing companies submitted plans for marketing, testing, etc., with the best plan winning. (The arrangement may have been "novel" for drug development, but is standard for many types of government contracts.)

The institute approved Bristol's plan in three months -- but it took the Food and Drug Administration several years to do so. "We ran into a new parameter with FDA," Dr. Gordon said. The oncology advisory committee demanded proof of superiority to existing therapies as well as the usual safety and efficacy. "They were breaking new ground here, being on the record as demanding superiority," he noted.

· Proof of superiority is seen as no problem for a testicular cancer drug which FDA's oncology advisors will consider this month, Dr. Gordon continued. The company foresees another problem: "spearhead approval." Gordon said the advisors may fear the drug will be used for other, unapproved uses, and delay introduction.

· Hoffmann-La Roche had a similar experience with a drug to treat rare photosensitivity in children. FDA worried that the agent might be used merely to prevent sunburn, and wanted extensive labeling and education. "I can sympathize," Hoffmann-La Roche vice president for research Dr. John Burns said. But approval took 480 days, and another 180 before final release.

· In one case, Dr. Burns described how an FDA official began the cooperative venture: The head of cardio-renal drugs was concerned that nitroprusside was being put together in hospitals without proper regard for stability and other problems. He contacted Hoffmann-La Roche. The company came up with a clinical study, filed an NDA for what is now Nitrile and the drug -- not patented -- is now available.

"We like that attitude," Dr. Burns said of the FDA initiation. "If they approach us on similar products we will be willing to work with them."

· Informal collaboration also exists with NIH. Hoffmann-La Roche is studying prophylactic treatment for persons possibly exposed to carcinogens, using retinoids it produces. Although there is no formal agreement, the company -- and other pharmaceutical firms -- are giving the Vitamin A derivative to NCI for its own tests.

· Dr. Burns described a classic joint venture: L-dopa development. NIH had set up a

NATIONAL SCIENCE FOUNDATION
OFFICE OF THE DIRECTOR
Washington, D.C. 20550

Notice No. 72 March 29, 1978

IMPORTANT NOTICE TO INDUSTRIAL FIRMS, UNIVERSITIES AND COLLEGES, AND OTHER NATIONAL SCIENCE FOUNDATION GRANTEE ORGANIZATIONS

SUBJECT: **Industry/University Cooperative Research Activity**

This Important Notice announces the intention of the Foundation to provide funding for the encouragement of cooperative research between industry and universities and colleges.

There has been a growing concern voiced by the Congress, the National Science Board, and the scientific and technological community about the need for more effective communication and cooperation between scientists in colleges and universities and scientists in industry. The universities produce knowledge and trained manpower, and the industrial sector translates knowledge into socially and economically useful developments. The ties between these two segments of the Nation's scientific and technological resources need to be strengthened.

As a direct response to this situation, the National Science Foundation plans to increase funding for the support and encouragement of cooperative research between universities and industrial firms. To qualify for support, proposals must be prepared jointly by academic and industrial researchers and must be submitted jointly by their respective institutions. The research should focus on fundamental scientific questions rather than on technological development. The Foundation will make awards to either academic or industrial organizations depending on which is the more appropriate for a particular cooperative research effort.

Proposals are to be submitted to NSF in accordance with instructions contained in the NSF published document "Grants for Scientific Research (NSF 76-38)." Proposals are to be identified on the cover page as candidates for the industry/university cooperative competition.

Eligibility and Proposal Preparation

Universities and colleges and established profit-making industrial firms including small businesses (or groups of such firms) are eligible for the competition. A major consideration will be the extent to which the cooperating entities represent bona fide independent operations as evidenced by the absence of interlocking relationships. A further consideration will be the extent to which the proposed research may be expected to make a long-term contribution toward product and/or process innovation.

Criteria for Grant Awards

Proposals will be judged first on scientific excellence, using NSF criteria and established peer review procedures. The potential of the research to enhance cooperation

NATIONAL SCIENCE FOUNDATION
WASHINGTON, D.C. 20550

April 6, 1978
PA/M (78-16)

MEMORANDUM TO SCIENCE WRITERS AND EDITORS

Subject: Midwest Small Business Conference to be Held May 22-23 in Chicago

A Midwest Small Business Conference will be held on May 22-23 at the O'Hare Marriott Hotel in Chicago to describe research opportunities and procedures in the National Science Foundation (NSF) for small businesses with strong capabilities in science or technology. Emphasis will be on the new Applied Science and Research Applications (ASRA) program.

The conference is being sponsored by NSF and will include representatives from most Federal agencies that have substantial Research and Development programs. Activities will focus on R&D programs at NSF and other participating agencies, but will not include other types of procurements. During the two-day period, opportunities will be provided for group and individual discussions with NSF staff and other agency representatives on research ideas and possible agency interest.

For R&D purposes, a small business is defined as an independently owned and operated firm with not more than 500 employees, including all affiliated companies.

Further information and registration procedures may be obtained from the Lakeshore Group, Ltd., 207 E. Buffalo Street, Milwaukee, Wisconsin 53202, (414) 272-5420.

R. Goulet

Richard Goulet
Public Information Branch

4:00 p.m. ASRA Group Program Area Meetings

5:00 p.m. Adjourn

7:30 p.m. - 10:00 p.m. Individual appointments with ASRA staff, Wirths, and Lasken

TUESDAY

8:30 a.m. Dr. Jack Sanderson, Opening Remarks

8:45 a.m. Keynote Address, "Small Business and Science and Technology, a Vital Alliance"
- Senator Gaylord Nelson, Chairman, Senate Select Committee on Small Business

9:30 a.m. Introductory Remarks on Federal R&D Agency Participation
- Mr. Milton D. Stewart, Special Assistant to the Administrator, Small Business Administration

9:40 a.m. Instructions on how the individual consultation process will work during the day.

9:45 a.m. Individual Consultantion with Federal Agency Representatives, also continuation of NSF Appointment Schedule

Noon Lunch

1:00 p.m. Luncheon Panel, "Small Science- or Technology-Based Firms and Venture Capital"
- Moderator: Mr. William H. Wetmore, Director, ASRA Intergovernmental Science and Public Technology Program

Outside panel -- Mr. Stanley Golder, President, National Association of SBIC's, Sr. Vice President, 1st National Bank of Chicago; Mr. David Morganthaler, President, National Association of Venture Capitalists; Mr. Herbert D. Doan, Chairman, Doan Resources Corp., Member, National Science Board

2:00 p.m. - 5:00 p.m. Individual Consultantions with Federal Government Agencies

NOTE: No invitations have yet been sent to any potential non-NSF participants. All invitations will be cleared by Jack Sanderson.

§ 650.3 Source of authority.

(a) Section 12(a) of the National Science Foundation Act of 1950, as amended (42 U.S.C. 1871(a)), provides as follows:

Each contract or other arrangement executed pursuant to this Act which relates to scientific research shall contain provisions governing the disposition of inventions produced thereunder in a manner calculated to protect the public interest and the equities of the individual or organization with which the contract or other arrangement is executed; Provided, however, That nothing in this Act shall construed to authorize the Foundation to enter into any contractual or other arrangement inconsistent with any provisions of law affecting the issuance or use of patents.

(b) Section 11(e) of the same Act provides as follows:

The Foundation shall have the authority, within the limits of available appropriations, to do all things necessary to carry out the provisions of this Act, including, but without being limited thereto, the authority * * *

(e) to acquire by purchase, lease, loan, gift, or condemnation, and to hold and dispose of by grant, sale, lease, or loan, real and personal property of all kinds necessary for, or resulting from, the exercise of authority granted by this Act.

The President's Policy provides guidance as to basic policies to be followed by executive agencies with respect to inventions or discoveries made in the course of their awards. The provisions set forth in this part are intended to implement the National Science Foundation Act in accordance with the basic guidelines and philosophy of the President's Policy.

§ 650.4 Procedures for selection of clauses in awards.

(a) The clause at paragraph (b) of this section shall be used in every award except (1) where § 650.5 of this part is applicable, or (2) where the award is for a fellowship or traineeship as provided in § 650.6 of this part, or (3) where the award falls within a class of awards as provided in § 650.7 of this part, or (4) where the award is subject to an Institutional Patent Agreement entered into pursuant to § 650.8 of this part.

(b) The following clause shall be included in Foundation awards in accordance with paragraph (a) of this section:

RIGHTS IN INVENTIONS

(a) Whenever any invention which is, or may be, patentable is conceived or first actually reduced to practice in the course of or under this _____,[1] the _____,[2] shall furnish the Foundation with complete information thereon; and the Foundation shall have the right to determine whether or not and where a patent application shall be filed, and to determine the disposition of the invention and title to and rights under any patent application or patent that may result. The Foundation, in making such a determination, shall take into account the public interest and equities of the grantee. In any case, the Foundation may arrange to have the invention described in a printed publication.

(b) The _____,[2] for itself and for its employees, agrees that all documents will be executed and all other actions taken necessary or proper to carry out the determination of the Foundation.

(c) Except as otherwise authorized in writing by the _____,[3] _____,[2] will insert in each subcontract having experimental, developmental, or research work as one of its purposes, provisions making this article applicable to the subcontractor and its employees and any lower-tier subcontractors and their employees.

[1] Insert "grant" or other applicable term as the case may be.

[2] Insert "grantee" or other applicable term as the case may be.

[3] Insert "Grants Officer" or other applicable term as the case may be.

§ 650.5 Requests for special provisions at time of award.

(a) At the request of the prospective grantee, special provisions other than the clause at § 650.4(b) of this part may be negotiated where the award falls within section 1(b) of the President's Policy or where exceptional circumstances, as set forth in section 1(a) of the President's Policy, exist. In accordance with section 1(c) of the President's Policy, such provisions may also be negotiated at the time of award with educational or other nonprofit institutions having a demonstrated capability for effective patent management.

(b) In negotiating such provisions the procedures, requirements, and limitations of, and the clauses prescribed at 41 CFR 25–9.103(c) shall be applicable.

§ 650.6 Fellowships and traineeships.

Each fellowship awarded by the Foundation shall include the provision below. This provision defines the rights of the Foundation and is not intended to preclude educational institutions from obtaining rights in accordance with their policies. A substantially similar provision shall be used in Traineeship awards.

(1) The institution has a formal patent policy which is administered on a continuous basis by an officer or organization responsible to the institution.

(2) The institution can give assurance that employees are legally obligated to assign to the institution any inventions made by them in the course of or under awards.

(3) The institution has an effective invention disclosure system.

(4) The institution has an active and effective promotional program for the licensing and marketing of inventions which is consistent with the objectives of the President's Policy.

(c) Institutional Patent Agreements will (1) reserve to the Government the rights specified in § 650.10 of this part; (2) require the institution or its patent management organization normally to license inventions on a nonexclusive basis and failing this to limit, unless otherwise approved by the Foundation, exclusive licenses granted under domestic patents to a period of three years from first commercial sale or eight years from the date of the inception of the license agreement, whichever occurs first; provided that, after the period specified above for the duration of exclusive licenses, additional licenses will be made available on a nonexclusive basis at no greater royalties; (3) limit the use of patent management organizations to those specified in the IPA or approved by the Foundation; (4) provide that the institution use any net royalty income retained by it for the support of education or scientific research; (5) provide that the Foundation may exempt specific awards and contracts from the application of the IPA; (6) include a provision similar to that set forth in § 650.9(c)(2); and (7) include such other terms and conditions as are considered necessary.

(d) Institutions desiring to enter into IPA's should contact the Office of General Counsel for additional information. The General Counsel has been given authority to negotiate IPA's on behalf of the Foundation subject to approval of an institution's qualifications for patent management by the NSF Patent Policy Review Committee and approval and execution by the Grants and Contracts Officer.

(e) Except as provided in § 650.10(f) of this part, the General Counsel, or his designee, is authorized to act on behalf of the Foundation in connection with decisions and actions which may be required under Institutional Patent Agreements (such as the granting of time extensions, required approvals, or other administrative actions).

(f) In accordance with applicable criteria and guidelines established by the Director and/or individual Assistant Directors, NSF Program Managers or other Foundation personnel shall identify and refer to the NSF Patent Policy Review Committee any potential awards to institutions holding IPA's which might be considered for exclusion from the coverage of the IPA.

[39 FR 41982, Dec. 4, 1974, as amended at 40 FR 34598, Aug. 18, 1975]

§ 650.9 Greater rights determination after disclosure.

(a)(1) Grantees desiring to retain rights in inventions made under or during the course of awards containing provisions that condition the retention of principal rights in such inventions by the grantee on the determination of the Foundation, such as those prescribed at § 650.4(b) of this part, should address their request to the General Counsel who has been delegated authority to make such determinations. In all such cases the General Counsel shall seek the recommendations and advice of the Patent Policy Review Committee.

(2) Such requests should contain the following information:

(i) The award number, and subcontract number, if applicable, under which the invention was made;

(ii) A complete invention disclosure or reference to one that has previously been furnished, including any NSF identifying numbers, if known;

(iii) A description of the relationship of the invention to the main purpose of the award;

(iv) The grantee's evaluation of the commercial possibilities of the invention both in its original embodiment and in possible adaptions to other uses;

(v) An explanation of why it is believed that rights greater than free public use are needed to bring the invention into use;

(vi) The nature and extent of the rights desired;

(vii) A description of the stage of development of the invention, and an estimate of the cost of development, capital and time required to bring the invention to the point of practical application as defined in the President's Policy;

application filed on the invention within 6 months from the date of the determination, or such longer period as may be authorized by the Foundation for good cause shown by the grantee. Each determination will also include appropriate provisions concerning foreign rights. The determination may also include such other provisions as are considered appropriate.

(4) Whenever the clause at § 650.4(b) has been used or an Institutional Patent Agreement is applicable and the grantee does not wish to retain principal rights and neither the Foundation nor any other Government agency notified of the invention by the Foundation wishes to take principal rights in the invention, it shall normally be dedicated to the public through publication. However, principal rights may be left in the inventor(s) if he (they) so request upon demonstration of an intention to exploit the invention and a description satisfactory to the Foundation of the means by which this is to be accomplished. All such requests will be made and processed in accordance with the procedures set forth in this section and determinations thereon shall contain the requirements of paragraphs (c) (1) and (3) of this section.

[39 FR 41982, Dec. 4, 1974, as amended at 40 FR 34598, Aug. 18, 1975]

§ 650.10 Minimum government rights.

In all cases where the grantee or any other person or entity has been allowed to retain or obtain principal rights in an invention or possible future inventions, whether at the time of award or after an invention has been identified, the Foundation shall reserve the following minimum rights, if not otherwise required by or inconsistent with any other provision of this part.

(a) A nonexclusive, nontransferable, paid-up license to make, use, and sell the invention throughout the world by or on behalf of the Government of the United States (including any Government agency) and States and domestic municipal governments, unless the Director determines that it would not be in the public interest to acquire the license for the States and domestic municipal governments.

(b) The right to sublicense any foreign government pursuant to any existing or future treaty or agreement, but only if the Director determines it would be in the national interest to acquire this right.

(c) The principal or exclusive rights to the invention (or the right to acquire the same) in any country in which the grantee does not elect to secure a patent.

(d) The right to require written reports at reasonable intervals on the commercial use that is being made or is intended to be made of the invention.

(e) The right to require the inclusion of the following appropriately completed statement in the second paragraph of the specification of any patent application or patent: "The Government has rights in this invention pursuant to Grant (or other award designation) No. _____ awarded by the National Science Foundation."

(f) The right to require the granting of a nonexclusive or exclusive license to a responsible applicant on terms that are reasonable under the circumstances (1) unless it is determined that effective steps have been taken within three years after a patent issues on the invention to bring the invention to the point of practical application, or that the invention has been made available for licensing royalty-free or on terms that are reasonable under the circumstances or unless cause can be shown why the Foundation should not exercise this right for some further period of time; (2) to the extent the invention is determined to be necessary to fulfill health or safety needs; or (3) to the extent the invention is determined to be needed for other public purposes stipulated in the award. Determinations and other actions taken pursuant to this paragraph (f) shall be by the Director or by such person(s) as he may designate.

(g) The right to approve any license covering the invention proposed to be granted to any of the following persons or organizations:

(1) Any person who participated as an employee of the grantee in the research leading to the conception and/or actual reduction to practice of the invention;

(2) An organization of which a person described in subsection (g)(1) of this section was an active promoter or organizer or in which such a person is an officer, director, or holds a substantial interest;

(3) An organization of which the grantee was an active promoter, organizer, or financer.

Approval of such a license shall be given only if the grantee can show that a bona fide effort was made without success to interest other organizations, known to

CHAPTER VI—NATIONAL SCIENCE FOUNDATION

PART 650—PATENTS

Disposition of Rights in Inventions

Effective immediately, Chapter VI, Part 650 of Title 45 of the Code of Federal Regulations is amended as stated below. This amendment is identical to the proposed amendment published in the FEDERAL REGISTER on March 21, 1975 (40 FR 12819). Only one comment was received and has been duly considered. This amendment provides for certain limitations on the use of Foundation funds for further development of inventions made in the course of or under Foundation awards in cases where the inventing organization has been allowed to retain principal rights in such inventions.

Chapter VI, Part 650 of Title 45 of the Code of Federal Regulations is amended as follows:

1. § 650.8(c) is amended by adding the following new subparagraph (6) after subparagraph (5) and renumbering the present subparagraph (6) as subparagraph (7): "(6) include a provision similar to that set forth in § 650.9(c)(2); and".

2. Paragraphs (2) and (3) of § 650.9(c) are renumbered "(3)" and "(4)" respectively. A new paragraph (2) is added as follows:

(2) The willingness of a grantee to assume the costs and risks associated with the bringing of an invention to the point of practical application is a significant factor influencing most determinations that the grantee should be allowed to retain principal rights in an invention made under the award. Consequently, a provision limiting the use of Foundation funds for further development of such inventions will normally be included as a condition of each such determination. For this purpose, a provision such as the following shall be used:

(a) Unless specifically approved by the Grants and Contracts Officer, the grantee shall not use funds provided by the Foundation for performing development, engineering, or design work directed toward a commercial embodiment of the invention.

(b) Subsection (a) shall not apply to efforts made to improve the invention for the primary purpose of enhancing its utility in connection with scientific research conducted by the grantee. Further to the extent that the work statement in the award or proposal upon which the award was based clearly specifies a line of research to be pursued, subsection (a) shall not apply to the pursuance of such research.

3. In the last paragraph of § 650.9(c)(4) (previously § 650.9(c)(3)) delete "(2)" and substitute "(3)" therefor.

Dated: August 8, 1975.

H. GUYFORD STEVER,
Director.

[FR Doc.75-21650 Filed 8-15-75;8:45 am]

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[6820-24]

Title 41—Public Contracts and Property Management

CHAPTER 1—FEDERAL PROCUREMENT REGULATIONS

[FPR Amdt. 187]

PART 1-9—PATENTS, DATA, AND COPYRIGHTS

Patents

AGENCY: General Services Administration.

ACTION: Final rule.

SUMMARY: The Federal Procurement Regulations (FPR) are amended to provide for the use of Institutional Patent Agreements in contracts with universities and nonprofit organizations. The Committee on Intellectual Property and Information, Federal Coording Council for Science, Engineering, and Technology, recommended that universities and nonprofit organizations with satisfactory technology transfer programs be granted rights to inventions made under contracts with Federal agencies. Institutional Patent Agreements permit those institutions to retain the rights to inventions and related patents that result from such contracts.

EFFECTIVE DATE: March 20, 1978, but may be observed earlier.

FOR FURTHER INFORMATION CONTACT:

Philip G. Read, Director of Federal Procurement Regulations, 703-557-8947.

SUPPLEMENTARY INFORMATION: This amendment prescribes changes in §§ 1-9.107-4, 1-9.107-6, and 1-9.109-7 of the FPR.

The table of contents for subpart 1-9.1, Patents, is amended to change an item and add an item as follows:

Sec.

1-9.107-6 Clauses for domestic contracts (short form) and Institutional Patent Agreements.

1-9.109-7 Negotiation of Institutional Patent Agreements.

Subpart 1-9.1—Patents

Section 1-9.107-4 is amended to add paragraph (a)(8) as follows:

§ 1-9.107-4 Procedures.

(a) * * *

(8) In accordance with the language regarding exceptional circumstances in § 1-9.107-3(a) and/or the language regarding special situations in § 1-9.107-3(c), agencies may enter into Institutional Patent Agreements (see § 1-9.107-6(c)) with universities and nonprofit organizations having technology transfer programs meeting the criteria of § 1-9.109-7(b). The agreements permit those institutions, subject to certain conditions, to retain the entire right, title, and interest in inventions made in the course of their contracts. When such an agreement has been made with a university or nonprofit organization, it shall be made applicable to each contract with the institution in lieu of the Patent Rights clauses in § 1-9.107-5 and § 1-9.107-6, unless a determination has been made to exclude the contract from the agreement.

* * * * *

Section 1-9.107-6 is amended to change the title and add a new paragraph (c) as follows:

§ 1-9.107-6 Clauses for domestic contracts (short form) and Institutional Patent Agreements.

* * * * *

(c) *Patent Rights—Institutional Patent Agreement.* (1) When an agency has determined in accordance with § 1-9.109-7 that a university or a nonprofit organization should receive an agreement as authorized by § 1-9.107-4(a)(6), an agreement substantially as set forth in paragraph (c)(2) of this § 1-9.107-6 shall be used. The agreement shall be appropriately completed as indicated in the numbered notes appearing at the end of the agreement. Changes may be made in the agreement but shall be limited to changes required by applicable statutes or by special administrative needs. However, agencies shall endeavor to insure that agreements continue to include at least the following features:

(i) A requirement for the prompt reporting of all inventions to the applicable agency along with an election of rights;

(ii) Reservation of all rights specified in § 1-9.107-3 (e) through (h);

(iii) A requirement that the institution make such inventions available on a nonexclusive basis except where the desired practical or commercial application has not been achieved or is not likely to be expeditiously achieved through licensing;

(iv) A condition limiting any exclusive license to a period not substantially greater than necessary to provide the incentive for bringing the invention to the point of practical or commercial application and to permit the licensee to recoup its costs and a reasonable profit thereon;

(v) A restriction that royalty charges be limited to what is reasonable under the circumstances or reasonable within the industry involved;

(vi) A requirement that the institution's royalty receipts, after payment of administrative costs and payments to inventors, be utilized for educational or research purposes;

(vii) A provision permitting the agency to exclude individual contracts from the operation of the agreement;

(viii) A requirement for progress reports after designated periods;

(ix) A prohibition against assignment of inventions without Government approval to persons or organizations, other than assignments to approved patent management organizations subject to all the conditions of this paragraph (c)(1); and

(x) A provision permitting the agreement to be terminated by either party upon 30 days written notice.

(2) The Institutional Patent Agreement prescribed for use is as follows:

INSTITUTIONAL PATENT AGREEMENT

This Agreement is made and entered into by and between the United States of America as represented by the ———— (1), hereinafter referred to as the "Agency," and ———— hereinafter referred to as the "Institution."

Whereas, in accordance with the President's Memorandum and Statement of Government Patent Policy dated August 23, 1971, and the provisions of 41 CFR 1-9.107-4(a)(6), it has been determined that the Institution has a technology transfer program meeting the criteria of 41 CFR 1-9.109-7 in that the Institution's patent policy as set forth in ———— (2), and its technology transfer practices have been reviewed and found acceptable; and

Whereas, the Institution is desirous of entering into an agreement whereby it may retain the entire right, title, and interest in and administer inventions made in the course of or under research supported by the Agency, subject to certain rights acquired by the Government:

Now, therefore, in consideration of the foregoing, the parties hereto agree as follows:

be interested in the subject matter of the invention, in becoming licensees, or can otherwise show why the public interest will best be served by the proposed licensing arrangement. Notwithstanding anything above, this paragraph (g) shall not apply in the case of an award to a for-profit grantee.

§ 650.11 Availability of inventions to the public.

(a) A major objective of the Foundation is to encourage the use of inventions arising out of activities supported by the Foundation. It is important that any useful product or process developed or improved under an award is made available to the public on reasonable terms. In some cases, to ensure such availability it may be necessary, either at the time of award or in connection with the determination under § 650.9 to require the grantee to furnish to responsible applicants technical data or rights in other inventions to the extent necessary to practice the invention made or product or process developed or improved under the award.

(b) Program managers or other Foundation personnel shall refer cases involving preexisting proprietary technology (such as "proprietary data," "trade secrets," patents, or patent applications) to the General Counsel or the Patent Policy Review Committee in accordance with applicable Staff Memoranda.

§ 650.12 Delegations.

The General Counsel is authorized to make any determinations required by these regulations to be made by the Director, including determinations required by the President's Policy to be made by the head of the agency, except those specified in § 650.10(f).

PART 660—PROJECT NOTIFICATION AND REVIEW SYSTEM; NOTIFICATION TO STATES OF AWARD INFORMATION

(viii) A statement of the grantee's plans and intentions to bring the invention to the point of practical application including:

(A) If further development is to be conducted by the grantee, a description of the facilities, source of funds, personnel, and marketing outlets available for the purpose and the extent to which such development is to be undertaken by the grantee or others on his behalf and/or

(B) If he intends to license the invention, a brief description of his licensing program;

(ix) A statement of any equities in the invention which the grantee believes it has in the invention which would be appropriate for consideration by the Foundation, with particular emphasis on direct contributions to the cost of making the invention as opposed to general factors such as the provision of facilities or experience in research;

(x) If other Government agencies have contributed to the cost of making the invention, the identification of such agencies and the grant or contract involved, and the approximate share of each;

(xi) A listing of other countries in which the grantee would be interested in filing applications for patents;

(xii) If publication of the substance of this invention has occurred or is planned or there has been a use or sale such as might possibly create a future statutory bar to the patenting of the invention, the name of the journal, the date or probable date of publication, a reprint of the article if it has been published or a copy of the draft as submitted for publication, and/or details regarding the use or sale of the invention;

(xiii) An identification and indication of the ownership of any patents, patent applications, or invention disclosures known to the grantee which would affect the practice of the invention.

(b) Determinations under this section shall be made on the basis of the guidelines set forth in the President's Policy and this part. In addition, the relationship of the invention to other technology controlled by the grantee shall be considered as discussed in § 650.11 of this part.

(c) (1) In cases where principal rights in an invention are left with a grantee which, itself, is not expected to further develop the invention, the Foundation requires the grantee to make reasonable attempts to license inventions on a nonexclusive basis; provided that an exclusive license may be granted if the grantee determines that an exclusive license is necessary as an incentive for development of the invention or because market conditions are such as to require licensing on an exclusive basis in order to bring the invention into use. This determination shall be in writing and supplied to the Foundation at or before the time an exclusive license is granted. Any such exclusive license granted under a domestic patent or patent application will normally be limited to a period of three years from first commercial sale or eight years from the inception of the license agreement, whichever occurs first. Thereafter, unless the original exclusive license period is extended with the approval of the Foundation, additional licenses will be made available on a nonexclusive basis at a royalty not greater than that charged to the exclusive licensee.

(2) The willingness of a grantee to assume the costs and risks associated with the bringing of an invention to the point of practical application is a significant factor influencing most determinations that the grantee should be allowed to retain principal rights in an invention made under the award. Consequently, a provision limiting the use of Foundation funds for further development of such inventions will normally be included as a condition of each such determination. For this purpose, a provision such as the following shall be used:

(a) Unless specifically approved by the Grants and Contracts Officer, the grantee shall not use funds provided by the Foundation for performing development, engineering, or design work directed toward a commercial embodiment of the invention.

(b) Subsection (a) shall not apply to efforts made to improve the invention for the primary purpose of enhancing its utility in connection with scientific research conducted by the grantee. Further to the extent that the work statement in the award or proposal upon which the award was based clearly specifies a line of research to be pursued, subsection (a) shall not apply to the pursuance of such research.

(3) In addition to the requirements of paragraph (c) (1) of this section, any determination under this section shall reserve to the Government the rights set forth in § 650.10 of this part. In addition, if it has not already done so, the grantee will be required to have a domestic patent

RIGHTS IN INVENTIONS

(a) Whenever any invention which is, or may be, patentable is conceived or first actually reduced to practice in the course of the fellowship, and a patent application is filed thereon, the Fellow shall furnish the Foundation with complete information thereon and a copy of the patent application with date of filing and serial number.

Title to and rights in any such invention shall remain in the Fellow; provided, however, that the Fellow hereby grants (and agrees to execute upon request a confirmatory license) a nonexclusive, nontransferable, paid-up license to make, use, and sell the invention throughout the world by or on behalf of the Government of the United States (including any Government agency) and States and domestic municipal governments, unless the Director determines that it would not be in the public interest to acquire the license for State and domestic municipal governments. The Fellow further agrees that unless the Fellow, his licensee or his assignee, has taken effective steps within three years after a patent issues on any such invention to bring the invention to the point of practical application or has made the invention available for licensing royalty-free or on terms that are reasonable under the circumstances, or can show cause why he should retain the principal or exclusive rights for a further period of time, the Government, acting through the Director of the National Science Foundation or his delegee(s), shall have the right to require the granting of a nonexclusive or exclusive license to a responsible applicant(s) on terms that are reasonable under the circumstances. It is also agreed that the Government, acting through the Director of the National Science Foundation or his delegee(s), shall have the right to require the granting of a nonexclusive or exclusive license to a responsible applicant(s) on terms that are reasonable under the circumstances (i) to the extent that the invention is determined to be required for public use by governmental regulations or (ii) is determined to be necessary to fulfill health or safety needs.

(b) As used herein the term "to the point of practical application" means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine and under such conditions to establish that the invention is being worked and that its benefits are reasonably accessible to the public.

(c) As requested by the Foundation, the Fellow shall make periodic written reports on the commercial use that is being made or is intended to be made of any such inventions.

(d) The Fellow agrees that the following statement will be included in the second paragraph of the specification of the patent application and any resulting patent:

"The Government has rights in this invention pursuant to a fellowship awarded by the National Science Foundation."

(e) Nothing herein shall affect or limit the rights that the Government may have in any invention pursuant to the terms of any other award to any other party.

§ 650.7 Special classes of awards.

With the approval of the General Counsel, alterations to the clause prescribed at § 650.4(b) may be used allowing or guaranteeing the grantee's retention of specific rights in special classes of awards where the amount of support is small and where all or a part of the work will take place at profit-making organizations, for example, an "Option B" type Engineering Research Initiation Grant or a Faculty Research Participation Grant.

§ 650.8 Institutional Patent Agreements.

(a) The Foundation has determined that the public interest in the availability of inventions will normally best be served by allowing educational and other nonprofit institutions having a technology transfer program meeting the criteria set forth in paragraph (b) of this section the right to a first option to ownership in inventions made in the course of or under awards (other than fellowships or traineeships) and contracts, subject to the limitations described in paragraph (c) of this section. This right will be embodied in an Institutional Patent Agreement (hereinafter sometimes referred to as an "IPA"), which will generally apply to all awards made to and contracts made with the institution, other than contracts to operate a National Research Center or similar facility. The purpose of IPA's is to reduce unnecessary administrative burdens when institutions have effective means and active programs for exploiting inventions in the public interest. The Foundation reserves the right to and may deny a request for an IPA or terminate an existing IPA with an otherwise qualified institution in cases where the institution's record of invention disclosures to the Foundation, the level of Foundation support to the institution, or other factors appear to minimize the advantages of issuing or continuing an IPA in comparison with the administrative burdens which would otherwise exist.

(b) Among the criteria which will be considered in determining whether an institution has a satisfactory technology transfer program are the following:

PART 650—PATENTS

Sec.
650.1 Scope of part.
650.2 Definitions.
650.3 Source of authority.
650.4 Procedures for selection of clauses in awards.
650.5 Requests for special provisions at time of award.
650.6 Fellowships and traineeships.
650.7 Special classes of awards.
650.8 Institutional patent agreements.
650.9 Greater rights determinations after disclosure.
650.10 Minimum government rights.
650.11 Availability of inventions to the public.
650.12 Delegations.

AUTHORITY: Secs. 11(e) and 12(a) of the National Science Foundation Act, as amended (42 USC 1870(e) and 1871(a)).

SOURCE: 39 FR 41982, Dec. 4, 1974, unless otherwise noted.

§ 650.1 Scope of part.

This part sets forth polices, procedures, and clauses with respect to rights in inventions made in the course of or under grants, fellowships, and other arrangements (other than contracts subject to Title III of the Federal Property and Administrative Services Act of 1949, as amended) entered into by the National Science Foundation. Policies, procedures, and clauses with respect to rights in inventions made under contracts subject to the Federal Property and Administrative Services Act are set forth in 41 CFR 25–9.

§ 650.2 Definitions.

As used in this part—

(a) The term "award" includes grants, and other arrangements (other than contracts subject to Title III of Federal Property and Administrative Services Act of 1949, as amended) entered into by the Foundation which are made for the purpose of supporting experimental, developmental, or research work or which contain a significant element of such activity. Examples of such awards include scientific research project grants, student originated studies, and cooperative agreements for the support of research. For the purpose of this part, the term "award" does not include grants, or other arrangements which do not require substantial experimental, developmental or research work such as facilities and equipment grants, institutional formula grants, grants for the conduct of summer institutes, and travel and conference grants. The term "award" also includes fellowships and traineeships;

(b) the term "Director" means the Director of the Foundation;

(c) the term "Foundation" means the National Science Foundation;

(d) the term "grantee" means the recipient of an award, and may, as the context requires, include subcontractors of a grantee at any tier;

(e) the term "invention" includes any art, method, process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the Patent Laws of the United States of America or any foreign country;

(f) the term "to the point of practical application" means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine and under such conditions as to establish that the invention is being worked and that its benefits are reasonably accessible to the public;

(g) the term "President's Policy" means the President's Statement of Government Patent Policy issued August 23, 1971 (36 FR 16887, August 26, 1971); and

(h) the term "Patent Policy Review Committee" refers to a committee made up of Foundation personnel and established by the Director to administer certain aspects of Foundation patent policy.

MIDWEST SMALL BUSINESS CONFERENCE

PROPOSED
AGENDA

MONDAY, May 22, 1978

O'Hare Marriott — Chicago, Illinois

Chairman: Dr. Jack Sanderson
Assistant Director for Applied Science and Research Applications (ASRA)
National Science Foundation

8:00 a.m. Registration

9:00 a.m. Keynote Address, "Innovation, Small-Scale Science, and National Priorities"
- Senator Adlai E. Stevenson, III

9:45 a.m. Overview of ASRA Program
- Dr. Jack Sanderson

10:15 a.m. Coffee Break

10:30 a.m. Panel -- ASRA Program Opportunities
- Dr. Jack Sanderson, Chairman
- Dr. Charles Thiel, Division Director, Problem-Focused Research Applications
- Dr. Vaughn Blankenship, Division Director, Applied Research
- Mr. Robert Lauer, Director, Industrial Program

These panel presentations should consist of 20-minute statements by participants followed by questions and answers.

12:15 p.m. Lunch

1:00 p.m. Luncheon Panel, "Small Business and National Science Policy"
- The Honorable Vernon Weaver, SBA Administrator
- The Honorable Tom Harkin, U.S. House of Representatives

- Dr. Russell O'Neal, National Science Board Member

3:00 p.m. NSF/ASRA -- Policy and Procedures Panel
Moderator: Mr. Richard Green, Director of Operations, ASRA
Mr. Roland Tibbetts, ASRA Proposal Process
Mr. Theodore Wirths, Other NSF Activity
Mr. Jesse Lasken, Patents and Proprietary Information

between academic and industrial organizations will be a factor in the award decision. In general, active participation by both academic and industrial researchers will be required.

Some cost sharing by academic and industrial organizations participating in the program is desirable. Cost-sharing may involve funds, laboratory space, and/or personnel services.

Inquiries

Inquiries concerning support for cooperative research efforts may be directed to the following NSF directorates and officers as most appropriate:

Dr. Ronald E. Kagarise
Deputy Assistant Director
Mathematical and Physical Sciences
and Engineering (202/632-4240)

Dr. James H. Brown
Deputy Assistant Director
Biological, Behavioral, and Social
Sciences (202/634-1553)

Mr. Richard Green
Director of Operations
Applied Science and Research Applications
(202/632-7426)

Mr. Daniel Hunt
Deputy Assistant Director
Astronomical, Atmospheric, Earth,
and Ocean Sciences
(202/632-4166)

Publication and Patent Policy

Timely publication of research results will be required. Patent rights will be governed by the usual NSF policy as expressed in Section 650 of Title 45 of the Code of Federal Regulations.

Richard C. Atkinson

Richard C. Atkinson
Director

large-scale program of clinical trials that "never got off the ground." Hoffmann-La Roche took over the work. A major problem was supply of this therapeutic agent -- a laboratory curiosity, as Burns described it. A crash program to produce it was instigated successfully. This, Dr. Burns said, shows the importance of production capability -- which industry has, and NIH does not.

FDA "acted most responsibly," he continued. The company submitted data as for an NDA -- in pieces, as it was developed, and the drug was approved "in rapid fashion." The whole process, Burns concluded, required the cooperation of FDA, NIH, the 20 centers which did the clinical trials, and Hoffmann-La Roche.

· Sometimes foreign governments and companies must also join in. One Latvian-synthesized drug required three years of negotiations, during which two Russian agencies argued over jurisdiction. A "road show" of experts went to Britain to obtain approval of NIH-industry plan for another cancer drug developed from a multinational corporation's analog.

Not all the stories were successes: Dr. Clarice Reid, who heads NIH's sickle cell disease program, said Becton-Dickinson had offered to supply certain equipment for her work. The company wanted no compensation -- but stipulated that the government must assume liability. With the specter of swine flu insurance still visible, the general counsel refused the offer. "Still, it shows an effort on the part of companies (to help)," Dr. Reid said.

· Arrangements are becoming more complicated, Dr. Gordon noted. He is also concerned about patents of collaboratively-developed drugs. Traditionally, the company has patent rights. But he was "disturbed recently when NCI asked if the company would develop a drug without these rights...If this is the future of NCI, it indicates a rocky (relationship) until it is resolved," Dr. Gordon warned. "I'm rather pessimistic about our...relationship. The market is becoming large enough so that industry can sponsor basic research itself. Industry is paying more and more of these joint drug development costs anyway...(it) is increasingly being shifted to the private sector."

Besides, he said, the institute will have a problem meeting the rising cost of drug development. "If it can shift the burden to industry, NCI can use its funds elsewhere."

· Although Dr. Burns said he was "optimistic," he had doubts too: Comparing 1978 to 1955, he said, "It takes longer now to do the studies. It takes longer to even get authority... There's a feeling of suspicion, 'some group is getting something out of this.' GLPs (good laboratory practices) are becoming extremely difficult: having someone constantly looking over your shoulder is disturbing, expensive, and duplicative...I'm even more concerned about the clinical side. Clinical pharmacologists and clinical investigators will have FDA and drug company monitors looking at their work as never before."

But obviously, Dr. Burns is not ready to give up collaboration yet. "I've just asked Dr. Clarice Reid to come to Nutley," he told the meeting. "We have been interested in sickle cell disease, but have not known how to go about getting into the work. Perhaps a collaborative effort can be worked out."

Dr. Clarice Reid
Chief
Sickle Cell Disease Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Building 31, Room 4A19
Bethesda, Maryland 20014

Dr. Saul A. Schepartz
Deputy Director
Division of Cancer Treatment
National Cancer Institute
Building 31, Room 3A-51
Bethesda, Maryland

Mr. Lawrence D. Smith
Pharmacist Director
Neurological Disorders Program
National Institute of Neurological
and Communicative Disorders and Stroke
Federal Building, Room 114
Bethesda, Maryland 20014

Dr. Robert Temple
Director
Division of Cardio-Renal Drug Products
Bureau of Drugs
Food and Drug Administration
Parklawn Building, Room 13B39
Rockville, Maryland 20852

PARTICIPANTS
DEVELOPMENT OF THERAPEUTIC AGENTS FOUND WITH GOVERNMENT SERVICES

Dr. Arthur J. Atkinson, Jr.
Professor
Department of Pharmacology
School of Medicine
Northwestern University
Chicago, Illinois 60611

Dr. Daniel Azarnoff
Director
Clinical Pharmacology-Toxicology Center
University of Kansas Medical Center
39th and Rainbow Streets
Kansas City, Kansas 66103

Dr. Barry Bloom
President
Pfizer Central Research
Pfizer Inc.
Eastern Point Road
Groton, Connecticut 06340

Mr. Howard Bremer
Patent Counsel
Wisconsin Alumni Research Foundation
P.O. Box 7365
Madison, Wisconsin 53707

Dr. George Brewer
Professor
Department of Human Genetics
University of Michigan Medical School
1137 East Catherine Street
Ann Arbor, Michigan 48104

Dr. Burnell Brown
Professor and Head
Department of Anesthesiology
University of Arizona
College of Medicine
Tucson, Arizona 85724

Dr. John Burns
Vice President for Research
Hoffmann-LaRoche Inc.
340 Kings Land Road
Nutley, New Jersey 07110

DEVELOPMENT OF THERAPEUTIC AGENTS FOUND WITH GOVERNMENT SUPPORT

Billings Auditorium, National Library of Medicine
May 31 - June 1

May 31, 1978

9:00 a.m.	Welcome - Dr. Ruth Kirschstein
9:15 - 10:15 a.m.	Introduction - Dr. Daniel Azarnoff, Chairman Discussants - Dr. John Oates Dr. Arthur Atkinson Dr. George Brewer Dr. Leon Goldberg ~~Dr. Burnell Brown~~ Dr. Dan Knapp A round table discussion of the obstacles to development of therapeutic agents discovered with support from the NIH.
10:30 a.m.	Coffee
10:45 a.m.	Continuation of round table discussion
11:30 a.m.	Regulatory requirements for the stages of drug development - Dr. Robert Temple
12:00 noon	Discussion
12:30 p.m.	Lunch
	Patent Issues Related to Drug Development
1:30 p.m.	NIH/HEW policy with respect to patentable discoveries made with its support - Mr. Norman Latker
2:30 p.m.	Effect of university policy on development of patentable discoveries - Mr. Howard Bremer
3:30 p.m.	Discussion
	Experiences of Other Institutes with Development of Therapeutic Agents
4:00 p.m.	Dr. Saul Schepartz
4:30 p.m.	Mr. Lawrence Smith
5:00 p.m.	Adjourn

References

1. Report of the Commission for the Control of Huntington's Disease and the Consequences: Report to Congressional committee, October 17, 1977. Available from NINCDS, Bethesda, MD 20014
2. Drug companies accused of lagging in research to curb rare diseases. New York Times, October 18, 1977, p 34
3. Trout ME: Drug licensing: the case for royalties on off-patent drugs. Hospital Formulary 12:342-347, 1977
4. Van Woert MH, Rosenbaum D, Howieson J, et al: Long-term therapy of myoclonus and other neurologic disorders with L-5-hydroxytryptophan and carbidopa. N Engl J Med 296:70-75, 1977
5. Walshe JM: Wilson's disease: new oral therapy. Lancet 1:25-26, 1956
6. Lewis R: Doctor accuses 3 firms in lack of life-saving drugs. Chicago Sun Times, April 16, 1960, p 1
7. Walshe JM: Management of penicillamine nephropathy in Wilson's disease: a new chelating agent. Lancet 2:1401-1402, 1969
8. Walshe JM: Drugs for rare diseases. Br Med J 3:701-702, 1975
9. Kennedy D: Creative tension: FDA and medicine. N Engl J Med 298:846-850, 1978

to permit a sufficiently profitable return before the patent expires. The cost of the first two factors mentioned has increased excessively during the past 15 years. At present the development of a drug from initial discovery of a scientific lead to the time of product marketing takes an average of seven to 10 years and an investment of $12 to 15 million. In this economic climate, advances in basic scientific knowledge that could be translated into successful new therapy of diseases are carefully sorted and evaluated by pharmaceutical manufacturers for cost of research and development versus size of market and profit. Only ventures deemed potentially lucrative can be accepted as appropriate projects for a pharmaceutical company's research division. Potential research projects involving drugs for uncommon or nonprofitable diseases are discarded. As the cost of meeting FDA marketing requirements increases, the scope of research interests of the pharmaceutical industry diminishes. This point has recently been well documented by the Commission to Combat Huntington's Disease and Its Consequences in its testimony presented before a Senate appropriations subcommittee. The Commission concluded that the drug companies do not believe there is sufficient profit in finding cures or producing medicines to combat relatively rare diseases and therefore do little research on these diseases.[1] This point of view was confirmed by Jim Russo, spokesman for the Pharmaceutical Manufacturers Association.[2]

A closely related problem is the manufacture of drugs of limited commercial value, also known as service drugs. Such a drug has usually been shown to be efficacious and safe in preliminary clinical investigations, but is considered not to be sufficiently profitable by pharmaceutical companies to market because anticipated sales volume is too limited to compensate for the costs of obtaining FDA approval, producing and marketing or because the drug is not patentable. The progressively increasing FDA regulations, which require extensive and expensive toxicity, teratogenicity and carcinogenicity studies in addition to multiple clinical trials, have increased the number of drugs that fall into this category. As stated by Dr. M. E. Trout, vice-president and director of medical affairs, Sterling Drug, Incorporated, New York City, "...it is no secret that such products [service drugs] are not being developed any more because of the tremendous expense of both basic and clinical research."[3]

A case in point is the use of the investigational drug combination L-5-hydroxytryptophan (L-5HTP) and carbidopa in the treatment of certain rare types of a neurologic symptom known as myoclonus. Myoclonus consists of uncontrollable jerky muscle movements at unpredictable times because of various types of brain damage. This drug combination has been safely and successfully used by several investigators to treat patients with myoclonus for over four years, and further development of this therapy is needed to make it available to all patients who might potentially benefit from it. In a recent study of 18 patients with intention myoclonus, 11 derived 50 per cent or greater improvement from L-5HTP and carbidopa therapy.[4] In some patients the response has been dramatic, enabling them to walk and take care of themselves for the first time since the onset of their illness. Because L-5HTP is not patentable and is considered a drug of little commercial value, there are no existing mechanisms either to continue treating patients who are benefiting from it or to initiate national clinical trials to evaluate further its overall efficacy and safety. The problem is not scientific but a matter of economics. The carbidopa, which is an essential part of therapy, is provided by Merck Sharp and Dohme Research Laboratories. However, L-5HTP has to be purchased from a biochemical supply house in powder form at a cost that is too high for most patients or clinical investigators. The cost could be greatly reduced, and the quality improved, if L-5HTP was produced by a pharmaceutical company. This predicament has been presented to various pharmaceutical companies, the Pharmaceutical Manufacturers Association, the FDA and the National Institutes of Health (NIH), none of which have been able to solve this problem. Although all have agreed that there is a need for the development of service drugs, there is no formal mechanism by which this development can be accomplished at present.

This is not an isolated example of this problem. In 1956, J. M. Walshe, of Cambridge, England, discovered that penicillamine was an effective treatment for patients with Wilson's disease.[5] Penicillamine changed Wilson's disease from a fatal disease to one that is curable in about 90 per cent of patients. Several years after Dr. Walshe's momentous discovery the manufacturer of penicillamine decided to discontinue its production because the anticipated financial return was too meager. Fortunately, this decision was reversed after Dr. I. H. Scheinberg, of Albert Einstein College of Medicine, presented the problem to the public press.[6] It is ironic that penicillamine has now been found to be extremely valuable for therapy of cystinuria, heavy-metal intoxications, rheumatoid arthritis and certain collagen diseases, in addition to Wilson's disease; none of these applications would have been discovered without the perseverance of Drs. Walshe and Scheinberg. One has to wonder how many other drugs of little commercial value would have been found to have wider uses, including therapy of more common disorders, if they had not been rejected by the marketing departments of pharmaceutical companies. Dr. Walshe continues to struggle against the vicissitudes of pharmaceutical research for rare disorders. In 1969, he discovered that triethylene tetramine (trien) was an effective substitute for those patients who could not tolerate penicillamine because of severe adverse effects such as nephropathy.[7] Dr. Walshe has had to purify and encapsulate trien in his own laboratory over the years because he has been unable to persuade any pharmaceutical company to undertake its production. In a letter to the editor of the *British Medical Journal* he states, "Meantime the ques-

Revisions in U.S. Patent Law: Still Pending

A powerful group maintains that if federally sponsored research leads to new inventions, the government should get exclusive rights; many scientists and their institutions disagree

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.

—U.S. CONSTITUTION, ARTICLE I, SECTION 8.

WASHINGTON

"It could determine whether an innovation actually gets developed or sits around on the shelf forever," insists one university spokesman.

"It would surely make the difference in whether the country is able to remain technologically competitive in the world market," says a government official.

Yet, contends a U. S. Senator, the American people would be "robbed blind" by it. . . .

What these and a growing number of other politicians, scientists, and consumer advocates are debating is whether the government should enact a law granting all inventors exclusive patent rights to their inventions—even when they come as a by-product of federally financed research.

According to experts on patent law, the answer is not legalistic mumbo jumbo. It will, they say, largely determine how fast the country will develop technical and scientific know-how and how much the public will have to pay for it.

The federal government now supports an estimated two-thirds of all research in the United States. Yet it has never established a uniform patent policy for the inventions that such research produces.

22 Patent Arrangements

Over the past 30 years, in fact, individual Washington agencies have developed some 22 different patent arrangements, ranging from exclusive agreements that give inventors and research institutions the first option on all future inventions, to policies that almost automatically turn over inventions to anyone who wants to develop them.

While most analysts acknowledge that such discrepancies are unfair, few agree on what the government's overall patent policy should be. Recent attempts to come up with a uniform federal policy have shown few signs of settling the 30-year old debate. For example:

▶ A two-year study begun last December by Senator Gaylord Nelson, Democrat of Wisconsin, on the effects of patent policies on technological and economic growth has provoked heated debates but has done little to resolve the differences among scientists and politicians over what the federal patent policy should be.

Hearings on the subject are expected to continue in the Senate Subcommittee on Monopoly and Anticompetitive Activities on May 22 and 23.

▶ A bill affecting patent policy, HR 6249, was introduced in the House of Representatives in April, 1977, by Democratic Congressmen Ray Thornton of Arkansas and Olin E. Teague of Texas. In the year since, however, hearings have never been scheduled on HR 6249, partly because of Congress's busy legislative schedule and partly because no consensus on the patent issue has been reached. The measure, which is pending before both the House Committee on Judiciary and the Committee on Science and Technology, would affirm the individual agencies' control over future patent rights.

▶ The Carter Administration has refrained from saying what it thinks federal patent policy should be. Although option papers outlining the various alternatives are now being prepared for the President by his staff, officials close to the issue say it is unlikely the Administration will take a stand anytime soon.

In recent months, bitter arguments over patent policies have erupted at many government and university gatherings, most recently at the annual meeting of the American Institute of Physics here last month.

At a special meeting last month with officials of the Department of Energy, university research administrators charged that, by denying exclusive patent policies to researchers conducting energy-related experiments, the agency had removed most incentives for further innovation in the field—at a time when innovation was crucial to the nation's welfare.

The notion of giving inventors the exclusive right to make, use, and sell their inventions for a limited period of time is nothing new. U. S. patent laws date back to the 1790's and have generally been seen as incentives to encourage researchers to develop their innovative processes and products to the point that they are commercially feasible.

Who Should Own the Patent?

When the government itself began to pour tax dollars into scientific research, however, the question over who should own the patent rights became more complicated. The inventors? The institutions where the inventions take place? Or the government agencies that support the research?

There are powerful advocates for the view that patent rights for federally financed innovations are the property of the government and should be made generally available to the American public on a noncompetitive basis. They include such heavyweights as consumer advocate Ralph Nader; Admiral Hyman Rickover, head of the Navy's nuclear-propulsion program; Senator Nelson, chairman of the Senate Subcommittee on Monopoly and Anticompetitive Activities; Sen. Russell B. Long, chairman of the Senate Committee on Finance; and the Justice Department's Anti-Trust Division.

They argue that by "giving away" exclusive patent rights to the inventor, the government allows him and his research institution to "collusion with" private companies, to set up "monopolies" and charge "windfall prices" for the fruits of tax-supported research.

"The American taxpayers are dealt a one-two punch," contends Senator Nelson.

"First they are forced to pay through the nose for this risk-free, tax-supported research and development.

"Then they pay dearly all over again, for the grossly inflated prices these companies charge for the products they market under the patent rights given to them by the government."

Admiral Rickover, lawyers from the Department of Justice, and Senator Long, among others, have argued that a law should be passed requiring the government to retain patent rights to all inventions developed at its expense, unless there are exceptional circumstances.

On the other side are many university scientists, along with other government officials, who contend that such arguments are what one patent lawyer calls "knee-jerk reactions" expounded by individuals who have little understanding of how the process of innovation actually works.

"People think inventions arise in full-blown, complete fashion ready to be sold to the American public," says Norman J. Latker, patent counsel for the Department of Health, Education, and Welfare.

"They think all inventions emerge from the laboratory like Edison's light bulb, ready to be plugged into the socket. What they don't understand is how much time and money is involved in the development process after the patent has been obtained."

From University to Industry

The transfer of technology from the university laboratory to industry usually occurs in one of three ways. Some inventors patent their own ideas and sell them directly to a manufacturer; some universities contract with outside agents to handle faculty inventions; and some universities have their own licensing arms that scout the faculty for patentable ideas and then try aggressively to sell them to industry.

"It is impossible to persuade firms, particularly small firms, to put up the capital required to bring innovations into the commercial marketplace—*unless* you can give them some guarantee that they can at least get their money back from their investment," contends Howard Bremer, director of the technology licensing program of the Wisconsin Alumni Research Foundation.

"Few people," Mr. Bremer says, "understand how much risk there is that the investment will never pay off."

Universities point to statistics from the General Accounting Office and the Energy Research and Development Administration about the risks of developing drugs. In the pharmaceutical industry, the government agencies estimate that for every 2,000 new compounds synthesized, only one ever reaches the market. The agencies say that the 1973 cost of successfully developing the average drug was over $11.5-million.

The problem is compounded, says Niels Reimers, director of Stanford University's technology licensing program, by the fact that when the government makes non-exclusive licenses generally available, "foreign industry has equal access in using the results of government-funded research."

Without exclusive patent rights for innovators, argues Mr. Reimers, the American public would either be deprived of important technological advances or be forced to pay the prices set by foreign competitors who develop them into commercial products.

William Carey, executive officer of the American Association for the Advancement of Science, says it is "an absurd situation" for the government to pump nearly $30-billion a year into research and development and then bar the door so "inventions can't get out."

In February, the General Services Administration published a set of regulations that largely supported the universities' contentions. The regulations, which were to have gone into effect March 20, would have extended universities' patent rights from three to five years before coming under government control.

Consumer advocate Ralph Nader and his associates entered the dispute at that point, charging that the government was giving away patent rights to products paid for by tax dollars.

The proposed regulations would permit universities and commercial enterprises over the next decade to "reap hundreds of millions of dollars of profits from work supported by the federal government," Mr. Nader and his supporters said.

Not only was such a policy "unwise" and "contrary to the public interest," it was "unconstitutional," they argued.

'Giving Away' Patent Rights

In a letter to Jay Solomon, head of the General Services Administration, Mr. Nader argued that the agency did not have statutory authority to force all federal agencies to "give away" their patent rights to federal contractors.

Senator Nelson and his committee also intervened in the dispute. They talked the Office of Management and Budget into a 120-day delay so that the regulations could be given further study.

Although patent and licensing officials at major universities admit that in recent years they have been aggressively promoting university inventions to business, they contend their efforts rarely if ever pay off as spectacularly as their critics contend.

"You can count on one hand the number of inventions that make it big each year," says one campus official. "It doesn't take very many hands to total up all the commercially successful university inventions over the years."

The critics counter, however, that those university inventions that have been commercially successful cover many areas and have been extremely lucrative for some universities.

One of the most famous, they say, is Jay W. Forrester's memory core for computers, which was created at the Massachussetts Institute of Technology in the mid-1960's. Following patent litigation, the institute reportedly got a lump-sum royalty payment of $13-million for the invention from the International Business Machines Corp.

Other commercially successful, university-developed inventions include the toothpaste additive stannous fluoride, which was licensed by the Indiana University Foundation

Continued on Page 6, Column 1



CHRONICLE PHOTOGRAPH BY JOHN C. PHILLIPS

"The American taxpayers are dealt a one-two punch," says Sen. Gaylord Nelson. "First they are forced to pay through the nose for this risk-free, tax-supported research and development. Then they pay dearly all over again for the grossly inflated prices these companies charge."

Combustion Inst. Hq.

The service said this approach did not mean creation of a new class of information that could be witheld from the public. Rather, it concluded, "it would be applying the general terms of the FOIA to a specific piece of information."

SECRECY ORDER REPORTED WITHDRAWN
ON WISCONSIN UNIVERSITY RESEARCH

The Commerce Department's Patent and Trademark Office reportedly is withdrawing a Federal secrecy order imposed on a computer security research project at the University of Wisconsin, Milwaukee.

A spokesman for the patent office said, however, he was unable to determine whether the order had actually been withdrawn.

The secrecy order was issued on an invention disclosure after a university alumni group attempted to patent a computer security device developed as a result of the research study. An invention disclosure is required to be filed when an invention is conceived in the course of Federally sponsored research.

The order, dated April 21, concluded that the study "has been found to contain subject matter, the unauthorized disclosure of which might be detrimental to the national security." It was reported that the National Security Agency prompted the patent and trademark office to deliver the order.

A patent cannot be issued and the research cannot be lawfully divulged unless the order is overturned by the patent commissioner. Unauthorized disclosure could constitute a violation of patent laws, which carry penalties up to two years in prison and $10,000 in fines.

With the order withdrawn, it is possible that the invention disclosure could be made available under the Freedom of Information Act, since the university's proprietary interests have been protected by the filing of a patent application. If the order remained in force, however, access probably could be denied under the FOIA by Exemptions 3, for data required to be kept secret by statute, and Exemption 1, for national security information.

The computer security study was done by George I. Davida, a University of Wisconsin associate professor of electrical engineering and computer sciences. It was financed by the National Science Foundation, which in December 1977 awarded Davida, then a graduate student, $89,728 for the three-year study. According to a university spokesman, the grant contained no provision barring disclosure of the study's finding and gave no indication to Davida that he was conducting sensitive research.

Werner A. Baum, chancellor at the Milwaukee campus, responded to the secrecy order with a letter to National Science Foundation Director Richard C. Atkinson, asking the foundation to join in the protest, and arguing that the Patent Office's action "infringes on the standard foundation policy of research disclosure, and more fundamentally, establishes a precedent which has a chilling effect on academic freedom."

Moreover, university officials were reported to have gotten in touch with Secretary of Commerce Juanita Kreps and requested that she review the matter.

In a June 8 letter, Atkinson told Baum that he, too, was concerned with

A bi-weekly newsletter on Freedom of Information and Privacy

ACCESS REPORTS

Editor: Wallis E. McClain, Jr.

Volume 4 Number 12, June 13, 1978

WASHINGTON FOCUS: Lack of a comprehensive and coordinated policy covering the private as well as public aspects of privacy may be putting the United States at a disadvantage in the international community . . . . Several European countries, including Denmark, France, Germany, Norway and Sweden, have passed data-protection laws to guard the privacy of their citizens. A feature of most -- alien to most privacy specialists in this country -- is that they prohibit exporting personal information beyond national borders, unless the recipient country can guarantee that the data will be protected . . . . So far, the United States cannot meet that test, and that is beginning to create headaches for multinational businesses. A full-scale international effort has begun to deal with the complex problems presented by "transnational data flow," as it is becoming known . . . . Attorney General Griffin Bell's leadership in the Justice Department has been faulted in a review of his performance by the Committee for Public Justice, a civil liberties group headed by Lillian Hellman and Orville H. Schell. In the group's newsletter, Justice Department Watch, Bell was blasted for -- among other things -- failure to follow up on implementation of his own policy directives in the area of freedom of information.

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NO JUSTIFICATION SEEN IN DENYING ACCESS ON GROUND 'PATENTABLE' DATA MAY ARISE

Recent use of the term "patentable material" by the National Institutes of Health as justification for the closing of advisory committee meetings seems to

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discriminated against. What is more, the mandate for cost effectiveness precludes trying out innovative approaches whose value can only be measured if someone is willing to gamble on them.

If the domestic policy review is to solve such questions, it will depend in large part on the willingness of regulators to see matters in a new light. According to Philip Smith, there is "a sense that people like [EPA Administrator] Doug Costle and [FDA Administrator] Don Kennedy want to work with industry, and they don't want to fight all the time. I think we have a team of people now in government that may be able to do something."

THE INVESTMENT CLIMATE

But industry should not expect a major overhaul of regulatory practices to emerge from the study. EPA Administrator Douglas M. Costle concedes "a tremendous growth in the last decade in health and safety regulations—13 major statutes in our area alone." Though Costle agrees that the economic impact of such rules should be more closely quantified, he contends that "this rapidly widening wedge of regulation has been a response to a massive market failure—failure of the marketplace to put an intrinsically higher value on pollution-free processes."

Most regulators agree that not enough research has been done on the true nature of the environmental problems they are empowered to combat, but they also argue that regulation has led to cost-saving practices, especially in the area of resource recovery, where closed-cycle processes now help capture reusable material. OSHA officials also cite examples where the agency has laid down rules that have led to cost-cutting innovations. But Eula Bingham, the OSHA administrator, emphasizes that the "legislatively determined directive of protecting all exposed employees against material impairment of health or bodily function" requires tough regulation without quantitative weighing of costs and benefits. "Worker safety and health," she insists, "are to be heavily favored over the economic burdens of compliance."

Bingham and her boss, Labor Secretary Ray Marshall, may represent an increasingly isolated view, however. Economic issues have come to dominate thinking within the Carter Administration, and it is precisely these questions that industry has stressed in its discussions with science adviser Press and other White House officials. Just over a month ago, Treasury Secretary W. Michael Blumenthal told a meeting of financial analysts in Hal Harbour, Fla., "We are now devoting a very sizable chunk of our private investment to meeting government regulatory standards . . . and in some of these areas we may well be reaching a breaking point." Blumenthal also noted: "Our technological supremacy is not mandated by heaven. Unless we pay close attention to it and invest in it, it will disappear."

A month before the Blumenthal speech, GE's Buechе suggested to an American Chemical Society gathering that "we step back and look at R&D for what it really is: an investment. It is an investment that, like more conventional investments, has become increasingly less attractive."

Buechе, along with most other research managers, rejects the idea of direct federal subsidies to industrial R&D. Instead, he points out that "perhaps 90 percent of the total investment required for a successful innovation is downstream from R&D [and thus] it becomes . . . clear why we must concentrate on the overall investment climate." Buechе attacks Administration proposals to eliminate special tax treatment of long-term capital gains, plumps for more rapid investment write-offs, and says "it is extremely important to provide stronger incentives for technological innovation by making permanent and more liberal the 10 percent investment tax credit."

CRITICS IN INDUSTRY

Buechе's arguments suggest the broad—yet often indirect—way in which federal policy runs counter to the best interests of innovation. Fear of antitrust moves from the Federal Trade Commission or the Justice Dept., for instance, has prevented many companies from sharing research aimed at a problem common throughout an industry—including new technology aimed at solving regulatory questions. At General Electric, the legal staff must now be notified if a competitor visits a company research facility, even if no proprietary material is involved.

For their part, Justice Dept. trustbusters claim that fears that their policies stifle innovation are not justified. They say they are flexible enough to recognize the differences in the pace of innovation from industry to industry, and that is why they allow a fair number of mergers among electronics companies. "That's an industry where you don't have to worry about someone cornering the market," says Jon M. Joyce, an economist in the Justice Dept.'s antitrust division. "There's just a lot of guys out there with good ideas."

Industry further claims that the inability to secure exclusive licenses on government-sponsored research leaves much good technology on the shelves, while federal attempts to market new products are often silly at best. Richard A. Nesbit, director of research at Beckman Instruments Inc., recalls a government circular that waxed rhapsodic over the federal commitment of billions of dollars to R&D. Included with the letter was a syringe for sampling fecal matter, and the suggestion that Beckman might want to license the technology. "I wondered if they spent billions to develop that," Nesbit recalls. "The omission was ludicrous."

Even national accounting procedures draw criticism from industry. A major target is the 1974 ruling by the Financial Accounting Standards Board that stipulated that R&D spending could no longer be treated as a balance sheet item, but must be listed as a direct profit or loss item in the year spent. H. E. McDonald, president and chief operating officer at Sperry Rand Corp., recently told an executive management symposium, "The ramifications of that rule change are quite complex, but the net effect has been to dry up a lot of potential venture capital investments. . . . I can say quite candidly that Univac would not be here today if we had not had the advantage of the old rule for so many years."

The shortage of risk capital has had a tremendous impact on small, technology-oriented companies trying to arrange new public financing. According to a Commerce Dept. survey, 686 such companies found $1.367 billion in public financing in 1969. In 1975, only four such companies were able to raise money publicly, and their numbers rose to just 30 in 1977. Equally ominous is the experience at Union Carbide, which, according to Tinsley, has not been able to compete for venture capital and has thus canceled plans to start a number of small operations built around interesting new technology. Years ago, says Tinsley, Carbide was reasonably successful at getting such funding. "And you must remember that these ideas are perishable," he says. "They don't have much shelf life."

The Treasury Dept., in fact, has an ongoing capital-formation tak force that will be integrated into the policy review under the direction of Deputy Secretary Robert Carswell. Carswell notes that "you can't draw a clear line" between R&D support and investment in general, but "if it turns out that we find some form of capital formation gives the economy a greater multiplier effect than another form, we at the Treasury would not shy away from whatever policy would help most."

WASHINGTON'S CHANGING ROLE

Even as it has pursued policies detrimental to industrial R&D, the federal government has withdrawn as a major initiator of innovation. Research managers generally believe that companies are better equipped than government to bring new technology to society because they are more attuned to market pull. But Lawrence G. Franko of Georgetown University, an international trade expert, recently pointed out to a congressional committee that the U.S. Government has in the past played an important role "as a source of demand for new products and processes, and as a constant, forbearing customer in computers, semiconductors, jet aircraft, nuclear-power generation, telecommunications, and even some pharmaceuticals and chemicals. . . ."

According to the Defense Dept.'s Davis, both Defense and NASA "have faded" in this role the result of the Vietnam war and concerns over the military-industrial complex. "The consumer marketplace and other government agencies have not been able to pick up where DOD and NASA left off," she says. "The Department of Energy should be able to help with this, but it hasn't yet. And the Department of Transportation just never bloasomed in this role." An unreleased IRI study for the Energy Dept. summed up industry's views. The company officers interviewed said government could spur industry's energy R&D only by creating a national energy policy, increasing its managerial competence, and offering financial incentives rather than massive contracts.

On the other hand, there have been some recent, notable government efforts to spur the innovation process. "We've talked to the leading semiconductor companies about our hopes for their innovation," says Davis. She says that the Defense Dept. expects to program $100 million over the next five years for industrial innovation in optical lithography, fabrication techniques involving electron-beam technology, better chip designing and testing to meet military specifications, and system architecture and software implementation.

At the Transportation Dept., chief scientist John J. Fearnsides wants to involve the private sector much earlier in the government's R&D process, thereby allowing industrial contractors to develop technology alternatives instead of having to cope with rigid specifications at the outset. Such a policy, some believe, might have resulted in major savings for the Bay Area Rapid Transit system, for instance. "It is more expensive to fund a wider range of choices, but only at first," says Fearnsides.

The NSF also has announced a new industry-university grant program for cooperative exploration of "fundamental scientific questions." The aim is to make "a long-term contribution toward product and/or process innovation."

THE FAILURES OF BUSINESS

While agreeing on the need for federal policies that bolster innovation those knowledgeable about industrial research think that the companies themselves share some of the blame for stagnation and must be willing to examine their practices critically. Alfred Rappaport, a professor of accounting and information systems at Northwestern University's graduate school of management, believes that one reason the U.S. lags in R&D is that the incentive compensation systems that corporate executives live under tend to deter intelligent risk-taking. "Incentive programs are almost invariably accounting-numbers oriented and based on short-term earnings results," he says. "That puts management emphasis on short-term

INDUSTRIAL INNOVATION

● Mr. STEVENSON. Mr. President, technological innovation was responsible for 45 percent of the Nation's economic growth from 1929 to 1969. It remains the key to our ability to compete in the world. A $30 billion trade deficit is not so much the result of the oil bill as it is our inability to pay for it with exports. Other nations do so. Indeed, even with appreciated currencies they run trade surpluses. The key to recovery and stable prices is industrial innovation, including innovation in the production of food. But the Nation is losing its edge. More R. & D. now takes place outside than inside the United States. This subject is discussed in the July 3 issue of Business Week.

Mr. President, I urge my colleagues to read "Industrial Innovation" and ask that it be printed in the RECORD.

The article follows:

VANISHING INNOVATION

A grim mood prevails today among industrial research managers. America's vaunted technological superiority of the 1950s and 1960's is vanishing, they fear, the victim of wrongheaded federal policy, neglect, uncertain business conditions, and shortsighted corporate management. They complain that their labs are no longer as committed to new ideas as they once were and that the pressures on their resources have driven them into a defensive research shell, where true innovation is sacrificed to the certainty of near-term returns. Some researchers are bitter about their own companies' lax attitudes toward innovation, but as a group they tend to blame Washington for most of their troubles. "[Government officials] keep asking us, 'Where are the golden eggs?'" explain Sam W. Tinsley, director of corporate technology at Union Carbide Corp., "while the other part of their apparatus is beating hell out of the goose that lays them."

That message—and its implications for the overall health of the U.S. economy—is starting to get through. Following months of informal but intense lobbying led by such executives as N. Bruce Hannay, vice-president for research and patents at Bell Telephone Laboratories, Inc., and Arthur M. Bueche, vice-president for research and development at General Electric Co., the White House has ordered up a massive, 28-agency review of the role government plays in helping or hindering the health of industrial innovation. "Federal policy affecting industrial R&D and innovation must be carefully reconsidered," wrote Stuart E. Eizenstat, the White House's domestic policy adviser, in a recent memo outlining the review's intent.

One thing that the study clearly will not accomplish is a quick fix for the deepening innovation crisis. The problem is regarded as immensely complex by the Administration, and is inextricably tied to other economic dilemmas now facing Carter's White House. "Historically, the government's role has been to buy more science and R&D," says Martin J. Cooper, director of the strategic planning division at the National Science Foundation (NSF). "Now maybe we better go with investment incentives." Says Jordan J. Baruch, Assistant Commerce Secretary for science and technology, who will be the review's day-to-day manager: "This study developed in an environment of people concerned about economics, business, and technology."

The Administration's concern is underscored by the fact that it is organized as a domestic policy review, the highest sort of attention a problem can receive within the executive branch. Among its objectives, such a review must produce options for corrective action by the President. According to Ruth M. Davis, Deputy Under Secretary of Defense for research and development, "this is the only such review at the policy level in 20 years that transcends the interests of more than one agency."

The White House also seems determined not to conduct the study in a governmental vacuum. Baruch is soliciting input from

In contrast to the Department of Energy, the Department of Health, Education, and Welfare has permitted universities to enter Institutional Patent Agreements (IPAs).

These give the universities the option of granting exclusive licenses for a limited period, usually not more than five years after the first commercial sale of an invention. The government retains the right to buy any resulting product on a royalty free basis. It may also "march in" if it finds the exclusive licensing contrary to the public welfare.

The HEW IPA program "clearly has been the most successful in government in enabling innovation. No other agency can point to such a record of success," Reimers says.

But now universities are becoming "increasingly alarmed" that HEW may change its policies. "HEW Secretary Joseph Califano's recent 'marching in' to cancel an exclusive licensing to a small Massachusetts company (American Science and Engineering) in favor of the market-dominating firm (Technicare) in the same field has obvious potential for being devastating to a university's ability to encourage industry to invest risk capital to develop an embryonic invention from government funded research," he notes.

"Universities not holding IPA's now report that approvals of patent waiver requests by HEW have been virtually halted." These permit exclusive licensing on a case-by-case basis.

"When waivers are not granted, the historical record shows the chance of delivery of an invention to the public is minimal," Reimers adds.

Patent rights are frequently lost during the waiver period, especially in foreign countries. Most professors publish their research findings immediately, yet foreign patents can only be obtained if filed before publication. Because of differences in patent protection, foreign coverage has become more valuable than domestic patents, in many instances.

Those seeking to end exclusive licensing practices have rarely, if ever, investigated actual case histories of how industry adopts innovations based on federally funded research, Reimers says. "It is incomprehensible that they have not bothered to do so, and ironic that the policies they espouse will achieve the opposite result from that which they intend."

Substantial data on technology transfer is included the hearings of the House Committee on Science, Research, and Technology, headed by Rep. Ray Thornton, on the Uniform Federal Research and Development Utilization Act of 1977. This supports a licensing type policy.

At Stanford, Reimers and a small staff receive four to six inventions a month from Stanford faculty. These are screened for marketability, often in conjunction with small local firms.

If the inventions are marketed successfully, any net proceeds are divided equally between the inventor, the inventor's academic department, and the University, helping support more research and education.

"We endeavor to license at an early stage," Reimers notes. "Our mode of operation is directed to promptly placing an invention with a company motivated to bring it forward to a product, and then to go on to the next invention."

STANFORD UNIVERSITY NEWS SERVICE STANFORD, CALIFORNIA 94305 (415) 497-2558

FOR INFORMATION CONTACT: Bob Beyers
EDITORS: Details follow asterisks.
FOR IMMEDIATE RELEASE
STANFORD—

Strong political momentum is building for changes in U.S. patent licensing policy which will entrench big business, help foreign competitors, and make it far harder to bring innovations to the marketplace, according to Niels Reimers, director of Stanford's technology licensing program.

Ironically, the strongest support for the changes comes from those normally allied with innovation, consumers, and small business—Admiral Hyman Rickover, Senators Gaylord Nelson and Russell Long, and the Justice Department's Anti-Trust Division.

All have protested the "giveaway" of patent rights on inventions coming as a byproduct of federally funded research. Assistant Attorney General John H. Shenenfield recently testified that such patents should be made freely available on a noncompetitive basis to prevent "windfall profits," especially by large firms.

While this "sounds good," according to Reimers, its actual effect would be "devastating" to U.S. leadership in technological innovation. Without short-term exclusive rights small firms can't take the risk of bringing innovations to the commercial market. But large foreign firms can—and are—doing so with ideas gleaned from U.S. funded research.

* * *

White House Science Adviser Frank Press last month noted that rising competition from both advanced and developing nations has made the U.S. exceptionally dependent on marketing future innovations.

"Many of our intermediate and some of our high technologies are being successfully adopted by the developing countries who, on some items, can now successfully compete with us. . . .

"As this transfer of technology and industrial capacity takes place on one level, it is essential that the advanced countries continue to advance their innovation and productivity. Otherwise, the major markets will begin to collapse around the world, we will be resorting to protectionism instead of industrial creativity to save our domestic economies, and eventually global chaos will ensue.

"The harsh truth is that we are now very much locked into a dynamic system of global economic growth, and it is one based on technological change and innovation. . . . There are enormous pressures ahead for us to innovate and improve productivity."

Press indicated the Commerce Department would study "such things as the impact of federal regulations on industry, the availability of investment capital, assertions that industry is becoming increasingly defensive in its research and development, that it is turning from longer-term research and bolder innovation to emphasis on short-term needs and product improvement."

Of special interest to Reimers and other members of the Licensing Executives Society, which meets in Washington Friday, April 7, is Press' statement that "we are considering ways to change this situation. . .to increase the development and implementation of innovation."

Nevertheless, the study found that small firms got only 8 percent of federal R&D contracts.

In a related development, the chairman of a House small bnsiness subcommittee, Rep. Alvin Baldus, D-Wis., charged that the Department of Energy—which hands out billions in procurement contracts—consistently favors the biggest companies.

According to Baldus, DOE gave 64.8 percent of its business ($4.1 billion worth) to just 23 big firms. He has asked the General Accounting Office to investigate the barriers to participation by small companies, as well as DOE's practice of renewing contracts year after year without competitive bidding.

An OMB spokesman said the study had not been deliberately suppressed, but simply shuffled aside during the change in administration. He said it is OMB policy to encourage the direction of R&D funds to smaller firms.

According to the study, smaller firms tend to be muscled aside in the race for federal dollars because of the complexity of government procurement procedures, the length of time between application and award, the cozy relationships that build up between government agents and officials of big corporations and the erratic nature of government contract awards.

It recommended a 10-point program to encourage small firms to bid on R&D contracts, including increasing quotas for small business and cutting the paperwork that discourages them from even trying.

One of the principal reasons smaller firms tend to be more innovative, the study says, is that they have less of a vested interest in existing products. They have less to protect.

According to one of the sonrces quoted in the stndy :

"The largest company, which obtains the biggest economies of scale and hence high profits from existing products, has a strong interest in cost-reducing improvements in production techniques which further strengthen its position.

"Small companies which are having difficulty in competing in the big league for existing products have a bigger incentive to try to enlarge their market share by innovating radically new products."

Tbe Defense Department was found to be the most closely wedded to big business, with over 94 percent of its R&D contract dollars going to the corporate giants.

[From the Washington Post, Apr. 11, 1978]

Our Indolent Pursuit of Foreign Technology

(By Daniel S. Greenberg)

Listeuing in on the complaints that officials in industry, labor and government are making ahout foreign industrial competition, one gets the impression that some of them would rather curse the darkness than light a candle.

Consider, for example, one of the fastest-growing themes in the protectionist camp—namely, that foreign firms are scooping up the results of vast quantities of our taxpayer-financed research and using it to innovate products that outsell domestic goods.

Is that true? You can safely bet your Japanese-made television set that it's true. Which is why the president of tbe International Association of Machinists and Aerospace Workers charged last year that Japan has reaped $15 billion from the purchase of $1.5 billion of American technical know-how. It's why leaders of the American electronics industry have been pushing for curbs on the export of American scientific and technical knowledge. And it's why the White House has included the export of such knowledge in a recently ordered government study of what ails industrial innovation in this country.

But before the drumbeat for technological protectionism gets any louder, it would be useful to take note of certain facts concerning foreign mining of American science and technology. Our industrial competitors work hard and sys-

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Patent Policy Versus Innovation

The United States is engaged in a massive research and development effort which, measured in current dollars, is edging close to the level of $50 billion annually, counting outlays in both the federal and the private sector. The budget for R & D in government calls for more than $28 billion in the next fiscal year. There is no doubt that the R & D input is strong. The *output* side may be a very different story.

We support R & D to learn something that we do not know, and to make use of what we learn. Like any other type of investment, R & D is expected to yield returns. In the case of government-financed R & D the question arises, Are the investors getting full and timely return? Are the results of federally funded R & D finding their way into the market?

The evidence, as usual, seems mixed. About 8000 inventions are said to be generated each year from government-financed R & D, many of which are patentable. Not enough of these apparently reach the market. Some 30,000 government-owned patents are piled up awaiting takers. To that extent, the national economy is not being enriched and utilization is forestalled. It is a baffling situation until one realizes that the blockage occurs largely in the government's patent policy.

The government operates on the proposition that the economic rewards from federally funded R & D should be captured by the government, or shared only grudgingly with others, since public funds were used. The view prevails that if rights to the discovery were released to private developers on an exclusive basis unreasonable private enrichment could occur. There is scant evidence to support these apprehensions, but the doctrine is riveted into the government's thinking. The effect is that the market incentive to develop government-financed discoveries is circumscribed and inventions are isolated from normal risk-taking and pursuit.

It is not hard to see how this can inhibit the prospects for pass-through of discoveries from biomedical research or energy-related R & D. We see a prodigious R & D enterprise, fueled by tax dollars, constrained from diffusing its results because of a public policy barrier. Throughout the enterprise, discoveries sit stranded and aging. Meanwhile, we search for clues as to what is wrong with U.S. technological innovation, and how it is that foreign industry can undercut American competitiveness and employment.

As usual, public policies are muddled, conflicting more often than complementing one another. In the new study ordered by President Carter of the problems assailing industrial innovation, a fresh opportunity is provided to reexamine both the premises and the consequences of government patent policies. There is ample evidence that the costs of producing and marketing an invention are many times as great as the outlays on the R & D that led to the invention. Not many developers will take these risks with inventions resulting from federal R & D, in the absence of clear ownership.

It begins to appear that we have thought of "science policy" too much in terms of stimulating R & D and too little in terms of liberating its results. The benefits of federally funded R & D are hard enough to realize without the added drag of a dubious policy on patents. A public which is regularly lectured on the promise and performance of science may not be grateful to learn that government's rules are blocking research applications. That could be far more harmful to science than the Golden Fleece awards.

Public policy, if wisely designed, can stimulate economic pursuit of government-financed inventions while at the same time minimizing the risk of abuses. What is clear is that the present patent policies will not get us innovation, nor health and energy benefits, nor economic growth, nor trade competitiveness. We can hardly make the case that R & D contributes significantly to the nation's economy if, at the same time, we isolate its results from utilization. Here is a notable "Catch 22" in federal R & D policy, and it is time to bring it into the open.—WILLIAM D. CAREY

Voting six to three to overturn a lower-court ruling, the high court held that an employee of Atlantic Richfield Co. couldn't, under present law, patent his method for updating the limits at which alarms should go off on certain monitoring equipment used in the petroleum industry.

Justice John Stevens, writing for the matjority, observed that the only novel feature of the method was a mathematical algorithm, or problem-solving formula. The court previously has held that such formulas were like a "law of nature" or a "principle" and weren't patentable.

The question in this case was whether applications of such a formula, once it had solved the problem, to couventional manufacturing processes would make it eligible for patent protection.

Justice Stevens acknowledged that the inventor in this case, Dale R. Flook, wasn't seeking to completely preempt the mathematical formula because there were uses of the formula outside the petrochemical industries tbat would remain in the public domain.

Yet, while saying a process isn't "unpatentable simply because it contains a law of nature or a mathematical algorithm." Justice Stevens insisted that "tbe process itself, not merely the mathematical algorithm, must be new and useful."

The Pythagorean theorem wouldn't have been patentable "because a patent applicatiou contained a final step indicating that the formula, when solved, could be usefully applied to existing surveying techniques," he declared.

Justice Stevens noted that "to a large extent" the court's decision was "based on reasoning derived from opinions written before the modern business of developing programs for computers was conceived."

He emphasized that "neither the dearth of precedent, nor this decision, should therefore be interpreted as reflecting a judgment that patent protection of certain novel and useful computer programs will not promote the progress of science and the useful arts, or that such protection is undesirable as a matter of policy."

But the policy questious about what kinds of programs might be appropriate for patent protection would best be answered by Congress, he said.

Dissenting, Justice Potter Stewart, joined by Chief Justice Warren Burger and Justice William Rehnquist, complained that the decision struck a "damaging blow at basic principles of patent law." He maintained that the majority had incorrectly brought criteria of novelty and inventiveness into the initial inquiry into whether the subject matter was patentable.

Those factors should be considered only when deciding whether actually to issue a patent, Justice Steward asserted. He conceded that "it may well be" that ultimately the patent should be denied "because of anticipation, abandonment, obviousness, or for some other reason." But, he maintained that Mr. Flook's claimed process "clearly meets the standards of subject matter patentability" required under the present law.

The only issue before the court, he insisted, was "whether a claimed process loses its status of subject matter patentability simply because *one step* in the process" wouldn't be patentable "if considered in isolation."

[From the Washington Post, June 12, 1978, p. A4]

Bacterium Is Used in Producing Insulin

(By Robert Cooke and Richard A. Knox)

A team of biologists at Harvard University has found a way to use a common bacterium to manufacture the medically valuable hormone insulin.

The unprecedented scentific achievement appears to open the way to eventual mass production of almost any protein—including human hormones—by microscopic "factories" of bacteria.

Led by Prof. Walter Gilbert, the Harvard team used scientifically elegant gene-splicing techniques to induce the bacteria to turn out a precursor to rat insulin, a mammalian hormone vital in the metabolism of sugar. The precursor, called pro-insulin, can be converted to insulin once outside the bacterium. The researchers report their bacteria churn out about 100 molecules of rat pro-insulin per cell. Multiplied by billions of bacteria, a large amount of rat insulin could be produced.

Several U.S. research teams are believed to be within months of getting bacteria to produce the human form of insulin, a step that would have important practical significance for the millions of diabetics whose lives depend on daily insulin injections. Curently medical insulin is derived from the pancreas glands of slaughtered cows and pigs, but a 6 percent annual increase in the incidence of diabetes may eventually create a shortage of the hormone.

In addition, some diabetics do not tolerate the animal insulin, which is slightly different chemically from the human hormone.

The intense scientific competition to engineer an insulin-producing bacterium is based less on its immediate practical usefulness than on the desire to demonstrate that a lower organism can be induced to manufacture complex human proteins. This step would have immense scientific and medical implications; there are many human proteins unavailable for medical use or study that might become available through the same techniques that the Harvard group had used in the pioneering rat-insulin work.

The Harvard experiments were done in an especially secure laboratory at the Massachusetts Institute of Technology under guidelines formulated in 1976 by the National Institutes of Health.

Under those guidelines, the critical final experiments toward producing human insulin in bacteria could not be performed in any American laboratory outside the NIH's own top-security lab in Maryland. However, a revision of those rules, now on the desk of Health, Education and Welfare Secretary Joseph A. Califano Jr., would open up the human insulin experiments to dozens of U.S. laboratories.

The Harvard team used an ingenious strategy to "trick" the bacterium to produce insulin, a complex protein for which the bacterium has no use. First they made an artificial copy of the rat genes for insulin—the code that specifies how to assemble the molecules of insulin. Then they spliced the artificial gene into a small ring of genes called a plasmid.

They used a well-known plasmid containing the genes for penicillinase, an enzyme that enables bacteria to resist the antibiotic effects of penicillin.

Then they inserted the remodeled plasmid into a living bacterium, an enfeebled strain of a nbiquitous organism called Escherichia coli. The bacterium obediently began excreting complete insulin molecules attached to molecules of the penicillinase enzyme.

The penicillinase plasmid was used because it was known that the bacterium normally excretes the enzyme rather than keeping it within the cell. So the researchers figured—accurately, as it turned out—that the insulin would be piggybacked on the enzyme.

In order to make sure that the insulin would come out attached to the penicillinase molecule, they had to use a technique called "sequencing" to locate the genes for penicillinase so they could insert the insulin genes in the midst of the enzyme gene.

Sequencing was also used to make sure the spliced-in insulin genes were in the correct orientation (frontwards instead of backwards) and "in frame," meaning that the gene was copied accurately by the bacterium.

Aiding the Harvard team in the insulin work were researchers from the Joslin Clinic, a Boston diabetes research center. The team plans to publish a report in August in the Proceedings of the National Academy of Sciences.

ernment has any existing power to register or monitor such work. "Legislation on this matter has to come," says C. Joseph Stetler, president of the Pharmaceutical Manufacturers Assn. "There has to be some government involvement."

MORE STARTUPS

The risks in the field of genetics may well work to the advantage of smaller firms such as Cetus, which have less to lose. "Cetus is addressing the major innovations in an area in which industry has been quite backward in the last 25 years," says adviser Lederberg. Adds Cetus director Glaser: "It is scandalous that no practical consequences have come from a better understanding of DNA."

The practical consequences are probably not far away. Most pharmaceutical houses and many blue-chip chemical firms are either doing active work in genetics in their own labs or sponsoring it in other institutions so they can keep a close eye on it. More new companies like Cetus are popping up, such as neighboring Genentech Inc., formed in San Francisco last year by Professor Herbert Boyer of the University of California Medical School and a group of venture capitalists.

Just how far-reaching the results will be is difficult to foretell. Says Cetus' Cape: "We're all on the first page of *Genesis* in this field."

[From Business Week, Dec. 12, 1977, pp. 128 and 132]

A Commercial Debut for DNA Technology

A tiny San Francisco company, just two years old, has scored a biomedical research coup that may have left its competitors in the dust. Genentech Inc. will get the patent rights to a new means of producing a brain hormone called somatostatin. But the exciting news is that scientists for the first time have employed controversial recombinant DNA (gene-splicing) technology and the young science of artificial gene synthesis to produce the hormone. In addition, somatostatin has potential both as a research tool and as a medicine, and variations on its structure might well open the way for a whole new family of drugs capable of treating diseases that today defy medicine's best efforts.

The scientific breakthrough came at the University of California at San Francisco, where researchers—along with the City of Hope Medical Center in Duarte, Calif., and the Salk Institute—had been pursuing the new technique since mid-1976. "Molecular biology has reached the point where it can become involved in industrial applications," says Herbert W. Boyer, leader of the research team and a co-founder of Genentech, who now serves as a consultant to the company. "Our strategy," says Robert A. Swanson, Genentech's 30-year-old president, "is to concentrate solely on recombinant DNA and to manufacture and market products to major medical, pharmaceutical, and industrial companies."

LOTS OF COMPETITION

Genentech's connection with UC-San Francisco has led to unease among scientists in Boyer's lab—a feeling that is shared by some science policy advisers within the White House. And the advance comes at a time when many scientists and citizens still worry about recombinant-DNA research and its potential for harm.

Nevertheless, there are nearly 300 recombinant-DNA research programs now underway in the U.S., most of them funded by the National Institutes of Health (NIH), which oversee the safety of such experiments. Though Genentech followed NIH guidelines, because of the unique arrangement covering its research, the company will be first to exploit the somatostatin results commercially. Once production is under way—perhaps by the middle of next year—UC-San Francisco will share in the royalties, along with the City of Hope where the gene synthesis work was done.

Funding snch research is expensive: The somatostatin experiments alone cost several hundred thousand dollars. But Swanson claims to have raised nearly $1 million in backing so far from sources such as International Nickel Co. and his former employer, the venture capital firm of Kleiner & Perkins. Despite the obvious risks of exploiting an unproven technology, Swanson insists that "our investors have deep pockets."

Though Genentech seems to have a clear headstart, it is by no means alone in its determination to cash in on the potential of recombinant-DNA technology.

company in Berkeley, Calif. Though annual revenues have now pushed over the $2 million mark, profits have been minimal. But Cetus is about to reap income from royalties on a contract that may boost annnal revenues by $1 million. And it has a running start in what may be a big new business by the 1980s.

"The most dramatic technological revolntion of the next 25 years will be based on biological science," predicts Ronald E. Cape, a biochemist-turned-businessman and a cofounder of Cetus. Cape started Cetus five years ago with Peter J. Farley, a physician and business school graduate, to exploit new discoveries and processes that were emerging in genetics and microbiology. Research in those fields has earned more than half the Nobel Prizes in medicine in the last 20 years, but so far the work has not had much direct industrial impact. Cape thinks that such impact will come soon—first in pharmaceuticals and then in many other industries, including chemicals and mining.

RECRUITING A TEAM

The use of enzymes and living organisms in industrial processes is old hat—much of the world's ethyl alcohol, for example, is made by fermentation. But that technology, more of a practical art, is far removed from the chemistry of chromosomes and the meaning of genetic codes. So the first task for Cape and Farley was to assemble a staff from among scientists at the forefront of knowledge in the new genetics.

That tnrned ont to be the easiest part of the job to date. Says Farley: "It's like owning the first computer company and trying to attract mathematicians." Inclnded in the tiny company's array of directors and advisers are two Nobel laureates: Joshua Lederherg, a pioneering geneticist from Stanford University, and Donald A. Glaser, a physicist and microbiologist from the University of California. Others are Stanley N. Cohen, a leader in the techniques of gene manipulation; Arnold Demain, an expert in industrial fermentation from Massachusetts Institute of Technology; and British geneticist David A. Hopwood.

The star-studded roster helped Cetus to raise its first venture capital, in two private placements totaling $5 million. But that cost Cetus 28% of its 115,000 shares, and it was scarcely enough to support a pioneering development effort in an industry populated with major high-technology companies. "The name of the game," says Cape, "was to survive and prove ourselves."

For survival, the company chose to focus first on a field familiar to all pharmaceutical companies—screening natural bacteria and molds, snch as the penicillins, in a search for mutants that produce new antibiotic compounds or that are more efficient producers of known drugs. Normally, that is a tedious task: Technicians select bacteria that have been exposed to radiation or to chemical componnds that canse genetic changes, smear them onto the surface of nutrient gels, incubate them, and pick off the dot-size bacterial colonies that result. These are cultivated again in flasks. Then the soup that is left must be tested for antibiotic effectiveness.

BETTER BUGS

Cetus aimed to improve the process by using analytical techniques developed for nse in the most advanced microbiological research—in particular, methods arising from Glaser's work in growing mutant strains of bacteria. By reengineering Glaser's processes, Cetus was able to speed the job of screening and testing. It keeps its special equipment nnder proprietary wraps, but essentially its researchers pour a mutant-rich culture into a lab-sized machine that automatically grows, sorts, and nurtures the bacterial colonies. To assay the potency of the chemicals that the cultures produce, Cetus can run colorimetric analyses, bioassays, and more than a dozen other tests. The tests are all automatic, and some are run by computer control.

The speed is impressive. While most large pharmaceutical houses run about 500 such tests a week, Cetus can put 10,000 to 100,000 cultures through its equipment in the same period. "We're not numbers limited," says Farley. But Cetus' highly productive machines did not result in customers lining up outside the door. Nor did they lead to a raft of products that Cetus itself could make.

HARD CONTRACTS

One problem that Cetus did not understand at first was the difficulty of scaling up production from test tubes to a 50,000-gal. antomated process unit of the kind used by drug companies. "They didn't know what they didn't know," says one of

Both the universities and the agencies are, in general, in favour of this scheme. Despite reservations on details, both see it not only as a way of cutting down administrative paperwork and promoting standardised procedures, but also as encouragaing the transfer of technology to private industry.

What has concerned others, however, and has in particular attracted the Monopoly and Anti-competitive Activities Subcommittee of Senator Gaylord Nelson's Select Committee on Small Business, is whether, by allowing universities such rights, the government is giving away more than is in "the public interest" considering the size of its expenditure on university research. Ralph Nader's health research group, for example, in a move which led to the temporary postponement of the implementation of the new regulations, complained to the General Services Agency that the regulations would permit universities and commercial enterprises to "reap hundreds of millions of dollars of profits from work supported by the federal government. In particular such arguments have recently been made about research involving recombinant DNA techniques, for which Dr. Donald Fredrickson, Director of the National Institutes of Health, subsequently decided that no exemption from the standard IPA procedure need be made.

Universities dispute the allegations that patent licensing denies the federal government a major source of income. In particular they claim that the financial benefits received as royalties from the licensing of patents is often much lower than imagined. Addressing hearings of the Senate Subcommittee on behalf of a wide range of educational associations recently, for example, Dr. Thomas Jones, vice-president for research at Massachusetts Institute of Technology, said that the total university income from patent royalties were only about $9 million a year, and that few universities operated licensing programmes in the hlack.

It was also made clear by Dr. Jones, however, that the gain to nniversities of negotiating licenses directly with private industry is not primarily financial, but that such practices help to establish links between the two sectors. Industry is more prepared to collaborate with a university if it can be sure that the results of research will be available for licensing.

The universities will have a further chance to argue their case at a second series of hearings planned by the subcommittee for 20, 21 and 26 June. These hearings are expected to focus on ways in which the subcommittee feels that the proposed IPAs would be more liberal than those currently in force.

Two issues in particular have already attracted the attention of the suhcommittee, which is at present carrying out a two year study of federal patent policy. The first is the amount of time for which a university will be permittted to grant exclusive license to a manufacturer who is only prepared to undertake production on this basis. At present, exclusive licenses can be granted for a period of eight years, or three years from the date of first sale of a product, whichever is the shorter. Under the new regulations, the three years would be extended to five and allowance would also be made for time taken by a regulatory agency to make its pre-market clearance.

The universities argue that they must be able to maximise the attraction of a particular patent to a potential investor. "Market development costs are often much greater than the physical cost of invention. Private enterprise therefore has to he given some incentive in order to be confident of a reasonable profit", according to Mr. William Bremer of Wisconsin University.

The Senate Subcommittee, however, has expressed concern at the "monopoly" effect of issuing exclusive licenses. It claims that although under both the present and projected form of the IPA, these are intended to be the exception rather than the rule, in practice most licenses are granted on such a basis. A second concern is over who should decide whether a research worker should be granted a license to develop a discovery he has made. In the initial draft of the new regulations, it was suggested that, in line with current practice at the NSF, this would require the agreement of the agency which had sponsored the research.

When this draft was sent out for comment, however, many universities reacted strongly against it, claiming that it would reduce the incentive for the individual research worker to report a potentially patentable discovery. The provision has now been dropped from the proposed regulations, raising the subcommittee's concern that universities may offer exclusive licences to a research worker rather than seeking outside, more appropriate, licensees.

Are there any alternatives to IPAs? William Carey, executive officer of the American Association for the Advancement of Science, together with others, feels that they should be dropped altogether as an unnecessary impedauce on the flow of scientific ideas into the technological marketplace.

[From the New York Times, Apr. 15, 1978, p. 11]

RESEARCH-ORIENTED SCHOOLS FACE BATTLE ON RULES

(By Malcolm W. Browne)

A battle related to Federal sponsorship of scientific research at private universities, with hundreds of millions of dollars at stake, has reached the White House, and President Carter is expected to take a stand on the issues soon.

A number of universities specializing in Government-sponsored research are contending with consumer advocates and several branches of the Government itself over two questions: What kinds of patent rights Universities should hold to the fruits of Government-sponsored research, and whether the Government should continue to pay indirect costs of such research.

Both questions have already been brought before Dr. Frank Press, the President's adviser on science and technology policy.

Lester A. Fettig, who as director of the Office of Federal Procurement Policy, is closely involved with the university patent issue, said in an interview that an option paper was being prepared for the President, outlining various alternatives.

"MAXIMIZE NATIONAL TECHNOLOGY"

"Ultimately," he said, "the question will go to the President. It's that important an issue. Such fundamental matters as the fall in value of the dollar are directly related to the need to maximize national technology, and that in turn is affected by inducements provided by the patent system."

The patent controversy came to a head in February, when the General Services Administration published a proposed new set of regulations that would have extended universities' patent rights from three years to five years (the patents then come under Government control) and would have permitted universities to affiliate with commercial patent management companies, among other things.

In general, the research-oriented universities, some of which have large earnings from licensing their patents to private business, were pleased. The regulations were to have taken effect March 20.

However, Ralph Nader, the consumer advocate, and his associates charged that the Federal Government was engaged in a "give-away" of research paid for by public taxes to benefit private business. In a letter to the General Services Administration, Mr. Nader's group contended that over the next decade the proposed patent regulations would permit commercial enterprises to "reap hundreds of millions of dollars of profits from work supported by the Federal Government."

ASKED FOR A DELAY

At that point, Senator Gaylord Nelson, a Wisconsin Democrat, whose Committee on Small Business had already held the first in a series of hearings on the new rules, asked the Office of Management and Budget for a 120-day delay so that they could be given further study. The O.M.B., of which Mr. Fettig's office is a part, promptly complied.

Administrators at universities with extensive patent agreements with private industry became increasingly concerned. But another Government move inspired agitation verging on panic in some university offices.

On March 10, the Office of Management and Budget puhlished a proposed new set of regulations and accounting procedures for the indirect costs of federally sponsored research at universities. Such costs normally include various kinds of overhead, certain library costs and some of the costs involved in supporting graduate students who act as research assistants.

Officials of Stanford University in California, among other institutions, were aghast at the proposals.

Stanford announced that the changes would reduce Government reimbursement of indirect costs by 20 to 30 percent. In Stanford's case, this would meau a loss of at least $4.5 million annually; for all universities doing federally funded research, the loss would be about $170 million.

Stanford spokesmen said that such a loss of revenue would inevitably affect students through increased tuition fees and would degrade scientific research generally. Associate Controller Frank Riddle said: "What is so obviously lacking in these proposals is a national policy for basic research in higher education."

In an interview, John J. Lordan, director of the O.M.B. Financial Management Branch, called such charges "balderdash."

nets might extract iron ore weak in magnetism from a slurry. Such a process, Boom argues, could help a mining company begin recovering hematite, for example, and thereby postpone spending the $50 million to $100 million it takes to open a new mine. Several companies approached him about the process, says Boom, but none would touch it without patent protection. "If the university had an IPA, we think we could attract the commercial support," he says.

On the other hand, universities are by no means unanimous in their enthusiasm for patent rights to research. Richard M. Cyert, president of Carnegie-Mellon University, calls patents "sinkholes for funds" because the school must

The hard-line Energy Dept. is a particular target of the angry researchers

spend its own money to develop them. What is more, Cyert favors retention of patent rights only with the stern proviso that commercial possibilities should not dominate research aims. "The university should have two objectives," he says, "the transmission of knowledge and the creation of knowledge." And, he adds, "publication is more important to us than patents."

Yet without patent protection, the commercial prospects for new technology are dimmed. University researchers angrily claim that, in particular, the Energy Dept.'s hard-line opposition to IPA deals has stifled innovation. "We have weathered a strong attack from the university community," concedes the department's patent counsel, Robert M. Poteat. "The DOE approach," says Barnes of the University of Virginia, "has killed a lot of ideas."

An undeclared President. Whether or not the OMB rules and the congressional patent hearings end up killing even more ideas remains to be seen. Both OMB and Press's office have circulated a patent options paper among executive agencies asking for comment. HEW is conducting an internal review of its patent policies, and Jordan J. Baruch, Assistant Commerce Secretary for science and technology, is leading an even more ambitious study of the problems.

In the meantime, John J. Lordan, chief of the OMB's financial management branch, contends, "We are not trying to harm universities," and he points out that the OMB move is less strict than one suggested by HEW and does not go nearly as far as some proposals in Congress. The President has yet to declare himself on the patent issue, nor are there signs of internal pressure on OMB to scale back its expense-limitation regulations. In that climate, says an official in Press's office, "universities should be worried."■

NSF Patent Shift to Benefit Universities

The National Science Foundation is on the verge of announcing a major change in its patent policies that will allow qualifying institutions to be guaranteed in advance the royalties from faculty inventions that result from projects supported by NSF.

The new policy will also remove limitations previously imposed on the amount of royalties that could go to the individual inventor, thus opening the possibility that both the inventor and his institution can reap greater financial rewards from NSF-sponsored research.

The changes at NSF are generally in line with the thrust of recommendations mady by an interagency group operating under the Federal Council for Science and Technology (FCST). That group, known as the University Subcommittee on Patent Policy, has been studying ways to overcome barriers to technology transfer between the universities and industry.

According to Norman J. Latker, chief of HEW's patent branch and chairman of the subcommittee, the FCST group concluded it is "essential" that the government persuade universities to develop a management capability for transferring the inventions emerging from university research to those industrial concerns most likely to use the results. The inducement proposed by the subcommittee—and still under review within FCST—is that the government might, at the time it awards research funds, guarantee patent rights to any university that can demonstrate the requisite management capability.

That's essentially what NSF now proposes to do. Under a new policy that has been approved by the Foundation's policy-making National Science Board but has not yet been made public, NSF will be authorized to "enter into separate institutional agreements with academic or other nonprofit organizations which are capable of aggressively promoting the use of inventions and have competent patent counsel available and an active ongoing program of patent management." Such agreements may provide that all inventions made under NSF awards belong to the institution, subject to certain limitations, and they will require that the institution use any net royalty income "for the support of education or scientific research." The government will retain the right to use the invention without paying royalties.

Previously, the Foundation had generally determined patent rights on a "deferred determination" basis—that is, after an invention had emerged, NSF and the institution would negotiate over who owned the patent rights. Although NSF generally granted patent rights to most universities that requested them, the situation produced uncertainty in university and industry circles and is said to have hampered efforts to bring about closer collaboration between the two spheres.

The chief reason for the new policy, according to NSF counsel Charles F. Brown, is that the universities are generally in a better position than NSF to promote the use of their inventions. "We don't have the staff to sell licenses effectively," he told SGR. Moreover, since NSF's mission is to support research and education, Brown said, the Foundation considers it "socially desirable" for universities to be able to obtain income from patent royalties that can be applied to those purposes. Such income can be substantial (see box, page 3.)

Brown estimated that perhaps 30 to 40 institutions have the management capability to qualify under the new policy. Currently most universities either leave it up to faculty members to seek their own patents or contract with outside organizations, such as The Research Corporation, of New York, to handle patents and licensing. But many universities with large research volumes have set up special offices or related foundations which screen the faculty for patentable ideas and then aggressively try to sell those ideas to industry.

The second major change in NSF's patent policy was to remove a restriction that the individual inventor, who generally shares in the royalties with his institution, could receive only 15 percent of the gross royalties. Brown said the original reason for imposing the limitation was to keep investigators focused on basic research rather than concentrating on profits. But since NSF's basic research orientation has been "seriously eroded" by new applied programs, he said, "we figured it didn't make much difference" if the limitation was dropped. Brown noted that some schools, such as the University of California, award the inventor up to 50 percent, and thus manage to flush out a lot more ideas than would otherwise emerge.

A few other agencies already have policies similar to the impending policy at NSF. Latker said in a recent speech that both HEW and the Defense Department guarantee qualifying institutions a first option to administer inventions generated with government support. And he reported that NASA is "willing to entertain" requests for such institutional agreements. Those three agencies plus NSF, he noted, provide about $2 billion of the $3 billion in federal support for university research. As Latker expressed it, the concept "is here to stay and grow because it basically reflects a grass-roots desire."

99-R0408
A 4/14/98

STATUS OF NSF-FUNDED INVENTION

NSF File Number: Disclosure Date: Waiver Date:

Grantee Institution: Inventor(s):

Invention Title:

Individual or Organization seeking licensees for invention:

☐ U.S. Patent Application filed. Date: _____; S.N.: _____.

☐ U.S. Patent granted. Date: _____; No.: _____.

Status of patent application if not yet granted: _____.
If U.S. patent has been denied or the application has been abandoned, has the invention been disclosed in a publication? _____.

If so: Journal title: _____; Date: _____.

FIRST LICENSEE: _____; Date of license: _____.

Total license payments to grantee before Oct. 1, 1976: $_____.

Payments from Oct. 1, 1976 to Sep. 30, 1977: $_____; Oct. 1, 1977 to Sep. 30, 1978: $_____; Oct. 1, 1978 to Sep. 30, 1979: $_____.

Has the invention been put into commercial use under this license? _____.
If so, give date and describe briefly; if not, describe any intended commercial use (use back for extended comments). Date: _____;
Description:

SECOND LICENSEE: _____; Date of license: _____.

Total license payments to grantee before Oct. 1, 1976: $_____.

Payments from Oct. 1, 1976 to Sep. 30, 1977: $_____; Oct. 1,1977 to Sep. 30, 1978: $_____; Oct. 1, 1978 to Sep. 30, 1979: $_____.

Has the invention been put into commercial use under this license? _____.
If so, give date and describe briefly; if not, describe any intended commercial use (use back for extended comments). Date: _____;
Description:

Please provide above information for further licenses on the back, and check here: ____. Is invention available to other licensees? _____.
Are you still actively seeking licensees? Yes_____ No_____.

FOREIGN PATENT STATUS

Country of filing	Filing date	Filing No.	Date Granted	Patent No.

The Privacy Act of 1974 requires the agencies to give advance notice to the Congress and the Office of Management and Budget of their intent to establish or modify systems of records subject to the Act (5 U.S.C. 552a(o)). During the period January 9, 1978, through February 3, 1978, no new or revised systems of records were received. During the period February 6, 1978, through February 17, 1978, the Office of Management and Budget received the following reports on new (or revised) systems of records.

COPYRIGHT OFFICE

Systems of records. (1) Notices of institution of actions for the infringement of works refused registration.

(2) Deposit recordation file.

Report date. January 26, 1978.

Point of contact. Mr. Jon Baumgarten, General Counsel, Copyright Office, Library of Congress, Arlington, Va. 22202.

Summary. The first system will be used by the Copyright Office to determine whether the Register of Copyrights will join these actions on the issue of registrability of the copyright claim. The second system will be used to keep records of compliance with the requirement to deposit copies and phonorecords of copyrighted works and to locate and correspond with those who do not comply.

DEPARTMENT OF DEFENSE

System of record. DOD health services enrollment eligibility system.

Report date. January 27, 1978.

Point of contact. Mr. William Cavaney, Department of Defense, Forrestal Building, 1000 Independence Avenue, Washington, D.C. 20314.

Summary. This system is intended to "create a central automated file of all personnel who are legally eligible * * * to receive health care benefits from the Uniformed Services Health Services Delivery System" for determining eligibility for care, and to conduct longitudinal research for planning and managing medical resources.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

System names. (1) Blood donors for tissue typing sera and cell analysis and related research.

(2) Medical library management intern program.

Report date. February 3, 1978.

Point of contact. Mr. John D. Young, Department of Health, Education, and Welfare, Washington, D.C. 20201.

Summary. The purpose of the first system is "to provide data to be used in evaluating histocompatibility testing sera submitted by manufacturers for approval and release on the market." The second system will be used to "facilitate the processing aud review of applications" for the National Library of Medicine's management intern program.

services apply only to instruction and therefore are not normally allowable. However, when students actually engage in work under sponsored agreements, a proportion of student services costs measured by the relationship between hours of work by students on such sponsored work and total student hours may be allowed.

42. *Taxes.* a. In general, taxes which the institution is required to pay and which are paid or accrued in accordance with generally accepted accounting principles are allowable. Payments made to local governments in lieu of taxes which are commensurate with the local government services received are allowable, except for: (1) taxes from which exemptions are available to the institution directly or which are available to the institution based on an exemption afforded the Government, and in the latter case when the sponsoring agency makes available the necessary exemption certificates; and (2) special assessments on land which represent capital improvements.

b. Any refund of taxes, interest, or penalties, and any payment to the institution of interest thereon, attributable to taxes, interest, or penalties which were allowed as sponsored agreement costs, will be credited or paid to the Government in the manner directed by the Government, provided any interest actually paid or credited to an institution incident to a refund of tax, interest, and penalty will be paid or credited to the Government only to the extent that such interest accrued over the period during which the institution had been reimbursed by the Government for the taxes, interest, and penalties.

43. *Transportation costs.* Costs incurred the freight, express, cartage, postage, and other transportation services relating either to goods purchased, in process, or delivered, are allowable. When such costs can readily be identified with the items involved, they may be charged directly as transportation costs or added to the cost of such items. Where identification with the materials received cannot readily be made, inbound transportation costs may be charged to the appropriate indirect cost accounts if the institution follows a consistent, equitable procedure in this respect. Outbound freight, if reimbursable under the terms of the sponsored agreement, should be treated as a direct cost.

44. *Travel costs.* a. Travel costs are the expenses for transportation, lodging, subsistence, and related items incurred by employees who are in travel status on official business of the institution. Such costs may be charged on an actual basis, on a per diem or mileage basis in lieu of actual costs incurred, or on a combination of the two, provided the method used is applied to an entire trip and not to selected days of the trip, and results in charges consistent with those normally allowed by the institution in its regular operations.

b. Travel costs are allowable subject to c, d, e, and f below, when they are directly attributable to specific work under a sponsored agreement or are incurred in the normal course of administration of the institution or a department or research program thereof.

c. The difference in cost between first class air accommodations and less than first-class air accommodations is unallowable except when less than first-class air accommodations are not reasonably available to meet necessary mission requirements, such as where less than first-class accommodations would (1) require circuitous routing, (2) require travel during unreasonable hours, (3) greatly increase the duration of the flight, (4) result in additional costs which would offset the transportation savings, or (5) offer accommodations which are not reasonably adequate for the medical needs of the traveler.

d. Costs of personnel movements of special or mass nature are allowable only when authorized or approved in writing by the sponsoring agency or its authorized representative.

e. Foreign travel costs are allowable only when the travel has received specific prior approval. Each separate foreign trip must be specifically approved. For purposes of this provision, foreign travel is defined as "any travel outside of Canada and the United States and its territories and possessions."

f. When an amount for domestic travel is specified in the sponsored agreement, expenditures for such travel will not be allowed if they exceed the amount specified by more than 25 percent or $500, whichever is greater, except with an advanced approval of the sponsoring agency.

45. *Termination costs applicable to sponsored agreements.* a. Termination of sponsored agreements generally gives rise to the incurrence of costs or to the need for special treatment of costs, which would not have arisen had the agreement not been terminated. Items peculiar to termination are set forth below. They are to be used in conjunction with all other provisions of this Circular in the case of termination.

(taking into consideration recruitment purposes for which intended and normal institutional practices in this respect), are unallowable.

c. Costs of help wanted advertising, special emoluments, fringe benefits, and salary allowances incurred to attract professional personnel from other institutions that do not meet the test of reasonableness or do not conform with the established practices of the institution, are unallowable.

d. Where relocation costs incurred incident to recruitment of a new employee have been allowed either as an allocable direct or indirect cost, and the newly hired employee resigns for reasons within his control within twelve months after hire, the institution will be required to refund or credit such location costs to the Government.

33. *Rental cost of buildings and equipment.* a. Subject to the limitations described in b through d below, rental costs are allowable to the extent that the rates are reasonable in light of such factors as rental costs of comparable property, if any; market conditions in the area; alternatives available; and the type, life expectancy, condition, and value of the property leased.

b. The institution should make a reasonable, periodic determination whether comparable or suitable space or equipment is available within the institution. When comparable or suitable space is available, the institution must justify why noninstitution space is being rented.

c. Rental costs under "sale and leaseback" arrangements are allowable only up to the amount that would be allowed if the institution continued to own the property.

d. Rental costs under "less-than-arms-length" leases are allowable only up to the amount that would be allowed if the institution owned the property. For this purpose, a less-than-arms-length lease is one under which one party to the lease agreement is able to control or substantially influence the actions of the other. Such leases include those between: (1) divisions of an institution; (2) institutions or organizations under common control through common officers, directors, or members; and (3) an institution and a director, trustee, officer, or key employee of the institution or his immediate family either directly or through corporations, trusts, or similar arrangements in which they hold a controlling interest.

(e) Rental costs under leases which create a material equity in the leased property are allowable only up to the amount that would be allowed if the institution purchased the property on the date the lease agreement was executed. For this purpose, a material equity in the property exists when the lease:

(1) Is noncancelable or is cancelable only upon the occurrence of some remote contingency, and

(2) Has one of more of the following characteristics:

(a) Title to the property passes to the institution at some time during or after the lease period.

(b) The term of the lease corresponds substantially to the estimated nseful life of the property (i.e., the period of economic usefulness to the legal owner of the property).

(c) The initial term is less than the useful life of the property and the institution has the option to renew the lease for the remaining useful life at substantially less than fair rental value.

(d) The property was acquired by the leasor to meet the special needs of the institution and will probably be useable only for that purpose and only by the institution.

(e) The institution has the right, during or at the expiration of the lease, to purchase the property at a price which at the inception of the lease appears to be substantially less than the probable fair market value at the time it is permitted to purchase the property (commonly called a lease with a bargain purchase option).

34. *Royalties and other costs for use of patents.* Royalties on a patent or amortization of the cost of acquiring a patent or invention or rights thereto, uecessary for the proper performance of the sponsored agreement and applicable to tasks or processes thereunder, are allowable unless the Government has a license or the right to free use of the patent, the patent has been adjudicated to be invalid or has been administratively determined to be invalid, the patent is considered to be unenforceable, or the patent has expired.

35. *Sabbatical leave costs.* Costs of leave of absence by employees for performance of graduate work or sabbatical study, travel, or research are allowable provided the institution has a uniform policy on sabbatical leave for persons engaged in instruction and persons engaged in research. Such costs will be allocated

rates and premiums would have been allowed had insurance been purchased to cover the risks.

d. Actual losses which could have been covered by permissible insurance (through an approved self-insurance program or otherwise) are unallowable, unless expressly provided for in the sponsored agreement, except that costs incurred because of losses not covered under existing deductible clauses for insurance coverage provided in keeping with sound management practices as well as minor losses not covered by insurance, such as spoilage, breakage and disappearance of small hand tools, which occur in the ordinary course of operations, are allowable.

(e) Indemnification includes securing the institution against liabilities to third persons and other losses not compensated by insurance or otherwise. The Government is obligated to indemnify the institution only to the extent expressly provided for in the sponsored agreement, except as provided in d above.

17. *Interest, fund raising, and investment management costs.* a. Costs incurred for interest on borrowed capital or temporary use of endowment funds, however represented, are unallowable.

b. Costs of organized fund raising, including financial campaigns, endownment drives, solicitation of gifts and bequests, and similar expenses inclurred solely to raise capital or obtain contributions, are unallowable.

c. Costs of investment counsel and staff and similar expenses incurred solely to enhance income from investments are unallowable.

d. Costs related to the physical custody and control of mouies and securities are allowable.

18. *Labor relations costs.* Costs incurred in maintaining satisfactory relations between the institution and its employees, including costs of labor management committees, employees' publications, and their related activities, are allowable.

19. *Losses on other sponsored agreements or contracts.* Any excess of costs over income under any other sponsored agreement or contract of any nature is unallowable. This includes, but is not limited to, the institution's contributed portion by reason of cost-sharing agreements or any under recoveries through negotiation of flat amounts for indirect costs.

20. *Maintenance and repair costs.* Costs incurred for necessary maintenance, repair or upkeep of property (including Government property unless otherwise provided for) which neither add to the permanent value of the property nor appreciably prolong its intended life but keep it in an efficient operating condition, are allowable.

21. *Material costs.* Costs incurred for purchased materials, supplies, and fabricated parts directly or indirectly related to the sponsored agreements, are allowable. Purchases made specifically for the sponsored agreement should be charged thereto at their actual prices after deducting all cash discounts, trade discounts, rebates, and allowances received by the institution. Withdrawals from general stores or stockrooms should be charged at their cost under any recognized method of pricing stores withdrawals conforming to sound accouuting practices consistently followed by the institution. Incoming transportation charges are a proper part of material cost. Direct material cost should include only the materials and supplies actually used for the performance of the sponsored agreement, and due credit should be given for any excess materials retained, or returned to vendors. Due credit should be given for all proceeds or value received for any scrap resulting from work under the sponsored agreement. Where Government-donated or furnished material is used in performing the sponsored agreement, such material will be used without charge.

22. *Memberships, subscriptions, and professional activity costs.* a. Costs of the institution's membership in civic, business, technical, and professional organizations are allowable.

b. Costs of the institution's subscriptions to civic, business, professional, and technical periodicals are allowable.

c. Costs of meetings and conferences, when the primary purpose is the dissemination of technical information, are allowable. This includes costs of meals, transportation, rental of facilities, and other items incidental to snch meetings or conferences.

23. *Patent costs.* Costs of preparing disclosures, reports, and other documents required by the sponsored agreement, and of searching the art to the extent necessary to make sure invention disclosures, are allowable. In accordance with the clauses of the sponsored agreement relating to patents, costs of preparing documents and any other patent costs, in connection with the filing of a patent application where title is conveyed to the Government, are allowable. (See also section J34.)

ing if they can be removed without the need for costly or extensive alterations or repairs to the building to make the space usable for other purposes. Equipment and assets which meet these criteria will be subject to the six and two-thirds percent equipment use allowance.

(3) A reasonable use allowance may be negotiated for any assets that are considered to be fully depreciated, after taking into consideration the amount of depreciation previously charged to the Government, the estimated useful life remaining at the time of negotiation, the effect of any increased maintenance charges, decreased efficiency due to age, and any other factors pertinent to the utilization of the asset for the purpose contemplated.

d. Except as otherwise provided in b and c above, a combination of the depreciation and use allowance methods may not be used for a single class of assets (e.g., buildings, office equipment, and computer equipment).

e. Charges for use allowances or depreciation must be supported by adequate property records, and physical inventories must be taken at least once every two years to ensure that the assets exist and are usable, used, and needed. In addition, when the depreciation method is used, adequate depreciation records showing the amount of depreciation taken each period must also be maintained.

10. *Donated services and property.* The value of donated services and property are not allowable either as a direct or indirect cost, except that depreciation or use allowances on donated assets are permitted in accordance with Section J9a. The value of donated services and property may be used to meet cost sharing or matching requirements, in accordance with OMB Circular No. A–110.

11. *Employee morale, health, and welfare costs, and credits.* The cost of house publications, health or first-aid clinics and/or infirmaries, recreational activities, employees' counseliug services, and other expenses incurred in accordance with the institution's established practice or custom for the improvement of working conditions, employer-employee relations, employee morale, and employee performance, are allowable. Such costs will be equitably allocated to all activities of the institution in proportion to the distribution of salary and wage costs. Iucome generated from any of these activities will be credited to the cost thereof unless such income has been irrevocably set over to employee welfare organizations.

12. *Entertainment costs.* Costs incurred for amusement, social activities, entertainment, and any items relating thereo, such as meals, lodging, rentals, transportation, and gratulties, are unallowable.

13. *Equipment and other capital expenditures.* a. For purposes of this paragraph, the following definitions apply.

(1) *Equipment* means an article of nonexpendable tangible personal property having a useful life of more than one year and an acquisition cost of $300 or more per unit.

(2) *Capital expenditure* means the cost of the asset including the cost to put it in place. Capital expenditure for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Ancillary charges, such as taxes, duty, protective intransit insurance, freight, and installation may be included in, or excluded from, capital expenditure cost in accordance with the institution's regular accounting practices.

(3) *Special purpose equipment* means equipment which is usable only for research, medical, scientific, or other technical activities. Examples of special purpose equipment include microscopes, x-ray machines, surgical instruments, and spectrometers.

(4) *General purpose equipment* means equipment, the use of which is not limited only to research, medical, scientific or other technical activities. Examples of general purpose equipment include office equipment and furnishings, air conditioning equipment, reproduction and printing equipment, motor vehicles, and automatic data processing equipment.

b. The following rules of allowability shall apply to equipment and other capital expenditures:

(1) Capital expenditures for general purpose equipment, buildings, and land are unallowable except where such expenditures are specifically approved in advance by the sponsoring agency.

(2) Capital expenditures for special purpose equipment are allowable as direct costs, provided that the acquisition of items having a unit cost of $1,000 or more is approved in advance by the sponsoring agency.

(3) Capital expenditures for improvements to land, buildings, or equipment which materially increase their value or useful life are unallowable, except

the percentage of activity applicable to and chargeable to each sponsored agreement, (b) activity required to meet mandatory cost sharing, (c) activity applicable to each indirect cost category, and (4) activity applicable to other cost categories.

(4) To confirm that the distribution of activity represents a reasonable estimate of the work performed by the employee during the period, each report will be signed by the employee or by a responsible official having first hand knowledge of the work performed.

(5) For professorial and professional employees, the reports will be prepared each academic period or no less frequently than twice a year. For other individuals, the reports will be prepared no less frequently than monthly and will coincide with pay periods.

(6) Where the institution uses time cards or other forms of after-the-fact payroll documents as original documentation for payroll and payroll charges, such documents shall qualify as a personnel activity report provided that they are signed in accordance with (4) above.

e. *Salary rates for faculty members*—(1) *Salary rates for academic year.* Charges for work performed on sponsored agreements by faculty members during the academic year will be based on the individual faculty member's regular compensation for the continuous period which, under the policy of the institution concerned, constitutes the basis of his salary. Charges for work performed on sponsored agreements during all or any portion of such period are allowable at the base salary rate. In no event will charges to sponsored agreements, irrespective of the basis of computation, exceed the proportionate share of the base salary for that period. This principle applies to all members of the faculty at an institution. Since intra-university consulting is assumed to be undertaken as a university obligation requiring no compensation in addition to full-time base salary, the principle also applies to faculty members who function as consultants or otherwise contribute to a sponsored agreement conducted by another faculty member of the same institution. However, in unusual cases where consultation is across departmental lines or involves a separate or remote operation, and the work performed by the consultant is in addition to his regular departmental load, any charges for such work representing extra compensation above the base salary are allowable provided that such consulting arrangements are specifically provided for in the agreement or approved in writing by the sponsoring agency.

(2) *Periods outside the academic year.* (a) Except as otherwise provided in (b) below, charges for work performed by faculty members on sponsored agreements during the summer months or other period not included in the base salary period will be determined for each faculty member at a monthly rate not in excess of the base salary divided by the number of work months in the period for which the base salary is paid, and will be limited to charges made in accordance with other parts of this section. The base salary period used in computing charges for work performed during the summer months will be the number of months covered by the faculty member's official academic year appointment.

(b) Charges for teaching activities performed by faculty members on sponsored agreements during the summer months or other periods not included in the base salary period will be based on the normal policy of the institution governing compensation to faculty members for teaching assignments during such periods.

(3) *Part-time faculty.* Charges for work performed on sponsored agreements by faculty members having only part-time appointments will be determined at a rate not in excess of that regularly paid for the part-time assignments; e.g., an institution pays $5,000 to a faculty member for half-time teaching during the academic year. He devoted one-half of his remaining time (25 percent of his total available time) to a sponsored agreement. Thus, his additional compensation, chargeable by the institution to the agreement, would be one-half of $5,000, or $2,500.

f. *Noninstitutional professional activities.* Unless an arrangement is specifically authorized by a Federal sponsoring agency, an institution must follow its institution-wide policies and practices concerning the permissible extent of professional services that can be provided outside the institution for noninstitutional compensation. Where such institution-wide policies do not exist or do not adequately define the permissible extent of consulting or other noninstitutional activities undertaken for extra outside pay, the Government may require that the effort of professional staff working on sponsored agreements be allocated between (1) institutional activities, and (2) noninstitutional professional activities. If the sponsoring agency considers the extent of noninstitutional professional effort excessive, appropriate arrangements governing compensation will be negotiated on a case-by-case basis.

e. Apply the indirect cost rate to direct salaries and wages for individual agreements to determine the amount of indirect costs allocable to such agreements.

J. GENERAL STANDARDS FOR SELECTED ITEMS OF COST

Sections 1 through 45 below provide standards to be applied in establishing the allowability of certain items involved in determining cost. These standards should apply irrespective of whether a particular item of cost is properly treated as direct cost or indirect cost. Failure to mention a particular item of cost in the standards is not intended to imply that it is either allowable or unallowable; rather determination as to allowability in each case should be based on the treatment or standards provided for similar or related items of cost. In case of discrepancy between the provisions of a specific sponsored agreement and the applicable standards provided, the provisions of the agreement should govern.

1. *Advertising costs.* a. The term advertising costs means the costs of advertising media and corollary administrative costs. Advertising media include magazines, newspapers, radio and television programs, direct mail, exhibits, and the like.

b. The only advertising costs allowable are those which are solely for (1) the recruitment of personnel required for the performance by the institution of obligations arising under the sponsored agreement, when considered in conjunction with all other recruitment costs, as set forth in Section J32; (2) the procurement of goods and services for the performance of the sponsored agreement; (3) the disposal of scrap or surplus materials acquired in the performance of the sponsored agreement except when institutions are reimbursed for disposal costs at a predetermined amount in accordance with Attachment N, OMB Circular No. A–110; or (4) other specific requirements of the agreement.

c. Costs of this nature, if incurred for more than one sponsored agreement or for both sponsored work and other work of the institution, are allowable to the extent that the principles in sections D and E are observed.

2. *Bad debts.* Any losses, whether actual or estimated, arising from uncollectible accounts and other claims, related collections costs, and related legal costs, are unallowable.

3. *Civil defense costs.* Civil defense costs are those incurred in planning for, and the protection of life and property against, the possible effects of enemy attack. Reasonable costs of civil defense measures (including costs in excess of normal plant protection costs, first-aid training and supplies, firefighting training, posting of additional exit notices and directions, (and other approved civil defense measures) undertaken on the institution's premises pursuant to suggestions or requirements of civil defense authorities are allowable when distributed to all activities of the institution. Capital expenditures for civil defense purposes will not be allowed, but a use allowauce or depreciation may be permitted in accordance with provisions set forth in Section J9. Costs of local civil defense projects not on the institution's premises are unallowable.

4. *Commencement and convocation costs.* Costs incurred for commencements and convocations are unallowable.

5. *Communication costs.* Costs incurred for telephone services, local and long distance telephone calls, telegrams, radiograms, postage and the like, are allowable.

6. *Compenstaion for personal services*—a. *General.* Compensation for personal services covers all remuneration paid currently or accrued by the institution for services of employees rendered during the period of performance under sponsored agreemeuts. Such remuneration includes salaries, wages, and fringe benefits (see section J15). The costs of such remuneration are allowable to the extent that the total compensation to individual employees conforms to the established policies of the institution, consistently applied. *And provided*, That the charges for work performed directly on sponsored agreements and for other work allocable as indirect costs are determined and supported as hereinafter provided. Charges to Government agreements may include reasonable amounts for activities contributing and intimately related to work under the agreements, such as delivering special lectures about specific aspects of the ongoing activity, writing reports and articles, participating in appropriate seminars, consulting with colleagues and graduate students, and attending meetings and conferences.

b. *Payroll distribution.* For each organizational unit of an institution, amounts charged as salaries and wages for professorial or professional services applicable to sponsored agreements, whether treated as direct costs or as indirect costs, will be based on either a system of monitored workloads or a system of personnel

support solely, specifically, and directly, in whole or in part, any of the administrative or service activities described in F1 through 7.

b. Amounts negotiated as applicable institutional indirect costs for research centers or Government-owned-institution-operated laboratories shall be treated as offset provided that such amonnts represent a reasonable approximation of the indirect costs allocable to the center or laboratory. If such amounts do not represent a reasonable approximation of these costs, they shall be disregarded and the indirect costs for the centers and laboratories shall be determined in accordance with the indirect cost procedures set forth in these principles.

c. The items in this group shall be treated as a credit to those affected elements of each individual indirect category before that category is allocated to benefiting functions.

G. DETERMINATION AND APPLICATION OF INDIRECT COST RATE OR RATES

1. *Indirect cost pools.* a Subject to b below, the separate categories of indirect costs allocated to each major function of the institution as prescribed in Section F shall be aggregated and treated as a common pool for that function. The amount in the common pool shall be divided by the distribution base described in G2 below to arrive at a single indirect cost rate. The single indirect cost rate then is used to distribute indirect costs in the common pool to the individual sponsored agreements of that junction. Since a common pool is established for each major function of the institution, a separate indirect cost rate would be established for research, educational services, and other types of sponsored projects.

b. In some instances a single rate basis for use across the board on all sponsored projects within a major function at an institution may not be appropriate. A single rate for research, for example, would not take into account those different environmental factors and other conditions which may affect substantially the indirect costs applicable to a particular segment of Government research at the institution. For this purpose, a particular segment of sponsored research may he that performed under a single sponsored agreement or it may consist of research under a group of sponsored agreements performed in a common environment. The environmental factors are not limited to the physical location of the work. Other important factors are the level of the administrative support required, the nature of the facilities or other resources employed, the scientific disciplines or technical skills involved, the organizational arrangements used, or any combination thereof. Where a particular segment of federally-sponsored work is performed within an environment which appears to generate a significantly different level of indirect costs, provision should be made for a separate indirect cost pool applicable to such work. The separate indirect cost pool should he developed during the regular course of the rate determination process and the separate indirect cost rate resulting therefrom should be utilized provided it is determined that (1) such indirect cost rate differs significantly from that which would have been obtained under a. above, and (2) the volume of work to which such rate would apply is material in relation to other federally-sponsored work at the institution.

2. *The distribution basis.* Indirect costs shall be distributed to applicable sponsored agreements on the basis of modified total direct costs, consisting of salaries and wages, fringe benefits, materials and supplies, travel, and subgrants and subcontracts up to $5,000 each. For this purpose, an indirect cost rate should be determined for each of the separate indirect cost pools developed pursuant to 1. above. The rate in each case should be stated as the percentage which the amount of the particular indirect cost pool is of the modified total direct costs identified with such pool. Other bases may be used only where it can be clearly demonstrated that they produce more equitable results.

3. *Negotiated lump sum for indirect costs.* A negotiated fixed amount in lieu of indirect costs may be appropriate for self-contained, off-campus, or primarily subcontracted activities where the benefits derived from an institution's indirect services cannot be readily determined. Such negotiated indirect costs will be treated as an offset to total indirect expenses before allocation to instruction, organized research, and other institutional activities. The base on which such remaining expenses are allocated should be appropriately adjusted.

4. *Predetermined fixed rates for indirect costs.* Public Law 87–638 (76 Stat. 437) authorizes the use of predetermined fixed rates in determining the indirect costs applicable under research agreements with educational institutions. The stated objectives of the law are to simplify the administration of cost-type research and development contracts (including grants) with educational institu-

istrative offices of educational institutions and other expenses of a general character which do not relate solely to any major division of the institution; i.e., solely to (1) instruction, (2) organized research, (3) other sponsored programs, or (4) other institutional activities. The general administration and general expense category should also include the fringe benefit costs applicable to the salaries and wages included therein, an appropriate share of operation and maintenance expense, and depreciation and use allowances.

b. The expenses included in this category shall be grouped according to common function(s) to which they render services or provide benfits. The aggregate expenses of each group shall then be allocated to benefitting functions on the modified total cost basis. Modified total costs consist of salaries and wages, fringe benefits, materials and supplies, travel, and subgrants and subcontacts up to $5,000 each. When an activity included in this indirect cost category provides a service or product to another institution or organization, an appropriate adjustment must be made to either the expenses or the basis of allocation or both, to assure a proper allocation of costs.

4. *Departmental administration expenses.* a. The expenses under this heading are those that have been incurred for administrative and supporting services in academic deans' offices, academic departments and divisions, and organized research units. Organized research units include such units as institutes, study centers, and research centers. The expenses under this heading which may be allocated to sponsored agreements are limited to:

(1) Academic deans' offices. Salaries and operating expenses attributable to its administrative functions.

(2) Academic departments. (a) The salaries of the heads of academic departments, divisions, and organized research units attributable to their administrative duties. Salaries of professional staff, whose appointment or assignment involve the performance of such administrative work, may also be included to the extent that the portion so charged is clearly and specifically supported as required in Section J6.

(b) Other administrative and supporting expenses incurred within academic departments, such as the salaries of secretarial and clerical staffs, the salaries of administrative officers and assistants, travel, office supplies, stockrooms, and the like. *Provided,* That such expenses are treated consistently as indirect costs in all academic departments of the institution.

(3) Fringe benefit costs applicable to the salaries and wages included in (1) and (2) above, as well as an appropriate share of general administration and general expenses, operation and maintenance expenses, and depreciation and/or use allowances.

b. Allocation of departmental admiuistration expenses shall be performed as follows:

(1) The administrative expenses of the dean's office of each college and school shall be allocated to the academic departments within that college or school in proportion to the total salaries and wages of those departments.

(2) The administrative expenses of each academic department, and the department's share of the expenses allocated in (1) above shall be allocated to the functions performed by that department in proportion to the total salaries and wages applicable to those functions.

(3) An exception to the above may be permitted only where (a) certain administrative or supporting expenses are charged directly to an activity because it is performed in an environment which is substantially different from that applicable to other activities, and (b) a special indirect cost rate is developed for the activity in accordance with Section G1b.

5. *Sponsored agreements administration.* a. The expenses under this headiug are those that have been incurred by a separate organization(s) established primarily to administer sponsored agreements, including such functions as grant and contract administration, security, purchasing, personnel administration, and editing and publishing of research and other reports. They include the salaries and expenses of the head of such organization, his assistants, and their immediate staff, together with the salaries and expenses of personnel engaged in supporting activities maintaind by the organization, such as stock rooms, stenographic pools, and the like. The salaries of members of the professional staff whose appointments or assignments involve the performance of such administrative work may also be included to the extent that the portion so charged to sponsored agreements administration is clearly identified and supported as required by Section J6. This category should also include the fringe benefit costs applicable to the salaries and wages included therein, an appropriate share of

cable to those sponsored agreements and included in the direct cost of other activities for cost allocation purposes.

(3) Where it is determined that certain expenses are for the support of a service unit or facility whose output is susceptible of measurement on a workload or other quantitative basis, such expenses should be set aside as a separate cost grouping for distribution on such basis to organized research, instructional, and other activities at the institution or within the department.

(4) Where organized activities (including identifiable segments of organized research as well as the activities cited in Section B1c) provide their own purchasing, personnel administration, building maintenance or similar service, the distribution of general administration and general expenses, or operation and maintenance expenses to such activities should be accomplished through cost groupings which include only that portion of central indirect costs (such as for overall management) which are properly allocable to such activities.

(5) Where the institution elects to treat the cost of the pension plan and other staff benefits as indirect charges, such costs should be set aside as a separate cost grouping for selective distribution to related cost objectives, including organized research.

(6) The number of separate cost groupings within a category should be held within practical limits, after taking into consideration the materiality of the amounts involved and the degree of precision attainable through less selective methods of distribution.

d. Selection of distribution method. (1) Where an allocation can be made by assignment of a cost grouping directly to the area benefited, the allocation should be made in that manner.

(2) Where the expenses under a cost grouping are more general in nature, the bases for the indirect cost categories cited in Section F shall be used in allocating such costs to cost objectives unless one of the following conditions is met:

(a) The institution can clearly demonstrate that the use of a different base would result in a more equitable allocation of costs, or can demonstate that the use of a more readily available base would not increase the costs charged to sponsored agreements. In either case the use of the base must be approved in advance by the Government.

(b) The Government can clearly demonstrate that the use of another base would result in a more equitable allocation of costs.

(c) The institution qualifies for and elects to use the simplified method for computing indirect cost rates described in section H.

(3) In order to make the demonstrations described in (2) (a) and (b) above, a base should be selected that will produce equitable results to both the Government and the institution. The essential consideration in selection of the distribution base in each instance is that it be the one best suited for assigning costs or a pool of costs to related cost objectives in accordance with the relative benefits derived; the traceable cause and effect relationship, or logic and reason, where neither benefit nor cause and effect relationship is determinable. The base should be (a) readily expressible in terms of dollars or other quantitative measure (total direct expenditures, direct salaries, man-hours applied, square feet utilized, hours of usage, number of documents processed, population served, and the like); and (b) common to the benefiting cost objectives during the base period.

(4) Results of cost analysis studies may be used when they result in more accurate and equitable distribution of costs. Such cost analysis studies may take into consideration weighting factors, population, or space occupied if they produce equitable results. Cost analysis studies, however, should (a) be appropriately documented in sufficient detail for subsequent review by the Government, (b) distribute the indirect costs to the related cost objectives in accordance with the relative benefits derived, (c) be conducted to fairly reflect the true conditions of the activity and to cover representative transactions for a reasonable period of time, (d) be performed specifically at the institution at which the results are to be used, and (e) be updated periodically, but not less frequently than every two years, and used consistently. Any assumptions made in the study will be stated and explained. The use of cost analysis studies and periodic changes in the method of cost distribution must be fully justified.

e. Order of Distribution. (1) Indirect cost categories consist of depreciation and use allowance, operation and maintenance, general administration and general expenses, departmental administration, sponsored agreements administration, library, and student administration and services, as described in Section F.

(2) Depreciation and use allowances, operation and maintenance expenses, and general administrative and general expenses must be allocated in the order

involved in the determination of the reasonableness of a cost are: (a) Whether or not the cost is of a type generally recognized as necessary for the operation of the institution or the performance of the sponsored agreement; (b) the restraints or requirements imposed by such factors as arm's-length bargaining, Federal and State laws and regulations, and sponsored agreement terms and conditions; (c) whether or not the individuals concerned acted with due prndence in the circumstances, considering their responsibilities to the institution, its employees, its students, the Government, and the public at large; and (d) the extent to which the actions taken with respect to the incurrence of the cost are consistent with established institutional policies and practices applicable to the work of the institution generally, including sponsored agreements.

4. *Allocable costs.* a. A cost is allocable to a particular cost objective (i.e., a specific function, project, research agreement, department, or the like) if the goods or services involved are chargeable or assignable to such cost objective in accordance with relative benefits received or other equitable relationship. Subject to the foregoing, a cost is allocable to a sponsored agreement if (1) it is incurred solely to advance the work under the sponsored agreement; (2) it benefits both the sponsored agreement and other work of the institution, in proportions that can be approximated through use of reasonable methods; or (3) it is necessary to the overall operation of the institntion and, in light of the standards provided in this Circular, is deemed to be assignable in part to sponsored projects. Where the purchase of equipment or other capital items is specifically authorized under a sponsored agreement, the amounts thus authorized for such purchases are allocable to the sponsored agreement regardless of the use that may subsequently be made of the equipment or other capital items involved.

b. Any costs allocable to a particular sponsored agreement under the standards provided in this Circular may not be shifted to other sponsored agreements in order to meet deficiencies caused by overruns or other fund considerations, to avoid restrictions imposed by law or by terms of the sponsored agreement, or for other reasons of convenience.

5. *Applicable credits.* a. The term applicable credits refers to those receipts or negative expenditures that operate to offset or reduce direct or indirect cost items. Typical exampes of such transactions are: Purchase discounts, rebates, or allowances; recoveries or indemnities on losses; sales of scrap or incidental services; and adjustments of overpayments or erroneous charges. This term also includes "educational discounts" on products or services provided specially to educational institutions, such as discounts on computer equipment, except where the arrangement is clearly and explicitly identified as a gift by the vendor.

b. In some instances, the amounts received from the Federal Government to finance institutional activities or service operations should be treated as applicable credits. Specifically, the concept of netting such credit items against related expenditures should be applied by the institution in determining the rates or amounts to be charged to sponsored agreements for services rendered whenever the facilities or other resources used in providing such services have been financed directly, in whole or in part, by Federal funds. (See sections F8, J9a, and J38 for areas of potential application in the matter of direct Federal financing.)

6. *Costs incurred by State and local Governments.* Costs incurred or paid by State or local governments on behalf of their colleges and universities for fringe benefit programs such as pension costs and FICA and any other costs specifically incurred on behalf of, and iu direct benefit to, the institutions are allowable costs of such institutions whether or not these costs are recorded in the accounting records of the institutions, subject to the following:

a. The costs meet the requirements of C1 through 5 above.

b. The costs are properly supported by cost allocation plans in accordance with applicable Federal cost accounting principles.

c. The costs are not otherwise borne directly or indirectly by the Federal Government.

7. *Limitations on allowance of costs.* Sponsored agreements may be subject to statutory requirements that limit the allowance of costs. When the maximum amount allowable under a limitation is less than the total amount determined in accordance with the principles in this Circular, the amount not recoverable under a sponsored agreement may not be charged to other sponsored agreements.

29. Public information services costs.
30. Rearrangement and alteration costs.
31. Reconversion costs.
32. Recruiting costs.
33. Rental cost of buildings and equipment.
34. Royalties and other costs for use of patents.
35. Sabbatical leave costs.
36. Scholarships aud student aid costs.
37. Severance pay.
38. Specialized service facilities.
39. Special services costs.
40. Student activity costs.
41. Student services costs.
42. Taxes.
43. Transportation costs.
44. Travel costs.
45. Termination costs applicable to sponsored agreements.

K. Certification of Charges.

Principles for Determining Costs Applicable to Grants, Contracts, and Other Agreements With Educational Institutions

A. PURPOSE AND SCOPE

1. *Objectives.* This Attachment provides principles for determining the costs applicable to research and development, training, and other sponsored work performed by colleges and universities under grants, contracts, and other agreements with the Federal Government. These agreements are referred to as sponsored agreements.

2. *Policy guides.* The successful application of these cost accounting principles reqnires development of mutual understanding between representatives of universities and of the Federal Government as to their scope, implementation, and interpretation. It is recognized that—

a. The arrangements for Federal agency and institutional participation in the financing of a research, training, or other project are properly subject to negotiation between the agency and the institution concerned, in accordance with such Government-wide criteria or legal requirements as may be applicable.

b. Each institution, possessing its own unique combination of staff, facilities, and experience, should be encouraged to conduct research and educational activities in a manner consonant with its own academic philosophies and institutional objectives.

c. Each institution, in the fulfillment of its obligations, should employ sound management practices.

d. The application of these cost accounting principles should require no significant changes in the generally accepted accounting practices of colleges and uuiversities. However, the accounting practices of individual colleges and universities must support the accumulation of costs as required by the principles, and must provide for adequate documentation to support costs charged to sponsored agreements.

e. Federal agencies involved in negotiating indirect cost rates and auditing should assure that institutions are generally applying these cost accounting principles on a consistent basis. Where wide variations exist in the treatment of a given cost item among institutions, the reasonableness and equitableness of such treatments should be fully considered during the rate negotiations and audit.

3. *Application.* These principles shall be used in determining the allowable costs of work performed by colleges and universities under sponsored agreements. The principles shall also be used in determining the costs of work performed by such institutions under subgrants, cost-reimbursement subcontracts, and other awards made to them under sponsored agreements. They also shall be used as a guide in the pricing of fixed-price contracts and subcontracts where costs are used in determining the appropriate price. The principles do not apply to:

a. Arrangemeuts under which Federal finaucing is exclusively in the form of scholarships, fellowships, traineeships, or other fixed amounts based on such items as education allowance or published tuition rates aud fees of an institution.

b. Capitation Awards.

c. Other awards under which the institution is not required to account to the Government for actual costs incurred.

The proposed Circular is the result of numerous recommendations made by Federal departments and agencies, State and local governments, and university officials. Its purpose is to provide one standard set of cost principles for Federal work done at universities.

The Office of Management and Budget has, as yet, made no decisions with respect to the proposed principles. All interested parties are encouraged to make their views known. Comments should be submitted in duplicate to the Financial Management Branch, Budget Review division, Office of Management and Budget, Washington, D.C. 20503. All comments should be received on or before May 1, 1978.

VELMA N. BALDWIN,
Assistant to the Director for Administration.

[Circular No. A–21, Revised]

TO THE HEADS OF EXECUTIVE DEPARTMENTS AND ESTABLISHMENTS

1. *Purpose.* This Circular establishes principles for determining costs applicable to grants, contracts, and other agreements with educational institutions. The principles deal with the subject of cost determination, and make no attempt to identify the circumstances or dictate the extent of agency and institutional participation in the financing of a particular project. The principles are designed to provide that the Federal Government bear its fair share of total costs, determined in accordance with generally accepted accounting principles, except where restricted or prohibited by law. Agencies are not expected to place additional restrictions on individual cost elements. Provisions for any increment above cost is outside the scope of this Circular.

2. *Supersession.* The Circular supersedes Federal Management Circular 73–8, dated December 19, 1973. FMC–73–8 is revised and reissued under its original designation of OMB Circular No. A–21.

3. *Applicability.* (a) All Federal agencies that sponsor research and development training and other work at educational institutions shall apply the provisions of this Circular in determining the costs incurred for such work. The principles shall also be used as a guide in the pricing of fixed price or lump sum agreements.

(b) In addition, Federally Funded Research and Development Centers associated with educational institutions shall be required to comply with the Cost Accounting Standards, rules and regulations set forth in 4 CFR Ch. III.

4. *Responsibilities.* The successful application of cost accounting principles requires development of mntnal understanding between representatives of educational institutions and of the Federal Government as to their scope, implementation, and interpretation.

5. *Attachment.* The principles and related policy guides are set forth in the Attachment, "Principles for determining costs applicable to grants, contracts, and other agreements with educational institutions."

6. *Effective date.* The provisions of this Circular shall be effective———. The provisions shall be implemented by institutions as of the start of their first fiscal year beginning on or after that date. Earlier implementation, or a delay in implementation of individual provisions, is permitted by mutual agreement between an institution and the Government.

7. *Inquiries.* Further information concerning this Circular may be obtained by contacting the Financial Management Branch Budget Review Division, Office of Management and Budget, Washington, D.C. 20503, telephone 202–395–4773.

JAMES T. MCINTYRE, JR.,
Acting Director.

ATTACHMENT CIRCULAR NO. A–21

PRINCIPLES FOR DETERMINING COSTS APPLICABLE TO GRANTS, CONTRACTS, AND OTHER AGREEMENTS WITH EDUCATIONAL INSTITUTIONS

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money before they run out of market opportunities. While their technologies raise no great problems, their unseasoned managements tend to err relatively often. New ventures, however, avoid both regulatory and market obstacles more readily than other companies, regardless of size.

Small companies (under 500) have relatively fewer management problems than either new ventures or medium-sized companies. Their trouble from regulatory, market and technology obstacles is average.

Medium-sized companies (500 to 2,500) encounter a disproportionate share of management problems. Apparently, these companies are too big for innovations to command the individual attention of top management, but too small to hire the kind of specialized management that innovation needs. Capital for innovations is a somewhat less important obstacle for a medium-sized company than it is for either large or small companies and, of course, much less than new ventures. Regulatory, marketing and technology obstacles are unexceptional.

Large companies (2,500 plus) are least troubled by management problems. Their regulatory and market obstacles are similar to those of medium and small companies. Technology tends to be a relatively greater problem for the large companies, who become involved in riskier technical efforts than their smaller counterparts.

These data represent the actual experience of 200 technological innovations that faltered or failed in 81 companies drawn from 11 producer-good industries. While the companies were not selected to be a sample of industry as a whole, the patterns of failure are probably similar across the board.—*S.M., E.S.*●

[From the Federal Register, vol. 43, No. 141, July 21, 1978, p. 31427]

NOTICES

[3510–18]

OFFICE OF THE SECRETARY

Advisory Committee on Federal Policy on Industrial Innovation

Notice of Establishment

On June 2, 1978, it was announced by notice published in the Federal Register (43 FR 24116) that it was anticipated that the Secretary of Commerce (the Secretary) would propose the establishment of the Advisory Committee on Federal Policy on Industrial Innovation.

After consultation with the General Services Administration and in accordance with the provisions of the Federal Advisory Committee Act (5 U.S.C. App. (1976)) and Office of Management and Budget Circular A–63 of March 1974, the Secretary has determined that the establishment of the Advisory Committee on Federal Policy on Industrial Innovation is in the public interest in connection with the performance of duties imposed on the Department by law and by the Presidential directive dated May 9, 1978 (memorandum to the Secretary of the Treasury, et al., from Stu Eizenstat, subject: Issue Definition Memorandum: Federal Policy on Industrial Innovation.)

The Committee will advise the Secretary of the views of its members with regard to Federal policy options designed to increase significaut industrial innovation in the United States as required by the Presidential directive, dated May 9, 1978.

The Committee shall consist of approximately 125 members to be appointed by the Secretary to assure a balanced representation of such interests as industry, business, academia, labor, consumers, environmentalists, and other public interests. Nominations for membership will be generally solicited by notice in the Federal Register.

The Committee will function solely as an advisory body, and in compliance with the provisions of the Federal Advisory Committee Act. Its charter will be filed under the act, 15 days from the date of the publication of this notice. The Committee will operate through subcommittees of its members.

As mentioned in the Federal Register notice of June 2, 1978, referenced above, interested persons are invited to submit to the Secretary nominations for membership to the Committee. Such nominations and any comments regarding the establishment of the Committee should be addressed to the Secretary of Com-

firm discovered that chrome plate was much cheaper and just as good. The entire production line for aluminum production remains mothballed by the firm. (The barrier in this case was classified as technology.)

The public interest often fails to express itself in the marketplace.—A major supplier of automobile components tried to introduce an anti-skid brake-control system for passenger vehicles. The firm carried the project almost to the production phase but was unable to arouse enough public interest in voluntary adoption of the system to market it. (The barrier in this case was classified as market.)

Lack of technical capabilities in the staff of a firm may delay the solution of a technical problem for so long that a project loses its competitive advantage by the time it becomes marketable.—One firm developed some prototype engines using a piezo-electric ignition system but sold the rights to the system to another firm. The second firm had to solve some technical (noise and time-delay) problems before the system could be marketed. Because the lack of technical expertise ate into time, when the system was finally ready, the market was no longer exclusive; the opportunity to achieve economies through large-scale production techniques was lost. The product was withdrawn after the costly, two-year delay; new techniques were used to develop an acceptable low-cost ignition system. (The barrier in this case was classified as management.)

The assumption that an innovation will violate antitrust regulations may prevent its development.—A medium-sized steel company developed a process for reclaiming zinc and iron by processing pelletized dust recovered from scrubbers of exhaust gases. The quality and quantity of the zinc by-product made the process look economically promising at the pilot-plant stage, if sufficient tonnage of reclaimed dust could be obtained. This would require access to more than one plant. When a joint venture with other steel companies was explored as a feasible basis for full-scale operation, however, the objection was raised that such a venture would violate anti-trust laws. The process has not been developed further in spite of its economic and ecological advantages—although the requisite joint venture might or might not violate antitrust laws: the Department of Justice will not provide this information until the process is in operation! (The barrier in this case was classified as regulatory.)

HOW TO SAVE THE GOOD ONES

The process of innovation is Darwinian, and not all innovations deserve to survive. Our respondents, therefore, were asked to judge, in a broad economic sense, whether the innovation was still "good" or "not good" in view of the events that led to its blocking. For example, although management's judgments were necessarily subjective, they were strong; when several respondents commented on the same innovation, they almost always agreed as to whether the innovation was "good" or "not good."

Ninety-two of the 200 innovations that faltered were judged by management to be ideas well worth saving. (All the innovations mentioned above were judged to be good ones, except for the two blocked either by technology or market factors.) To save the promising innovations, management should, of course, pay more attention to factors that block "good" rather than "not good" innovations. So it's important to note that management error and government regulations accounted for 28 and 20 percent, respectively, of the 92 "good" innovations that ran into trouble. The data clearly indicate:

Managers can save many good innovations by doing a better job of managing, particularly by asking the right questions at the right time.

Managers should press government to overhaul the regulatory process that block so many good innovations. Government administrators could ease this problem without necessarily addressing the substantive issues of regulation—although the latter may be most desirable. For example, the government could provide advisory guidance concerning the applicability of a regulation and the means by which the items in question could be adapted to meet regulatory requirements. In the absence of such advice, firms often discover too late that their innovations must be adapted expensively to meet regulatory requirements which had been "incorrectly" interpreted.

The data also show that few, if any, innovations might be saved by loosening the federal government's stringent standards, tough tests, etc.—most of which, in any event, are means in the public interest. The obvious conclusion is that management should not waste its time lobbying for less stringent regulations.

WHY INNOVATIONS FAIL

(By Sumner Myers and Eldon E. Sweezy, Institute of Public Administration)

"It was," said William Holden as the business executive in the movie Executive Suite, "just one attempt in a hundred to make one improvement in a hundred." The "it" was a new molding process which would presumably have improved the Tredway Corp's furniture line. Unfortunately, a key production test failed and the innovation was delayed. A failure of technology? Perhaps. But Holden felt that the test might have succeeded had he been there to make a key management decision rather than cooling his heels in the board room waiting for a hastily called meeting. A failure of management, then? Either way it would have been called an innovation failure in the real industrial world.

The failure rate for industrial innovations is high. One study found that although the rate varies among industries and companies, on the average "it takes some 58 ideas to yield one successful new product." The vast majority of ideas fail at the outset: only 10 or 12 per cent of the ideas submitted for initial screening and analysis enter the development pipeline toward commercialization.

What does this high failure rate mean? Is it simply evidence that the competitive battle ensures the survival of only the fittest innovations? Or does it represent a waste of potentially useful products and therefore of scarce industrial resources? Whatever the hypothesis, such a high rate of failure calls for an effort to understand its causes. With that understanding, management can better steer its product innovations around the barriers to successful commercialization.

We conducted a study of 200 innovations that passed initial screenings but failed after entering the commercialization pipeline for the Denver Research Institute, under the auspices of the National Science Foundation. Our results confirmed some of management's fondly held convictions, but exploded some others:

The greatest risk is still the marketplace. Uncontrollable market factors scuttle more new products and processes than anything else—27.5 percent of the innovations studied. Yet management often plunges ahead without trying hard enough to minimize that risk.

Limited sales potential blocked 16 per cent of the new products studied. Better research to identify new markets would help here, as would stronger national economy. In a sagging economy, innovations start slowly and succeed with difficulty—even with good market research, shrewd management, and all the technology in the world. A booming economy, on the other hand, spurs innovation by generating the new demand that drives the innovation process.

The inability to find buyers for something developed in the public interest—a large market problem that management is often criticized for avoiding—blocked 10 percent of the innovations surveyed. Even though managers sometimes let philanthropy overwhelm good sense in choosing which innovation to develop.

Poor management accounted for 23.5 per cent of the innovations that were cancelled, shelved, or inordinately delayed. Not surprising perhaps, but disturbing—over one-third of the management errors involved market factors which management could have controlled.

MANAGEMENT ERRORS—TOO MANY "GOOFS"

Whether pulled by the market or not, too many innovations fail because of management errors that seem preventable. And too many of these errors are simply "goofs"—forgetting to do the obvious. For example, one firm spent a good deal of money to develop a special welding torch for use in repairing automobile bodies. Not one was sold. Puzzled, management representatives visited potential customers to find out why. Only then did they learn the torch couldn't be used on the auto body with the upholstery already in place. The torch would have been a fire hazard. Obviously, management could have avoided this failure had it checked with its potential customers before developing such a product.

In sum, failures of management and marketing together accounted for half of the 200 innovations in the sample that faltered or failed. Yet, we also find from that data that management does a good initial job of screening many innovations that would obviously fail later on:

Only 9 per cent of the innovations stndied were stopped in the marketplace because the company was unable to find a market for them. Fragmented markets undoubtedly pose a larger problem, but they usually surface at the projec selection stage when management can simply reject the proposed innovation.

to a referral, not even retrieval, function; the Small Business Administration merely passes on small business requests for data and documents to other agencies—often without success.

The Atomic Energy Commission (now part of the Department of Energy) has long disseminated its unclassified research and development results that might have industrial applicability through report distribution, manuals, technical information packets, and special purpose seminars.

The Department of Agriculture, rather than limiting itself to distributing scientific reports, has translated its research results into practical bulletins for the general public, published in magazines read by farmers and ranchers. Agriculture has also pushed its research findings through the mass media, using large numbers of radio and TV farm broadcasts as the communications vehicle.

All these federal information dissemination activities have led to little documented research utilization. This is not surprising given the repeated empirical research findings that demonstrate the ineffectiveness of written communication as a medium for technology transfer.

SHOW AND TELL

Very different in character from mere information distribution have been the efforts by some government agencies to encourage research utilization via the funding and executing of demonstration projects. The Environmental Protection Agency has financed demonstration uses of new pollution abatement and control technology, and has even provided technical assistance to early users of this technology. The Department of Housing and Urban Development has launched major efforts to finance first uses of new construction methods and materials and has even tried, albeit unsuccessfully, to demonstrate ways of creating new cities.

Of special note is the Department of Agriculture's "permanent" institutionalization of the demonstration project. U.S.D.A. has established a national network of field stations and pilot research farms that provide ongoing research trials, in the local environment and with soil and weather conditions that are shared with the local prospective research-utilizing farmer. The continuing character of such field operations provides far more convincing evidence to the hesitant research user than does a one-shot demonstration.

APPLICATIONS ENGINEERS

At least two federal agencies have realized that effective industrial diffusion of their research results requires a strong coupling activity that attempts to match available technology to the prospective user's needs. The Atomic Energy Commission had a special problem of classified nuclear information; it established professional referees at each contractor site and A.E.C. lab to evaluate reports for declassification. A formal Industrial Cooperation Program was established to provide active information dissemination through seminars, facility tours, special demonstrations, and also to provide a mechanism for technical assistance to industry in the use of nuclear technology. The A.E.C. even performed work for private industry when this facilitated the process of technology transfer.

N.A.S.A., through its Technology Utilization Program, has made a significant though nearly fruitless effort since 1962 to transfer space research results into commercial use. Going beyond its information dissemination activities described earlier, N.A.S.A. employed in-house staff and technical consulting firms to prepare "Tech Briefs" of research results that are judged to have promising innovation potential.

As a further step toward enhancing commercialization of its research output, N.A.S.A. established ten Regional Dissemination Centers to try to bring space research outcomes to bear on industrial technology requirements in different areas of the U.S. Their frustrated attempts led to cancellation of most of the centers, probably because of the mismatch between technology and user needs. Said one tactful researcher of the N.A.S.A. Technology Utilization Program, "The Technology Utilization Program appears to be providing a large number of answers to unrecognized industrial needs." But at least N.A.S.A., unlike most federal agencies tried to bring its technology in contact with possible industrial users, with an applications engineer to attempt the coupling.

EXPERTS IN THE FIELD

The most ambitious and cleary most successful government effort at research utilization is the Cooperative Extension Service of the Department of Agriculture.

of "technology-push" innovations are: the intended user recognizes neither the need for the innovation nor its benefits; the potential user does not understand the innovation; adapting the innovation to suit user requirements is prohibitively expensive; the technology advocate is often perceived to be taking the "I know what is good for you" attitude.

Lack of clear market definition and familiarity.—The relative success of person-to-person technology transfer is based upon a growing rapport with the user which, very importantly, provides the developer with opportunities for contact and better understanding of the user's needs.

There is seldom a pure technical decision in research and development. We emphasize the requirement for a clear understanding of the needs, perceived and real, of the target user prior to development. No matter how early in the development cycle of the innovation, each decision has possible consequences for the form, usefulness, cost, and appeal of the results in the marketplace. Accordingly, it is necessary to have sufficient information about the market soon after the initial idea is formulated.

These three points strongly suggest steps that can increase the probability of research utilization: generator-to-user contact and information sharing; research based on market need; and clear market identification and familiarity. These steps argue for changes in how a research project is executed as well as for changes in utilization strategies for companies and government agencies seeking to increase the probability of their research results being utilized.

Significant user involvement.—The major hurdle to utilization of research results is the lack of conviction on the part of the customer that adoption of something new is worth the cost of change. However, the customer who is involved in the development of the innovation will have a strong conviction about the value of the results. Industry has used personnel transfers, joint undertaking, and formal and informal contacts among groups to stimulate this involvement.

The argument that users are not sufficiently sophisticated to participate in these activities ignores two points. The prime problem to be solved is a user problem, not a technical problem: the user has the best information regarding the acceptability of the solution. Studies in many diverse fields—education, scientific instrumentation, fire services, and semiconductor equipment—have documented the significant amount of user-generated innovations.

We have been involved in several episodes where a user who has been involved in the research becomes the strongest advocate for its utilizaion to other potential users. Each organization, after the research project was completed, became "salesperson" for the technology. Accordingly, we feel strongly that appropriate attention to the characteristics of the organization and personnel who participate, as noted previously, and meaningful continual mechanisms for involvement of the user, can help federal agencies and industrial organizations significantly enhance their utilization records.

Responding to market needs.—"Market research," broadly defined, as an essential part of an effective research planning process. An examination for felt needs and the types of acceptable solutions (in terms of economic, technological, aesthetic and consumer values criteria) can provide the information that targets a research effort with a greater probability of producing utilized results than one without such information. Consumer involvement in the research process can help to ensure the continued relevance of the output to market needs.

Providing the appropriate mix and balance of skills.—For effective research utilization to occur, a very diverse set of activities must be carried out, usually by people with different skills and orientation. Industrial organizations have recognized the multiple skills necessary and have brought marketing and management personnel and scientists and engineers with different orientations into the research and development organization.

The absence of key people with skills to perform the necessary tasks can result in characteristic failures in the innovation process, reducing the chances for successful utilization.

Achieving effective utilization of research requires careful planning, staffing, and execution of the research effort to take into account—from the beginning—what is necessary to facilitate utilization of the results. While no practice guarantees utilization of the results, the approaches examined here increase the probability that the research output will be adopted by its target users.

of technology," early user involvement, and new types of skills brought in to supplement the creative scientist/engineer—are consistent with these changes in emphasis. Industrial research organizations have also undertaken other new approaches to research utilization.

Three general approaches have been used by industrial research organizations to facilitate utilization. The most effective approach is person-to-person contact, while procedural and organizational link-pin approaches require interactions among personnel from the various organizations who have a stake in the outcome of the work.

Personnel approaches.—The movement of people, joint teams, and geographical positioning permits intensive person-to-person contact between the generator and user of the research. These activities are the most effective in promoting understanding, acceptance and utilization of research results. As explained by Brian Quinn and James Mueller in their classic article on the topic: "A new product is like a baby. You can't just bring it into the world and expect it to grow up and be a success. It needs a mother (enthusiasm) to love it and keep it going when things are tough. It needs a pediatrician (expert information and technical skills) to solve the problems the mother can't cope with alone. And it needs a father (authority with resources) to feed it and house it. Without any one of these the baby may still turn out all right, but its chances of survival are a lot lower."

The most difficult of the three to transfer is enthusiasm—a thoroughly person-to-person commodity. Nothing transfers enthusiasm so well as working with or watching a person who has faith, conviction, and excitement about an idea.

When a research result is to be transferred, movement of project personnel is a key factor in the project's survival through the tortuous journey toward manufacturing or the market. Those who worked with the project in the past are best able to assist in the adaptation of research results to specific "customer" needs.

Some industrial research organizations bring into the research lab some project personnel from the receiving unit and later transfer them with some of their own personnel into manufacturing. Personnel from the receiving unit (or units) have special sensitivities to the marketplace, technology, corporate directions, and so forth. And they possess skills in marketing, finance, business, manufacturing, and the like that are critical for answers to the technical and nontechnical questions that management decisionmakers who allocate resources must ask. The key questions of economic viability (competition, cost of materials, return on investment), market scope (size, segmentation, location), legal issues, and so on can be answered by terms composed of people with this kind of mix of skills and sensitivities, regardless of the source of the personnel.

Geographic proximity also contributes to the probability of successful technology transfer. Communication decreases markedly with increasing distance, and with decreased communication comes diminished understanding, diminished trust, and greater resistance to the thrusts of the "outside" organization. Hence industrial research organizations have found that co-location with the receiving unit, either by the housing of personnel under one roof or the total movement of the laboratory into closer proximity, facilitates the development of a relationship and aids utilization of their research results.

Procedural approaches.—Procedural bridges are exemplified by joint planning, joint funding, and joint appraisal of research. These strategies are less popular now in industrial research organizations because all too often they merely raise differences without providing adequate mechanisms for their resolution.

Joint funding alone has been found to be of little value. Industrial experience indicates that sharing costs creates expectations that are difficult to fulfill. The resulting disappointment leaves no one satisfied. Joint planning requires an intensive follow-up effort. Without the commitment and resources to maintain close contact throughout the project, joint planning does no contribute measurably to successful utilization.

Open, frequent, and regular joint appraisals by all the parties who feel they have a stake in the research (those without a real stake excluded) can be useful when coupled with regular project-related interactions by the project personnel.

One industrial research lab that was having difficulty transferring its research output to the product lines found this approach successful. The projects involved research, engineering, and the product-line divisions. A joint project team was composed of working-level members from each of the three divisions. A product-

as may be required by a granting or sponsoring agency. In cases of inventions resulting from work not supported by an outside agency, the inventor shall indicate his or her desire as to how application for a patent should be made.

[From the Congressional Record, May 19, 1978, pp. S7904–S7909]

Research Utilization and Government Patent Policy

Mr. Nelson. Mr. President, the road to research utilization is strewn with hazards, ranging from lack of market definition and lack of capital to poor management and—some would say—Government patent policy.

In its study of Government patent policy, the Monopoly and Anticompetitive Activities Subcommittee of the Select Committee on Small Business has noted a number of proposed explanations of how research utilization proceeds.

Some try to account for how it proceeded in the past. Others try to predict or guide how it will proceed in the future.

The problem with the former is including enough examples in sufficient detail to permit drawing a valid generalization. And the problem with the latter is the tendency to assign or assume an expanding Federal Government role.

Those who argue for or take for granted an expanding Federal Government role tend to favor a Government patent policy that gives contractors the commercial rights to inventions resulting from Government-sponsored research and development.

Mr. President, the March/April 1978 issue of Technology Review, published by the Massachusetts Institute of Technology, contains informative articles on research utilization and what can go wrong with it.

They identify a number of hazards to research utilization, based in part on a study of 200 innovations that passed initial screenings but failed after entering the commercialization pipeline.

The authors of "Strategies for Improving Research Utilization," Edward B. Roberts of M.I.T. and Alan L. Frohman of Boston University, include a sidebar on how Federal agencies approach research utilization.

The second major article, "Why Innovations Fail," by Sumner Myers and Eldon E. Sweezy of the Institute of Public Administration, probes the high rate of failure for industrial invocations.

Mr. President, I ask that this material be printed in the Record.

[The material follows:]

Strategies for Improving Research Utilization

(By Edward B. Roberts, M.I.T., and Alan L. Frohman, Boston University)

Technological innovation is implemented and adopted through a series of phases. Someone first has an idea; if it's good, the idea goes through a technical problem-solving stage before advancing to design and development. Finally if it fills a significant social need, the new product is utilized and diffused throughout the market.

Efforts to increase the number of research projects that result in successful new products—what we shall call "research utilization"—usually begin by examining the results of technical problems-solving, product development, or even production engineering to find the impediments to research utilization. A better approach is to alter the earlier stages of the entire innovation process in order to achieve new products or processes that are more likely to be used.

A new perspective for research-based innovators

Shifts in many facets of the industrial research organization over the last ten years—size, structure, charter, manpower mix, and type of leader—have resulted from the need to make better use of laboratory research results. The scope of the changes now encompasses technical and nontechnical problems and issues, and places still larger demands upon the technical staff. We shall discuss these changes in terms of objectives, activities, and staffing.

Shift in objectives.—Ten years ago, a central research organization's goals were "solving technical problems," "pushing ahead the frontiers of science," and "contributing to corporate goals through the generation of new ideas leading to novel technology." The prevalent assumption at the time was that generating

tion, shall be construed as making use of College resources and shall be subject to the provisions of Section A above.

C. Patents resulting from inventions and discoveries made by members of the faculty, the technical staff or by students in connection with government-sponsored research contracts, grants, fellowships or other such arrangements, shall be controlled by the terms of those arrangements. Faculty or staff members accepting government-sponsored research shall execute such agreements as will enable the College to meet its obligations to the sponsoring agencies.

D. Since the College carries on research for the purposes of extending medical knowledge and educating students, it accepts research grants or contracts from non-government sources with these purposes primarily in view. If inventions result from such research grants or contracts the College and the inventor or inventors will handle these inventions in accordance with the terms of Section A above, unless the terms of the grant or contract pertaining to the above research are in conflict with Section A, in which case the terms of the grant or contract shall apply.

E. An inventor may elect to dedicate his/her invention to the Public Domain providing that neither the inventor(s) nor his/her kin shall receive any financial benefit therefrom, subject to the following:

(a) All co-inventors shall agree to this dedication.

(b) There is no conflict with the terms of a sponsoring grant or contract.

(c) In cases where the College has contributed its funds and facilities, the College voluntarily relinquishes all its rights to title in the patent.

(d) The costs of patenting are to be defrayed by funds obtained by the inventor(s), the inventor's(s') own funds, or voluntary contribution by the College.

(e) Prior approval of the Patent Committee is obtained.

If publication disclosing an invention is sufficient to place it in the Public Domain, no filing for a patent may be required. However, in some instances, to protect the public interest, it may be necessary to obtain a patent and non-exclusive, royalty-free licenses will be issued on the basis of said patent.

IV. LICENSES

Licenses for commercial development of patents shall be sought to ensure that useful inventions shall be made available in products or services beneficial to the public at reasonable prices. In cases involving substantial developmental expenditures by the licensee, or for other special reasons, an exclusive license may be given, subject to the terms of any applicable grant or contract. All such licensing agreements shall be executed by the appropriate office of the University.

V. USE OF INCOME FROM PATENTS

A. If income is received from the sale or licensing of patent rights derived from contracts between a third party and the College, the College, its agents and/or any outside agencies will pay and reward the inventor within 90 days of receipt of the funds by the College in accordance with the provisions below.

B. If income is received from patents growing out of contracts or support from governmental, charitable or other non-profit organizations, the College, its agents and/or any outside agency involved shall pay to the inventor(s) or his/her estate and/or heirs (1) Fifty percent (50%) of the first Three Thousand Dollars ($3,000) of the gross income obtained under the patent; (2) Twenty-five percent (25%) of the gross income hetween Three Thousand Dollars ($3,000) and Thirteen Thousand Dollars ($13,000); and (3) Fifteen percent (15%) of the gross income in excess of Thirteen Thousand Dollars ($13,000).

C. If income is received from patents growing out of contracts with other organizations or from any other form of support, then the College, its agents and/or any outside agency involved shall pay to the inventor(s) or his/her estate and/or heirs. Fifty percent (50 percent) of the first $3,000 of the gross income derived from the patent and Twenty-five percent (25 percent) or any gross income in excess of $3,000.

D. After payment of such sums to the inventor as described above from funds obtained from the patent and the costs of processing the patent, a percentage of the gross royalties will also be granted to the inventor to be spent on research and educational programs at the College. For inventions processed through an outside agency, these percentages shall be 7.5 percent for the first $3,000 of gross royalties and 10 percent thereafter. For inventions not processed through an outside agency, the percentage shall be 20 percent of gross royalties. The determina-

	Year Ended June 30—	
	1975	1976
LIST OF INCOME FROM ROYALTIES—Continued		
Fruitless olive tree	$10	1,047
Fruit subsampling		2,300
Grapevine—Carnelian	171,452	35,303
Grapevine—Carmine	100	
Grapevine—Centurion	15,463	59,128
Induction artery gage		350
Interfiber bonding	500	500
Iodine 123		395
Isoelectric focusing ampholyxes		1,080
Lettuce harvester	100	
Machine for tieing knots	111	
Making foamed glass	1,500	6,000
Mastitis test	2,723	2,284
Measuring vanillylmandelic acid	400	3,000
Method of harvesting grapes	5,482	
Mult channel digital photometer	2,227	1,240
O'Brien bulk bin tiller	4,500	4,975
pH electrode	1,892	2,033
Pear tree	250	673
Plant thinning machine	88,565	143,390
LIST OF PAYMENTS TO INVENTORS		
ABC wastewater treatment		$221
Artificial population sampler	$552	1,177
Asparagus harvester	425	212
B–12 coenzymes	465	1,002
Blackbody reflectometer	59	
Bongo net	340	212
California tissue sectioner	1,200	1,199
Desalination membrane	10,015	20,300
Device for testing rocks in place	392	241
Electrocatheter probe		25
Electrocatheter velometer		36
Electromagnetic flowmeter	209	465
Electro belt apparatus		185
Electrophoretic apparatus	106	213
Eradication of crown gall	455	442
Firmness tester for fruit	87	68
Fruitless olive tree	39	
Fractionation apparatus	319	
Grapevine—Carnelian		12,665
Induction artery gauge	319	212
Isoelectric focusing ampholyxes	319	212
Low epoxy resin	258	
Machine for separating juices	132	
Machine for tieing knots		47
Mastitis test	1,352	1,116
Methods for harvesting grapes	99	2,231
Nakamura circuit	5	
O'Brien bulk bin filler	678	
Plant thinning machine	28,739	27,302
pH electrode	1,358	1,238
Sampler—Bulk foods		4,007
Sampler for bulk grapes	1,436	2,501
Siliceous ashes from rice hulls		425
Stabilization of epinephrine	29,515	34,676
Three electrode flowmeter	250	212
Tomato harvester	21,263	22,500
Tomographic gamma ray scanner	44	1,132
Total knee prosthesis	10,869	16,701
Treating picked grapes	4,688	4,035
2-amino butane	152	6,505
Total payments	116,339	163,775
Porous block for soil moisture		2,522
Polypeptide agents		25,224
Preserving human organs	13,050	4,200
Sampler—Bulk foods	8,500	8,584
Siliceous ashes from rice hulls	1,100	1,200
Sensor—External field		1,080
Sensor—Varable gage		80
Sampler for bulk grapes	5,885	7,764
Symmetrical olefins		1,900
Stabilization of epinephrine	84,398	79,311
Strawberry—Aiko		5,816
Thermoelectric heat flow response	40	96
Tomato harvester	58,399	115,652
Tomographic gamma ray scanner	3,000	14,506
Treating picked grapes—Method	6,289	10,572
Three electrode flowmeter		80
Total ankle replacement		1,500
Total knee prosthesis	33,668	11,008
Tufts strawberry	12,739	12,617
2-amino butane	24,766	20,639
Total income from royalties	618,967	637,109

5. An agreement to assign inventions and patents to The Regents of the University of California, except those resulting from permissible consulting activities without use of University facilities, shall be mandatory for all employees, academic and nonacademic. Releases shall be executed, where the equities so indicates, as determined by the University of California Board of Patents. Subject to overriding obligations assumed by The Regents, University faculty and staff members who are employed under research contracts, grants in aid or service to industry agreements or special state appropriations covering specific activities shall make such assignment of inventions and patents as is necessary in each specific case in order that the University may discharge its obligations, expressed or implied, under the particular agreement.

6. The Regents is averse to seeking protective patents and will not seek such patents unless the discoverer or inventor can demonstrate that the securing of the patent is important to the University.

7. The Regents agrees, for and in consideration of said assignment of patent rights, to pay annually to the inventor, his heirs, successors, and assigns, fifty (50) percent of the royalties and fees received by the Regents after a deduction of fifteen (15) percent thereof for overhead costs plus a deduction for cost of patenting and protection of patent rights. Distribution shall be made annually in February from the amount received during the penultimate year. In the event of any litigation, actual or imminent, or any other action to protect patent rights. The Regents may withhold distribution and impound royalties until resolution of the matter.

8. In the disposition of any net income accruing to The Regents from patents first consideration will be given to promotion of research.

To members of the Committee on Finance:

REPORTS AND RECOMMENDATIONS OF THE PRESIDENT

C. Report on university patent fund for the year ended June 30, 1976 (Attachments C1–C4)

The University Patent Fund was established by The Regents in 1952 to invest the accumulated earnings of University-owned inventions in the General Endowment Pool and to provide income to finance patent expenses and research activity. Income from University-owned inventionns has financed all patent expenses and has provided significant additions to the Patent Fund, the proceeds of which are used to support research and education within the University.

During the past fiscal year, there were appropriations from the fund of $226,601 and additions to the fund of $580,770. The year end balance totaled $2,000,465 (See Attachment C1).

Gross income from royalties of $637,109 exceeded total patent expenses of $242,530 by $394,579 which has been added to the principal of the fund. The expense figure of $242,530 includes distribution of $163,775 in royalties to inventors.

Among the highest income-producing inventions were the Plant Thinning Machine, Tomato Harvester, Stabilization of Epinephrine, Grapevine—Centurion, Grapevine—Carnelian, and Desalination Membrane. The combined income of these six patents represents almost 73 percent of the total gross royalty income.

Investments of the Patent Fund earned income of $186,191 during 1975–76.

During 1975–76, $81,408 was appropriated from the Patent Fund to support certain applied research projects which hold promise for the development of patentable inventions. On July 1, 1976, $145,193 was transferred to the General Fund in support of the 1977–78 budget for research in accordance with the recommendation of the Legislative Analyst. This represents 25 percent of the University's net royalty income and Patent Fund earnings.

According to The Regents' action of October 22, 1976, the Patent Fund income, beginning with the 1976–77 fiscal year, will be allocated by the President for education and research purposes as part of the regular budget process.

The tabulation below indicates the activity in the patent program during fiscal year 1975–76 as compared to 1974–75:

in a machine, article or device. Point out means which are essential, others which are important or useful and any *critical* limitations on any of these:

6. Chronology of principal events in conception and development:

(a) Earliest conception date (reference to substantiating evidence desirable):

(b) Date of disclosure (orally or in writing) to other persons and names of such persons:

(c) First written record pertinent to invention;

(d) Date and result of first test of the invention (if invention is (a) a process, its first test is the first successful trial; if (b) a composition of matter or a compound or (c) a machine, article or device, its first test is its first creation and evaluation with respect to new or improved properties or behavior):

7. Source(s) and amount(s) of all grant, contract or gift funds used by inventor regardless of purpose or use dnring the period starting with the date noted in item 6(a) and continuing to the present:

8. Identify those sources indicated in item 7 which contributed to the invention:

9. Date and place (e.g., particular periodical) of publication of disclosure of invention (whether publication has been accomplished or is projected):

The following two items may be completed at the option of the compiler:

10. Background of published information and practice in tthe field of the invention (known practices, periodical citations, patents, etc.):

11. Features embodied in this invention which would not have been obvious to or readily foreseeable by the typical skilled worker in the field:

Signiature of compiler

_____

(Signature of compiler)

Signature of Inventors, date, and witness to Inventor's Signature.

Certification by inventor's supervisor (department chairman, program director or coordinator):

I have reviewed the information provided above with particular reference to item 8, source of funds contributing to the invention. To the best of my knowledge, I believe the above statements to be accurate.

_____

(Signature of Superior)

_____

APPENDIX B

Name _____
(Last) (First) (Middle Initial)

Soc. Sec. No. _____

PATENT AGREEMENT

In consideration of my employment by The Regents of the University of Wisconsin (hereinafter referred to as the University) in connection with work which has been conducted or may hereafter be conducted in the performance of a grant, contract or award made to the University by any extramural agency, I hereby agree to refer promptly to the University (through the Dean to the Office of the Vice President for Business and Finance) any personally conceived discoveries or inventions arising out of the work sponsored or in any way aided by the grant, contract or award in order that the University may report the matter to the Grantor, Contracting Agency, or Awarding Agency for disposition in accordance with its established policies, procedures, and requirements. I hereby agree to cooperate with the Grantor, Contracting Agency, Awarding Agency, or the University's designee in the preparation and prosecution of any patent applications relating to such inventions and to execute all documents necessary or incidental to such applications and further agree to assign all rights to such inventions to the Grantor, Contracting Agency, Awarding Agency, or the University's designee if assignment is required under the terms of the grant, contract, or award.

In witness whereof I have hereunto set my hand this _____day of _____, 19____.

Signed:

_____

_____

The University has no wish to influence investigators regarding the disposition of their discoveries or inventions except where the University has an obligation as the result of being a signatory to a contractual arrangement which has a relation to the discovery or invention. In order to assure that its obligations are scrupulously met, the University administration requires that all inventions emanating from The University of Wisconsin, regardless of the source of support, be reported in a prescribed manner in order that they may be fully examined and a determination made with reference to any proprietary interest in them and to their disposition.

When any member of the University staff makes a discovery or invention in pursuance of his University duties, or on University premises, or with University supplies or equipment, he is required to report the fact to the Dean of his college on the appropriate form (Invention Record and Report, Form No. UW–P–1, Appendix A, page 9–10).

The Dean has the responsibility for judging whether the investigator has any obligation to assign rights to such discoveries or inventions to any third party. In particular, the Dean will be expected to judge the relation of the reported discovery or invention to the purpose of any grant or contract that may be involved.

The Dean will refer the invention to the University Business Office for review of the financing of the scientific investigation leading to the discovery or invention. Upon completion of the Dean's review and the Business Office analysis, the Central Administration of the University will have the responsibility for determining if an obligation to a grantor does exist and to insure that any such obligations are fully met.

UNRESTRICTED INVENTIONS

When, after review by the Dean and the Business Office, it has been determined that no third party is contractually entitled to control over the property rights in the invention, the inventor will be so advised and will be free to dispose of his invention according to his own discretion. Practically speaking, any one of three options is available to him:

Option 1. He may, on his own initiative, obtain patents on his invention and thereby administer, dispose of, or license such patents in whatever manner seems to him to be appropriate.

Option 2. He may assign the invention to the Wisconsin Alumni Research Foundation or to any other patent management organization for determination of patentability and potential public use and for administration of any patents obtained.

Option 3. He may dedicate the invention to the public by publishing his findiugs and taking no legal action. (In the United States, if a patent application has not been filed on an invention within one year after such publication, the invention is considered to be in the public domain, and there is then a statutory bar against obtaining a patent on the invention.)

It is suggested that the inventor thoroughly weigh the relative advantages and consequences of these three options in terms of which will most likely result in early public use and greater public advantage. The WARF staff is available for consultation with the inventor on these matters. Regardless of the option he may elect, the inventor is free, indeed urged, to establish his scientific priorities through publication of his research results.

WHAT IS AN INVENTION?

Inventions fall into either of two general classifications—those that are patentable under law and those that are not. Neither the courts nor the lexicographers have satisfactorily defined patentability, though some useful guidelines have been suggested. A concise statement about patentability appears in the *Journal of the Patent Office Society* (V. L, No. 7, p. 456, July 1968):

"The general criteria of patentability are that the invention or discovery be either a distinct new variety of plant . . .; or a new and ornamental design for an article of manufacture . . .; or a new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof. The difference between the subject matter sought to be patented and the prior art must be such that the subject matter of the former taken as a whole would not have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains."

[13] The term "primary" has been defined in *Malat* v. *Riddell*, 383 U.S. 569 (1966), to mean of first importance or principally, which defintion has in turn been generally interpreted to mean more than 50 percent of an organization's activities.

[14] Reg. § 1.513–1(c).

[15] Rev. Rul. 57–313, 1957–2 C.B. 316.

[16] Reg. § 1.513–1(d)(4)(ii).

[17] Notwithstanding the statutory exclusion of capital gains and royalty income from the definition of unrelated business taxable income as subsequently described in the text, such gains or income may nevertheless be subject to the tax on unrelated business income if there is "acquisition indebtedness" with respect to the patient. See I.R.C. sections 512(b)(4) and 514. Further, royalty income taxable income is treated as unrelated business taxable income. Sec. I.R.C. section 512(b)(15). Under the foregoing provisions, it is immaterial whether the university is engaged in a "trade or business."

[18] Cf. *Elrod Slug Casting Machine Co.*, 7 T.C.M. 157, 160 (1948).

[19] Whether the assignment of rights in a patent constitutes a "sale" or "license" is beyond the scope of this article. However, in determining whether there is a sale resulting in capital gain, the Internal Revenue Service is likely to be guided by I.R.C. section 1235, which requires that the property transferred must consist of all substantial rights evidenced by the patent or an undivided interest in the patent which includes a part of all of the substantial rights. In any event, I.R.C. section 512(b)(5) does not apply if the patent is stock in trade or inventory or property held primarily for sale to customers in the ordinary course of business.

[20] See also Rev. Rul. 73–193, 1973–1 C.B. 262.

[21] Reg. § 1.543–1(b)(3).

[22] S. Rep. No. 2375, 81st Cong., 2d Sess. 30–31 (1950).

[23] 1969–1 C.B. 129.

[24] Cf. *John C. O'Connor*, 16 T.C.M. 213, 221–22 (1957), *aff'd*, 260 F.2d 358, 58–2 U.S.T.C. § 9913 (6th Cir. 1958), *cert. denied*, 359 U.S. 910 (1959).

[25] Such as compensation for services; but it may be argued that payments are for other purposes, such as for know-how or are charitable contributions.

[26] Income from this type of activity would not necessarily be unrelated business taxable income if the activity is not regularly carried on.

[27] Cf. *Portable Ind., Inc.*, 24 T.C. 571 (1955), *acq.*, 1955–2 C.B. 8.

[28] It is the usual practice of universities to be assigned the patent to facilitate dealiugs with prospective licensees.

[29] 1973–1 C.B. 262.

[30] The statute recognizes that the organization will have expenditures; I.R.C. section 512(b)(2) excludes royalty income and "all deductions directly connected" thereto. Further, it is implicit in the Congress's assumption that receipt of income from patents would not result in competition with taxable business that it recognizes the need for expenditures, such as for developing an iuvention as well as the costs of obtaining a patent, including attorneys' fees and funds expended in makiug and perfecting a patent application.

[31] A joint venture has been defined as "a special combination of two or more persons where, in some specific venture, a profit is sought without an actual partnership or corporate designation." *Thompkins* v. *Comm.*, 97 F.2d 396 (4th Cir. 1938).

[32] See. Reg. § 1.512(b)–1, which states the following: "For example if a payment termed 'rent' by the parties . . . is a share of the profits retained by such organization as a partner or joint venturer, such payment is not within the modification for rents."

[33] See *William J. Lemp Brewing Co.*, 18 T.C. 586 (1952), *acq.*, 1952–2 C.B. 2.

Appendix A

Disposition of Inventions and Patents: The University of Wisconsin

In an institution such as the University of Wisconsin, where creativity is a major ingredient of research, new products, devices, processes and compositions are often found. It is onr purpose here to state for University faculty and staff what their responsibilities, privileges and options are when they have made au invention or discovery.

Historically, The University of Wisconsin has never claimed that it has proprietary rights in any invention generated at the University. In the absence of

those situations where the services would be incidental to the overall patent licensing or would be unnecessary or not contemplated at the time the license agreement is entered into.[27]

The university may become involved in assisting its faculty members to exploit their patented or patentable inventions. This involvement may be in the form of assisting the inventor in getting needed financing to promote the invention or may be more extensive in that the university or affiliate may itself evaluate, process, develop and manage the inventions. The university may also be empowered to sell or grant licenses in its name (if the patent is assigned to it[28]) or in the name of the inventor to licensees to exploit the patent. In exchange for these services, the university usually receives a portion of royalties and pay the balance to the owner of the patent.

In Rev. Rul. 73-193,[29] the Internal Revenue Service dealt with one aspect of this type of situation. In that ruling, the organization entered into agreements with educational and scientific institutions under which it evaluated, processed, promoted, developed and managed the inventions of faculty members, associates and staff members of educational and scientific institutions. Pursuant to the agreement, the staff members would assign title to their inventions to the organization which in turn negotiated licenses to third parties. The organization collected the royalty income from the licensees, retained a portion thereof as compensation for patent development and management services rendered, and distributed the remainder of the amounts collected to the institutions and inventors in the proportions specified. In addition to paying all the normal expenses involved in the patent management operations, the organization maintained all the books and records relating to the activities thereunder. In holding that the royalties did not retain the character of royalties in the organization's hands for purposes of I.R.C. section 512(b)(2), the Internal Revenue Service observed that the organization held legal title to the invention "only for the purpose of performing the agreed patent development and management services for the account of the beneficial owners. . . ."

This ruling points to the need to determine, in analyzing the character of the payments received by the university, even though denominated royalties, whether the university has an interest in the patent other than mere legal title. In Rev. Rul. 73-193, the agreement and facts show that the licensor had no beneficial interest in the property except the legal title. This ruling should have application only to those situations in which the university is not an owner of the patents, having at least a portion of the beneficial interest. As noted in the ruling, title alone is insufficient and the university should receive a portion of the payments in excess of the amount required to reasonably compensate it for the services performed in connection therewith. However, even if the university merely holds legal title to the patent, its situation is still distinguishable from Rev. Rul 73-193 if it limits its activities to managing patents derived from university-related research.

The Internal Revenue Service may raise some questions as to the possible application of this ruling in those cases where the payment is based in part on the performance of management services described in the ruling. However, most of the activities mentioned in the ruling are merely incidental to the performance of services that would ordinarily be undertaken by any owner of a patent engaged in licensing and incidental to the receipt of royalties. I.R.C. section 512(b)(2) indicates that Congress did not intend to prohibit the owner of a patent from making the necessary expenditures to make it productive of income.[30] Indeed, the statute provides that expenses related to the royalty income are deducted from it. That the royalty itself may or may not be passive is not really the issue in this ruling. Rather, the issue is whether the organization doing the licensing has something more than just bare legal title, that is, whether it is a joint owner of the patent, in which case the expenses and activities would be appropriate for an exempt organization. Thus, Rev. Rul. 73-193 should have no application to those situations in which the university does in fact own a beneficial interest in the patent.

Another means by which the university may derive income from a patent is to enter into an agreement with another party who has the manufacturing or technical wherewithal to commercially exploit a patent owned by the university. The Internal Revenue Service, in this situation, may attempt to characterize the relationship between the university and the "licensee" as being in reality a joint venture. Whether or not the university and the licensee have created the relation-

Footnotes at end of article.

The basic reason for excluding royalties from the definition of unrelated business taxable income was: Because your committee believes that they are "passive" in character and they are not likely to result in serious competition for taxable businesses having similar income. Moreover, investment producing incomes of these types [interest, dividends, some rents and royalties] have long been recognized as a proper source of revenue for educational and charitable organizations and trusts.[22]

Since the characterization of income as a "royalty" depends upon the facts and circumstances, the principal issue which usually arises is derived from the committee report's reference to "passive." The statemeut in the legislative history of Congress belief that investment in patents and the receipt of royalties therefrom are "'passive' in character and they are not likely to result in serious competition for taxable businesses having similar income" shonld give universities flexibility because it recognizes that, even though the university may be expending funds of its own to develop and stimulate the use of its patents by licensees, such expenses do not change the character of the royalties into something else. These expenditures would be the typical expenses ordinarly undertaken by businesses exploiting similar property. Thus, the mere fact that a university expends money for research, to obtain patents and to seek out suitable licensees should not alter the treatment of income it receives as royalties.

Rev. Rul. 69–430 [23] illustrates the concept of the royalty exclusion. In that ruling, the exempt organization owned publication rights to a book which did not contribute in any manner to the accomplishment of its exempt purposes. The organization *itself* undertook to exploit the book in a commercial manner by arranging for the printing, distribution, and retail sale of the book. It also arranged for publicity and advertising in connection with the distribution and sale of the book. While the ruling held that the activities of the organization constituted the conduct of an unrelated trade or busness, it concluded with the following paragraph:

However, had the organization transferred the publication rights to a commercial publisher in return for royalties, the royalty income derived would have been excluded from the computation of unrelated business taxable income under § 512(b)(2) of the Code."

Rev. Rul 69–430 points up an important factor which distinguishes royalties from income from an unrelated trade or business. In that ruling, the exempt organization itself engaged in the conduct of activities in connection with the distribution and sale of a book which was unrelated to its exempt purposes. It derived the income from its own commercial exploitation of the publication rights rather than, as in the usual case with royalties, from third persons who in turn carried on the actual commercial exploitation.

The activities performed by the organization in Rev. Rul. 69–430 were not the activities normally undertaken by the owner of important rights in a book and cannot be analogized to tbe expense undertaken by a university in developing and exploring the various uses of its patents prior to actual licensing. This ruling indicates that, once a right is in such a stage of development that it can be commercially licensed for manufacture or exploitation by third parties. the fact that the organization itself undertakes to manufacture or exploit will be the active conduct of a trade or business which may be unrelated to the organization's exempt purposes.

This brings us to problems with the licensing agreement itself. The licensing agreement may or may not contain a provision with respect to the performance of engineering or other personal services for the licensee by the university or its staff. If no provision is made in the agreement, the initial question is whether, in spite of the lack of an agreement with respect to such services, the Internal Revenue Service can challenge the characterization of the payments and allocate at least a portion of the payments to such services.

Few inventions in and of themselves are so great that they require no supporting technology or stand by themselves. Thus, it is unusual that the patent transfer will include the patent itself and no "know-how." The know-how transferred with a patent may take many forms, which may include engineering data, blueprints, various plans and patterns, formulae, and expertise of employees. The problem that arises is whether the amounts received by the university are in fact royalties or are more properly classified as amounts received for services rendered. Neither the regulations nor rulings under I.R.C. section 512 deal with this question. Thus, areas of analogous law must be considered, with the recogni-

Footnotes at end of article.

example of this is found in a revenue ruling which dealt with an exempt medical research foundation operating a medical illustration department furnishing services to various institutions and an electroencephalography clinic for several hospitals from which income is derived.[15] The ruling concludes that unrelated business income is earned from these sources since they are conducted in a manner similar to a commercial undertaking and the income is disproportionate in amount when compared with the size and extent of its exempt activities.

In a different vein, income from the sale of patents which result from the performance of university-related research should not be considered gross income from an unrelated trade or business if the patent is sold or licensed in substantially the same state as it was on completion of the exempt function. The regulations enuncite a principle that, if a product resulting from an exempt function is utilized or exploited in a further business endeavor beyond that reasonably appropriate or necessary for disposition in the state it is upon completion of exempt functions, the gross income derived therefrom would be from the conduct of an unrelated trade or business.[16] An example of this principle given in the regulations involves an experimental farm maintained for scientific purposes by a research organization. The income from the sale of milk and cream produced in the ordinary course of operation of the project would not be income from conduct of an unrelated business; however, if the organizations were to utilize the milk and cream in the further manufacture of food items, such as ice cream and pastries, the income from the sale of such products would be from an unrelated business, unless the manufacturing activities themselves contributed importantly to the acomplishment of an exempt purpose of the organization.

When the university supports or makes available in a profit-making manner certain patents developed from university research by providing extra or special support, either with money, facilities or equipment, for the development of the ideas or the production of various products, this additional activity beyond that reqnired to develop the idea may cause the university's activities to be treated as unrelated. This would be particularly true if, depending on the type of patent and its state of development, the university were called upon to continue or conclude development work for a licensee or to construct pilot models for use by a licensee. This further requirement of university involvement to produce a commercially acceptable product as opposed to simply adapting changes in a basic design produced from university research may result in the character of the university patent activities to be changed from related to unrelated.

From all of the above, it can be ascertained that the type of inquiry that can be expected to be made by the Internal Revenue Service with respect to a patent program of a university is whether the licensing activities of the institution are conducted in a manner and only to the extent necessary for dissemination of the results of the research or whether the activities include development and promotion in a manner similar to that of a competitive commercial enterprise.

GUIDELINES

Applying the foregoing principles to the administration of patents by a university, certain guidelines can be developed. The administration of the patents should be conducted in close relationship with and in furtherance of the university's research program for educational and scientific purposes. While the university may perform necessary functions in determining the usefulness and feasibility of an invention and obtaining the necessary patent protection, the university's expenditures for research and experimentation should be consistent with such purposes and not go beyond that which is necessary in light of such purposes. Further development and substantial expenditures for commercial exploitation or for the benefit of licensees should be guarded against. The university may conduct such educational programs as are necessary to make the invention and its usefulness known for the benefit of the public, which would probably include changes in basic design. However, the university should avoid promotion which would be in the nature of commercial advertising or involvement in development which may be directed toward producing a commercial product. Further, the university should seek to license the patent on a nondiscriminatory basis; it may grant exclusive rights, preferably for only a limited period, but in such cases it should be prepared to demonstrate that the granting of such

Footnotes at end of article.

mitment as part of its patent management program. The inventor, upon transfer of his interest in the patent to the university, will usually reserve the right to receive a part of the royalties paid by any licensee. Under these circumstances, the inventor is not receiving any "earnings" of the university, but rather the university is serving as a conduit to the inventor for those payments to which he is entitled under the reserved right.[8]

Thus, whether the university purchases the patent for its fair market value or the inventor transfers his rights to the patent to the university and the university retains a portion of the royalties for itself, the prohibition against inurement of net earnings should present no tax problem to the university.

OTHER EFFECTS ON EXEMPTION

Because additional involvement of the university may be called for by its patent management policy, it may become involved financially or through use of its special facilities in developing patients. Therefore, it is necessary to look more deeply into the effect on the tax-exempt status of the university by reason of such involvement.

I.R.C. section 501(c)(8) requires that a university be operated for one or more exempt purposes. The Treasury regulations indicate that this requirement is satisfied if the university "engages primarily in activities which accomplish one or more of such exempt purposes specified in section 501(c)(3)."[9]

There are ample ground to support the position that the conduct of a program to patent inventions which arise from university research and to license the same for the benefit of its faculty or staff or for the benefit of the university is in furtherance of the university's exempt purposes. Research is conducted on the university campus primarily to expand the frontiers of knowledge, to encourage and stimulate inquiry, and to contribute to the training of scientific and technical personnel. Thus, the existence of a program for administering patents arising from university research clearly is intended to and should have the effect of encouraging and stimulating research and therefore can be said to be directly related to carrying out the exempt purposes of the university. This analysis has its clearest application where the university patent program is limited to accepting patents from inventors who conducted their research while members of the faculty or staff of the university.

A patent licensing program should be considered related to the research and other public purposes of a university. The Treasury regulations themselves provide the necessary tie-in by expressly providing that scientific research is an exempt activity if patents resulting from such research are made available to the public on a nondiscriminatory basis.[10] Since most university patent policies encourage use of patents for the greatest possible public benefit, and sanction methods of introducing patents to commercial use that normally include the widest possible exploitation, such policies clearly place the public benefit over private profit-making and are in furtherance of its exempt purposes.

A further analogy may be drawn from the statutory provisions defining unrelated business taxable income. The statute expressly provides that "in the case of a college, university or hospital, there shall be excluded all income derived from research performed for any person. . . ."[11] This clearly recognizes the relatedness to exempt purposes of a university of research and all income derived therefrom.

APPLICATION OF THE UNRELATED BUSINESS INCOME TAX TO PATENT ACTIVITIES OF THE UNIVERSITY

I.R.C. section 511(a) imposes a tax upon the unrelated business taxable income of universities otherwise exempt from federal income tax under I.R.C. section 501(c)(3). The term "unrelated business taxable income" is generally defined in I.R.C. section 512 as the gross income derived from any unrelated trade or business regularly carried on, less allowable deductions directly connected with the carrying on of such trade or business.

Whether, notwithstanding the various exemptions contained in I.R.C. section 512(b), the patent development program of a university is subject to the tax on unrelated business income depends upon a number of factors. These are whether the university's patent activities are such that it is engaged in a trade or business, whether the activity is regularly carried on, and whether the activity is the conduct of a trade or business which is not substantially related to the exercise or performance by the university of its exempt functions.

Footnotes at end of article.

Holmesian interstices of the statute with judge-made law only under the gravest and most impelling circumstances.

As also pointed out in my dissenting opinion in *Bergy*, if, prior to the 1930 Act, plants had beeu within the scope of the patent statutes (as the majority and concurring opinions must assume), a plant patent would have had to comply fully with what is now 35 USC 112; but, under the 1930 Act, a plant patent for asexually reproduced plants need not do so (since such a patent could uot be declared invalid if its description "is made as complete as is reasonably possible"—see section 2 of the 1930 Act).

This would have constituted a repeal of the full-compliance requirement in the case of such patents without any Congressional discussion thereof. Repeal by implication is not favored statutory construction. *F.T.C.* v. *A.P.W. Paper Co.*, 328 U.S. 193, 202, 69 USPQ 215, 219, (1946). The conclusion follows that, prior to the 1930 Act, plants were not within the scope of the patent statutes.

As further pointed out in my dissenting opinion in *Bergy*, coverage of plants under the Patent Act of 1952 was considered by Congress to be limited to plants falling under Chapter 15 of 35 USC, and 35 USC 101 was not considered to extend to any plants whatsoever, thus making it necessary to enact the Plant Variety Protection Act (1970), 7 USC 2321 *et seq.*

Finally, the board made the following point:

We realize that 35 U.S.C. 101 does not expressly exclude patents on living organisms, but neither does it expressly exclude patents on mental processes, printed matter or methods of doing business.

This point was fully developed in my dissenting opinion in *Bergy*, where it was observed that claims directed to a process of using an algorithm to operate a system have been held to constitute patentable subject matter, while claims directed to the algorithm *per se* (or to methods of calculating, using the algorithm) do not.

Other points made by the majority in its opinion in *Bergy*, to which it refers here, are fully answered by my dissenting opinion in that case.[2]

The decision of the board should be affirmed.

[From the Congressional Record, May 19, 1978, pp. S7912–S7921]

TAX ASPECTS OF UNIVERSITY PATENT POLICY

Mr. NELSON. Mr. President, the Monopoly and Anticompetitive Activities Subcommittee of the Select Committee on Small Business will resume hearings next week on Government patent policy as part of the 2-year study it began in December 1977.

The hearings Monday, May 22, and Tnesday, May 23, will explore the history, legal basis and implications of Institutional Patent Agreements as an implement of government patent policy.

These agreements—used by the Department of Health, Education, and Welfare and the National Science Foundation—give universities and nonprofit organizations the right to patent inventions made in the conrse of federally funded research and development work.

In March, the Office of Federal Procurement Policy in the Office of Management and Budget granted my reqnest for a delay in the effective date of a General Services Administration procurement regulation anthorizing a newly worded Institntional Patent Agreement for Government-wide use.

OFPP administrator Lester Fettig directed GSA to delay the effective date of the regulation for 120 days—until July 18—to permit its further consideration by congressional committees and the Executive Office of the President.

In anticipation of the hearings, and for the benefit of the Senate and the public, I should like to include in the RECORD an article, "Tax Aspects of University Patent Policy," from the fall 1975 issue of the Journal of College and University Law. The article considers three tax aspects:

First. The effect of the university's patent-related activities on its tax-exempt status.

Second. The application of the tax on unrelated business income to the university's patent-related activities.

Third. The treatment of payments received by the university from its patent activities.

[2] I am also persuaded by the point so well made in Judge Baldwin's dissenting opinion.

of the patent laws enacted thereunder, if we were to interpret the statute as though it included the word "dead."

Similarly, analogy to oranges unfairly and unjustly resurrects the "product of nature" issue, which all parties had thought was settled. That question is not before us.

As with Fulton's steamboat "folly" and Bell's telephone "toy," new technologies have historically encountered resistance. But if our patent laws are to achieve their objective, extra-legal efforts to restrict wholly new technologies to the technological parameters of the past must be eschewed. Administrative difficulties, in finding and training Patent and Trademark Office examiners in new technologies, should not frustrate the constitutional and statutory intent of encouraging invention disclosures, whether those disclosures be in familiar arts or in areas on the forefront of science and technology.

[U.S. Court of Customs and Patent Appeals]

IN THE MATTER OF THE APPLICATION OF ANANDA M. CHAKRABARTY

(Appeal No. 77-535; Serial No. 260,563)

Baldwin, Judge, dissenting.

I find the majority's statement of the issue in this case to be ambiguous and I disagree with Chief Judge Markey's broad statement of the issue. As I see it, the issue is whether applicant's modification of a clearly unpatentable living organism is sufficient to render the resulting living organism statutory subject matter. The majority apparently bases its argument on the belief that the claimed organisms must fall into one of two categories—"products of nature" ("manufactures" of God or nature) or patentable subject matter ("manufactures" of man). The PTO admits that the modified organism does not fall into the product-of-nature category, because the organism is not naturally occurring.[1] Therefore, the majority believes the modified organism must fall into the statntory subject matter category. But the dichotomy underlyiug this syllogism is not the law.

The law, as propounded by the Supreme Court, defines three alternatives. Between true "products of nature" and statutory subjects matter or "manufactures" lies an intermediate category of things sufficiently modified so as not to be products of nature, but not sufficiently modified so as to be statutory "manufactures." Therein are found the borax-impregnated oranges of American Fruit, note 1 supra, and, in my view, the organisms now before us.

The present case focuses on the degree and nature of modification necessary to convert an admittedly unpatentable living thing into statutory subject matter. The Supreme Court, in *American Fruit*, considered whether impregnating fresh fruit skins with borax prevent molding changed the natural products into statutory subject matter. The Court stated that, in order to become statutory subject matter, the new article must possess "a new or distinctive form, quality, or property." 283 U.S. at 11, 8 USPQ at 133. There must be a "change in the name, appearance, or general character of the" natural product, 283 U.S. at 12, 8 USPQ at 133. It is not enough that the new article is better adopted to the use for which the natural product was already suited, 283 U.S. at 12, 8 USPQ at 133. I read *American Fruit* as saying that a modified natural product does not become statutory subject matter until its essential nature has been substantially altered. The issue in the present case becomes whether the modification effected by appellant altered the essential nature of the starting material.

Applying the *American Fruit* rule to the modification of living organisms and to the case before us, I believe that the essential nature of the unpatentable organism with which applicant started was its animateness or life. Appellant has not changed this essential nature; he has not created a new life. Rather, he has merely genetically grafted an extra plasmid on to the organism and, thereby, made the organism better at cleaning up oil spills. While this improvement in oil digesting ability does exclude the new organism from classification as a mere product of nature, like the borax-impregnated orange which was a better commercial product because it had a longer shelf life, this improvement in the utility

[1] Contrary to Chief Judge Markey's statement, I find no admission by anyone that the present invention is a statutory "manufacture." "Manufacture" and "man-made" are not synonymous for patent purposes. *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 8 USPQ 131 (1930).

The decision and opinion of the board are quite similar to its action and reasoning in the recent case of *In re Bergy*, 563 F. 2d 1031, 195 USPQ 344 (CCPA 1977), wherein we reversed the decision of the board (subsequent to its decision herein).

In the present case, the board first pointed out that the examiner had rejected the appealed claims only under 35 USC 101 [2] on the ground that they are not encompassed by the provisions" thereof, advancing two reasons therefor: (1) that the claimed microorganisms are "products of nature" and (2) that they are drawn to "live organisms." The board reversed the examined on point (i), agreeing with appellant that the claimed bacteria are not naturally occurring. The decision was expressed in a single sentence and the rest of the board's opinion was devoted to a discussion of the legal effect of the fact that the claimed bacteria are alive.

The board first discussed a number of cases which it had considered and concluded that there is "no case dealing directly with the point here in issue," including, possibly as of first importance, the Supreme Court's opinion in *Funk Brothers See. Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127 (1948). (In *Bergy*, supra, the board also stated that it had "not found any case directly in point.") The board than pursued exactly the same line of reasoning it did in *Bergy*, in large part in the same words, to reach the same conclusion it expressed in *Bergy*, that § 101 "does not include living organisms." the board's opinion that § 101 does not include any living organism was expressed in the form of its belief that Congress did not so intend. As in *Bergy*, this view was deduced from the enactment of the Plant Patent Act of 1930, citing this court's opinion in *In re Arzberger*, 27 CCPA 1315, 112 F.2d 834, 46 USPQ (1940).[3]

Responsive to the initial opinion of the board, appellant filed an extensive petition for reconsideration pointing out that the examiner had first raised the "living organism" question in his Answer to appellant's brief on his appeal to the board, wherefore appellant had not had an opportunity to present argument directed to the significance of the passage of the Plant Patent Act as an indication of the intent of Congress with respect to all living things, and argued that there was good reason to pass a special act for plants, other than the fact they are alive. That reason was that plants cannot be so described in a patent specification as to enable the reader to produce them, as was required of other inventions by R.S. 4888, the predecessor of 35 U.S.C. 112, first paragraph, for which reason special legislation relaxing that requirement in the case of plants was necessary. Thus, appellant argued, the passage of the Plant Patent Act is not to be taken as "an expression of *any* sort of Congressional intent with respect to the patentability of living organisms." The board's opinion on the petition reiterated that it knew of "no case dealing with the point here in issne," stating, more specifically, that "microorganisms per se have not squarely been ruled either eligible or ineligble for product patent coverage in any reported court or Patent Office decision," and adhered to its original opinion and decision. Appeal to this court was thereupon filed.

OPINION

Appellant's reply brief succinctly sums up the issue before us in these words:

In the instant appeal, appellants [sic] are seeking protection for a *new bacterium*, admittedly alive, in which such changes have been effected as to produce in this bacterium *new capabilities*. The Board of Appeals has agreed that this organism is *not a "product of nature"*. It is be accepted that all things in our world are either products of nature or things produced by man, then by the process of elimination the Board of Appeals has agreed with appellant's contention that his new bacterium is a thing produced by man, i.e. a manufacture. It should

[2] 35 USC 101 reads:

§ 101. *Inventions patentable*

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[3] Although *Bergy* reached this court and was decided before the instant appeal (*Chakrabarty*), the latter was the first to be decided by the board. The two cases were clearly pending in the board at the same time and were decided by entirely different 3-man panels. *Chakrabarty* was decided May 20, 1976, and *Bergy* June 22, 1976. Bergy appealed forthwith but Chakrabarty filed a petition for reconsideration which was decided October 19, 1976. *Bergy* was argued in this court on March 3, 1977, and *Chakrabarty* on December 5, 1977. Any common language found in the board's two opinions—and there is much—presumably originated in the *Chakrabarty* case.

"Under patent law, protection is presently *limited* to those varieties of plants which reproduce asexually, that is, by such methods as grafting or budding. *No* protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. Thus, patent protection is *not* available with respect to new varieties of most of the economically important agricultural crops, such as cotton or soybeans." [Emphasis added.]

Thus, the Patent Act of 1952 was considered to be limited to plants falling under 35 USC 161, and 35 U.S.C. 101 was not considered to cover any plants whatsoever.

The majority, in holding that the biologically pure culture of a microorganism defined by claim 5 constitutes patentable subject matter, relies heavily on the fact that processes of *using* the microorganism constitute patentable subject matter, saying:

"It seems illogical to us to insist that the existence of life in a manufacture or composition of matter in the form of a biologically pure culture of a microorganism removes it from the category of subject matter which can be patented while the functioning of a living organism and the utilization of its life functions in processes does not affect their status under § 101."

However, this court has pointed out that claims directed to processes of using an algorithm to *operate* a system constitute patentable subject matter while claims directed to the algorithm *per se* (or to methods of *calculating* using the algorithm) do not. See *In re Waldbaum*, — F. 2d —, —, 194 USPQ 465, 470 (CCPA 1977) (*Waldbaum II*). *Compare In re Richman*, —F. 2d —, —, — USPQ — (CCPA 1977) *with In re Flook*, — F. 2d —, — USPQ — (CCPA 1977). Similarly here, the fact that claims directed to a process of *using* microorganisms constitute patentable subject matter does not logically compel the conclusion that claims to biologically pure cultures of microorganisms are patentable.[2]

Moreover, by emphasizing the microorganism portion of a claim to the process of using the microorganism, the majority opinion is taking an approach rejected by this court in cases such as *In re Chatfield*, 545 F. 2d 152, 158, 191 USPQ 730, 736 (CCPA 1976); *cert. denied*, 46 U.S.L.W. 3202 (October 4, 1977), and *In re Deutsch*, 553 F. 2d 689, 691 n. 3, USPQ 645, 647 n. 3 (CCPA 1977), namely dissecting the claim and concentrating on one portion of the claim in determining the issue of patentable subject matter.

The majority opinion says "it is in the public interest to include microorganisms within the terms 'manufacture' aud 'composition of matter' in § 101." Although such a statement might be of interest to an appropriate committee of Congress, it has no relevance to the court's responsibility for determining Congressional intent. At noted by Chief Judge Markey in his concurring opinion in *In re McKellin*, 529 F. 2d 1324, 1333, 188 USPQ 428, 437 (CCPA 1976):

"[T]he patent law is statutory. Our representative form of government requires that the enactments of its Congress must always be, at the very least, the starting point. There being no common law of patents, we should take care to fill the Holmesian interstices of the statute with judge-made law only under the gravest and most impelling circumstances."

The majority opinion, after stating that "[w]e consider the product-of-nature issne . . . no longer in the case," then finds the issue "wholly lacking in merit." Since the culture defined in claim 5 is not a "manufacture" or a "composition of matter" and since we do not have the view of the board majority on the porduct-of-nature issue, I would not reach that issue on this appeal.

In view of the foregoing, the decision of the board should be affirmed.

[2] The majority also says that the claimed culture "is an industrial product used in an industrial process—a useful or technological art if there ever was one. See *In re Waldbaum*, 59 CCPA 940, 457 F. 2d 997, 173 USPQ 430 (1972) [*Waldbaum I*]." However, the question is not whether the claimed culture is in a technological art, but whether the claimed subject matter was intended by Congress to be within the scope of 35 USC 101. *Cf. Gottschalk* v. *Benson*, 409 U.S. 63, 175 USPQ 673 (1972). Further, it is to be noted that claims in the Waldbaum application were rejected by the PTO after this court's decision in *Waldbaum I, supra*, based on the Supreme Court's reasoning in *Benson*, which rejected was affirmed by this court in *Waldbaum II, supra*.

ficance and that disposes of the board's ground of rejection and the sole reason for refusal of a patent argued by the solicitor.

As for the board's fears that our holding will of necessity, or "logically," make all new, useful, and unobvious species of plants, animals, and insects created by man patentable, we think the fear is far-fetched. In any case, that question is not before us, as we have indicated above. Nor are we influenced by the legislative history of the Plant Patent Act of 1930 in the course of which nobody had anything to say about patent protection for microorganisms, so far as we know. The collective mind of Congress was not turned in that direction. We are not here concerned with interpretation of the Plant Patent Act as this court was in *In re Arzberger*, supra, which simply held that *that act* did not encompass bacteria.

The decision of the board affirming the rejection of claim 5 is *reversed*.

[U.S. Court of Customs and Patent Appeals]

IN THE MATTER OF THE APPLICATION OF MALCOLM E. BERGY, JOHN H. COATS, AND VEDPAL S. MALIK

(Patent Appeal No. 76–712; Serial No. 447,766)

Kashiwa, Judge,[1] concurring.

I agree wilth the result and the reasoning of the opinion by Judge Rich joined by Chief Judge Markey. Nevertheless, I wish to emphasize, out of a super-abundance of caution, that I read the majority opinion as setting forth an extremely limited holding. While the PTO and the dissenting opinion raise the specter of patenting higher forms of living organisms, quite clearly the majority opinion does not support such a broad proposition. Each case must necessarily be considered on its own facts. On the facts of this case, I join the narrow confines of the majority opinion.

[U.S. Court of Customs and Patent Appeals]

IN THE MATTER OF THE APPLICATION OF MALCOLM E. BERGY, JOHN H. COATS, AND VEDPAL S. MALIK

(Patent Appeal No. 76–712; Serial No. 477,766)

Miller, Judge, dissenting, with whom Baldwin, J., joins.

I do not agree that a biologically pure culture of microorganisms is within the scope of 35 U.S.C. 101 intended by Congress.

The board majority concluded—

"[35 U.S.C. 101] does not specifically proscribe patents on plants, yet it was found necessary to enact a special section in order to reward horticulturalists and agriculturalists (35 U.S.C., Chapter 15, Sections 161–164). If 35 U.S.C. 101 were to be broadly construed there would clearly not have been any necessity for Chapter 15 of 35 U.S.C.

"We are especially impressed by the legislative history of R.S. 4886 (U.S.C. Title 35, Section 31), the predecessor of the present Chapter 15 of 35 U.S.C. We believe that the legislative history reveals a clear Congressional intent that plants were not covered by the predecessor of 35 U.S.C. 101. . . .

"Based upon the legislative history . . . we do not believe that the terms 'manufacture' or 'composition of matter,' as employed in 35 U.S.C. 101, were intended to encompass any living organism, whether plants or the microorganism appellants are claiming here." [Emphasis added.]

The response of the majority opinion here is simply:

"Nor are we influenced by the legislative history of the Plant Patent Act of 1930 [ch. 312, 46 Stat. 376] in the course of which nobody had anything to say about patent protection for microorganisms. . . ."

It then attempts to distinguish between microorganisms and more-complex living things, such as those included within the common meaning of "plants," saying:

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[1] Judge of the United States Court of Claims sitting by designation pursuant to 28 USC 293(a).

so claimed. The dissenting board member was entirely correct in so interpreting our *Mancy dictum*. The examiner relied on it only to support his product-of-nature reasoning, and the board majority did not mention it, having abandoned that reasoning. Furthermore, it now appears to us, in light of what we have learned in this case about the separation and identification of new strains of *Streptomyces*, that our dictum was ill-considered. Had we known what we now know, we would likely have abjured the stated presumption.

Guaranty Trust Co. v *Union Solvents Corp.*, supra, as cited by the examiner as "especially pertinent" and again by the solicitor as a "judicial precedent" solely for the following passage appearing at the very end of the long trial court opinion (54 F. 2d at 410, 12 USPQ at 57, emphasis ours) :

Lastly, the defendant contends that the invention of the Weizmann patent is unpatentable since it is for the *life process* of a living organism. *Were the patent for bacteria per se, a different situation would be presented.* As before stated, the patent is *not* for *bacteria per se*. It is for a fermentation process employing bacteria discovered by Weizmann under conditions set for in the specification and claims. Undoubtedly *there is patentable subject-matter in the invention.* Cochrane v. Deneer, 94 U.S. 780, 24 L.Ed, 139; Risdon Iron & Locomotive Works v. Medart, 158 U.S. 68, 15 S. Ct. 745, 39 L. Sd. 899; Cameron Septic Tank Co. v. Village of Saratoga Springs, 159 F. 453 (C.C.A. 2) ; Dick v. Lederle Antitoxin Laboratories (D.C.) 43 F. (2d) 628."
[6 USPQ 40 (S.D.N.Y. 1930)].

The statement the examiner relied on, "Were the patent for bacteria *per se*, a different situation would be presented," is a trite observation of minimal magnitude as precedent, dealing with a non-issue on which no opinion was expressed. What we find of interest and, indeed, "pertinent" is the fact that the defendant urged the unpatentability of claims because they involved a *life* process of a *living* organism and the court *rejected* the argument. At the outset, the opinion states that one of the defenses was "nonpatentable subject matter." The real plaintiff in the case was Commercial Solvents Corporation, exclusive licensee under the Weizmann patent in suit, which corporation was making butyl alcohol and acetone by the Weizmann bacteriological fermentation process, and, with its predecessors, had been doing so since 1918. In 1929 the production was 107,500,000 pounds. The trial court noted that "The record shows that an important and extensive new industry has now been developed and established upon the Weizmann process." It was very clear to the court that it was dealing with a life process for, in describing the invention, it said, " 'Fermentation' is the chemical change, or the decomposition into new chemical compounds, of a substratum, by living organisms, such, for example, as yeast or bacteria." On the issue whether a *process* dependent upon living organisms and their life process was patentable subject matter, the court had no doubts. In the last case cited in the above quotation, *Dick* v. *Lederle*, two years earlier the court had found a scarlet fever toxin and antitoxin and process of making the same to be patentable subject matter notwithstanding the employment of life processes in their preparation. On appeal in the *Guaranty Trust* case, the Third Circuit Court of Appeals affirmed per curiam on the opinion of the trial judge, commenting, inter alia, that it had been persuaded "that the invention disclosed in the patent created a new and important commercial enterprise * * *."

These decisions illustrate what we believe to have been the state of the law ever since, namely, that *processes*, one of the categories of patentable snbject matter specified in § 101, are uniformly and consistently considered to be statutory subject matter notwithstanding the employment therein of living organisms and their life processes. Witness the action of the PTO in the present case in allowing the process claims. Other examples of such patentable process claims involving living bacteria are to be seen in the bacterial sewage treatment cases of which one is *City of Milwaukee* v. *Activated Sludge, Inc.*, 69 F. 2d 577, 21 USPQ 69 (CA 7 1934). (See quoted claims 8 and 10 of reissue patent No. 15,140 in fn. 4.) A still earlier one is the *Cameron Septic Tank Co.* case cited in *Guaranty Trust* and dicided by the Second Circuit Court of Appeals in 1908, wherein the trial court was reversed and bacterial-action process claim were held valid and infringed. (The original "septic tank.") It seems illogical to us to insist that the existence of life in a manufacture or composition of matter in the form of a biologically pure culture of a microorganism removes it from the category of subject matter which can be patented while the functioning of a living organism and the utilization of its life functions in processes does ont affect their status under § 101. Of course it is clear, as the dissenting board member noted, that there is nothing in the words of § 101 which excludes patents for living organisms.

The board majority opinion then makes two points in support of its conclusion that § 101 percludes patenting anything living. The first is based on this court's decision in In re Arzberger, 27 CCPA 1315, 112 F.2d 834, 46 USPQ 32 (1940), that bacteria are not included in the plant patent provision of former Title 35 (then part of § 4886 of the Revised Statutes, since 1952 separately treated in 35 U.S.C. 161–164), notwithstanding that they may be scientifically classified as plants, because Congress plainly did not intend them to be when, in 1930, it enacted the Plant Patent Act (46 Stat. 376). The case was concerned only with the plant patent statute and this court did not have before it any other issue, such as inclusion of bacteria in any other statutory category, appellant having applied for a "plant pateut" on a bacterium. The second aspect of the board majority's supporting reasoning is fully stated in the following paragraph:

"If we were to adopt a liberal interpretation of 35 U.S.C. 101 new types of insects, such as honeybees, or new varieties of animals produced by selective breeding and cross-breeding would be patentable. Moreover, those plants which are excluded from the scope of 35 U.S.C. 161, such as tuber propagated plants or plants which can be reproduced only sexually, would be patentable under 35 U.S.C. 101. We do not believe that Congress iutended 35 U.S.C. 101 to encompass any living organism, whetber they be plants or microorganisms."

The dissenting board member, stating that he had reviewed all of the precedents cited by eitber side and others as well, many of which he discussed in detail, expressed these views:

"* * * I do not believe that the fact that plant and bacteria have some properties in common is sufficieut basis for holding that bacteria are to he excluded from patent coverage. * * *

"* * * I do uot find it improper to claim living organisms * * *

"In view of the discussed cases, and since 35 U.S.C. 101 does not expressly exclude pattents to living organisms, it is my opinion that liviug organisms, as claimed, may be patented if such claims also fulfill the other requirements of the statute."

He also expressed disagreement with the examiner's view that claim 5 defined a "product of nature," or that being a product of nature was sufficient reason, alone, for holding an invention nonstatutory. He made these observations:

"Rather, I view a "product of nature" as being something that "exists" in nature and therefore evidence that it may uot be "new" as this expression finds meaning in the Patent Statute. Accordingly, I would treat "products of nature" like any other material and determine whether they are new or obvious in view of the state of the art.

"Certainly vitamin B–12, as it exists in liver, and adrenalin, as it appears in adrenal glands, are products of nature, yet the courts have held (Merck & Co., B–12 and Parke Davis and Co., adrenalin) [1] that when such materials are extracted and concentrated in a purified form they are patentable. Accordingly, it is not sufficient to determine wbether the pure culture claimed is a product of nature."

OPINION

Under the peculiar circumstances of this case, in which the board switched the supporting reasoning for the rejection of claim 5 as for nonstatutory subject matter without expressly making a new rejection, we deem it prudent to clarify the issue we have to decide. The brief of the PTO Solicitor sees but a single issue: "whether *living* organisms are the kind of 'manufacture' or 'composition of matter' intended by Congress to be included within 35 U.S.C. 101." (Emphasis ours.) Appellants argue that issue, making no objection to the board having raised it sua sponte, aud also—perhaps out of an abundance of caution—argue the product-of-natnre question sidetracked by the board. Appellants forcefully presented the latter issue before the board and submitted affidavits of three experts in the field to the effect that the "biologically pure culture" of claim 5 is not found in nature. The evidence appears to us to be incontrovertible. The dissenting member of the board accepted it. The board did not refute it, and the solicitor has not challenged it. The circumstances persuade us that the board went in search of auother reason to support the rejection because it realized the examiner's position was untenable. We consider the product-of-nature issue to have been abandoned and no longer in the case. However, since the solicitor in-

[1] *Merck & Co.* v. *Chase Chemical Co.*, 273 F. Supp. 68, 155 USPQ 139 (D. N.J. 1967); *Merck & Co.* v. *Olin Mathieson Chemical Corp.*, 253 F. 2d 156, 116 USPQ 484 (CA 4 1958); *Parke Davis & Co.* v. *H. K. Mulford Co.*, 189 Fed. 95 (S.D. N.Y. 1911), *aff'd*, 196 Fed. 496 (CA 2 1912).

tion of whether ultimately someone could patent a human being—and that should be up to Congress, not to a couple of judges."

PTO Associate Solicitor Gerald Bjorge stated this view in only half-facetious terms during oral argument in the GE case. "My children's Shetland sheepdog, he said, "was new and useful when it came' into the world. We feed and culture it, and it is our burglar alarm. My children's cat was new and useful and we feed and culture it, and it is our mousetrap. How does this court ever hope to distinguish between one living organism and another? Where and how will it draw the line?"

[U.S. Court of Customs and Patent Appeals]

IN THE MATTER OF THE APPLICATION OF MALCOLM E. BERGY, JOHN H. COATS, AND VEDPAL S. MALIK; DECIDED: OCTOBER 6, 1977

(Patent Appeal No. 76–712) (Serial No. 477,766)

Rich, Judge.

This appeal is from the majority decision of the divided Board of Appeals (board) of the United States Patent and Trademark Office (PTO) affirming the rejection of claim 5 of application serial No. 477,766, filed June 10, 1974. We reverse.

THE INVENTION

The subject of the application, which, when filed, had the noncommittal title "Process," is made clear from the Abstract of the Disclosure, which reads:

Microbiological process for preparing the antibiotic lineomycine at temperatures ranging from 18° C. to 45° C. using the newly discovered microorganism *Streptomyces vellosus*. The subject process advantageously results in the preparation of lincomycin without the concomitant production of lincomycin B (4-depropyl-4-ethyllincomycin). The absence of lincomycin B production results in increased lincomycin recovery efficiency.

On demand of the examiner, the title was later changed to "Process for Preparing Lincomycin." The application was filed with four claims to such a *process* which the examiner allowed. By a preliminary amendment, filed before any action on the application but not reached by the examiner until his second actiou, claim 5 was added together with the attorney's statement that "Basis for claim 5 can be found throughout the disclosure." That claim reads:

"5. A biologically pure culture of the microorganism *Streptomyces vellosus*, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbo, nitrogen and inorganic substances."

The designation of "NRRL 8037" in claim 5 is elucidated by the following statement in the specification:

THE MICROORGANISM

"The novel actinomycete used according to this invention for the prodnctiou of lincomycin is *Streptomyces vellosus*. One of its strain characteristics is the production of lincomycin without the concomitant production of liucomyciu B. Another of its strain characteristics is the production of comparable titers of linocomyciu at a temperature of 28° C. and 45° C. A subculture of this living orgauism can be obtained upon request from the permanent collection of the Northern Regional Research Laboratories, Agricultural Research Services, U.S. Department of Agriculture, Peoria, Illiuois, U.S.A. Its accession nnmber in this repository is NRRL 8037."

The specification continues:

"The microorganism of this invention was studied and characterized by Alma Dietz of the Upjohn Research Laboratory."

What follows that statement is an elaborate, highly technical, detailed description of the microorganism, including its type designation as "*Streptomyces vellosus* Dietz, sp.n.," occupying over ten pages of the printed specification, followed by exemplary descriptions of the production of lincomycin therefrom by fermentation processes and the recovery of the lincomyciu prodnced by the fermentation.

[From the Congressional Record, May 19, 1978, pp. S7883–S7890]

PATENTING LIFE

Mr. NELSON. Mr. President, if forms of life can be patented, should recombinant DNA research inventions developed with the support of the Department of Health, Edncation, and Welfare be patentable by universities in the same way drugs and other campus discoveries are?

As part of its continuing study of Government patent policy, the Monopoly and Anticompetitive Activities Subcommittee of the Select Committee on Small Business will hold hearings next week on the history and legal basis of institutional patent agreements.

These agreements give colleges, universities, and nonprofit organizations first option to own the rights to inventions resnlting from Government-sponsored research and development.

The Department has used institutional patent agreements in their present form since 1968 and reports it now administers 72 IPAs. The National Science Foundation began using an IPA in 1973.

In February, the General Services Administration declared that all agencies supporting university research could begin using a newly worded IPA as of March 20. At my request, the Office of Federal Procurement Policy in the Office of Management and Budget agreed to stay the new patent regulation until July 18.

Meanwhile, the National Institutes of Health were announcing their decision that, at least for the present, recombinant DNA research inventions developed with HEW support can be patented under existing institutional patent agreements. Dr. Robert M. Rosenzweig, vice president for public affairs at Stanford University, had written NIH in June 1976, saying both Stanford and the University of California felt the need for a formal advisory opinion on the patenting of recombinant DNA inventions developed under NIH grants or contracts.

Mr. President, whether such inventions shonld be patentable in the same way otber university discoveries are ought to be a major policy question in its own right. Consider this statement by the Patent and Trademark Office on January 13, 1977, when it announced it would offer accelerated processing of recombinant DNA patent applications:

"Recombinant DNA research appears to have extraordinary potential benefit for mankind. It has been suggested, for example, that research in this field might lead to ways of controlling or treating cancer and hereditary defects. The technology also has possible applications in agriculture and industry. It has been likened in importance to the discovery of nuclear fission and fusion."

The offer of accelerated processing was later withdrawn, but the statement stands.

In two recent decisions, the U.S. Court of Customs and Patent Appeals has ruled that life forms are patentable.

The first of these, on October 6, 1977, awarded a patent to tbe Upjohn Co. for a micro-organism is isolated and purified for use in preparation of the antibiotic lincomycin. The Patent and Trademark Office filed a petition for certiorari with the U.S. Supreme Court on March 3, from which the Court has 90 days to indicate whether it will hear the case.

In the second of these, the appeals court on March 2 ruled in favor of the General Electric Co.'s application for a patent on a new strain of oil-degrading bacteria, useful for biological control of oil spills. The Government has not decided whether it will appeal the ruling.

Mr. President, I ask that a column by Alan L. Otten in the Wall Street Journal of January 26 on patenting life be printed in the Record, along with the two decisions of the appeals court.

[The material follows:]

PATENTING LIFE

(By Alan L. Otten)

Washington.—A tiny number of government officials, lawyers and scientists have begun wrestling with a huge legal problem: Should forms of life be patented?

Ultimately, the Supreme Court or Congress may have to provide the answer. It's another area where rapidly expanding scientific knowledge is creating tricky new ethical, legal and social quandaries.

The question immediately at stake is whether patents should be granted for microorganisms, those minute living and reproducing bacteria, viruses and other

Recent proposed amendments to federal procurement regulations would provide for procurement regulations would provide for the use of Institutional Patent Agreements in contracts with universities and nonprofit organizations. 43 Fed. Reg. 4424 (1978). Such agreements would permit those institutions, subject to certain conditions, to retain the rights to inventions made in the course of contracts with the Government. Proposed 41 C.F.R. 1-9. 107-4 (a) (6); 43 Fed. Reg. 4424 (1978). Pursuant to such Institutional Patent Agreements, the institution must furnish the government agency involved a "complete technical disclosure for each subject invention within 6 months after conception or first actual reduction to practice . . . [and] prior to any sale, public use, or publication of the invention known to the institution." The disclosure must be "sufficiently complete in technical detail to convey to one skilled in the art to which the invention pertains a clear understanding of the nature, purpose, operation, and, to the extent known, the physical, chemical, biological, or electrical characteristics of the invention." Interim and final reports listing inventions are also required. Proposed Institutional Patent Agreement, section (e); 43 Fed. Reg. 4425 (1978).

The Proposed Institutional Patent Agreement also contains the following disclosure provision:

"(3) The Institution agrees that the Government may duplicate and disclose Subject Invention disclosure and, subject to paragraph (k), all other reports and papers furnished or required to be furnished pursuant to this Agreement. However, if the Institution is to file a patent application on a Subject Invention, the Agency agrees, upon written request of the Institution, to use its best efforts to withhold publication of such invention disclosures until a patent application is filed thereon, but in no event shall the Government or its employees be liable for any publication thereof." 43 Fed. Reg. 4425.

Paragraph (k), referred to above, provides that institutions which administer their inventions must report on "the status of development and commercial use that is being made or intended to be made of each subject invention . . . and the steps that have been taken by the Institution to bring the invention to the point of practical application. . . . To the extent data or information supplied to this section is considered by a licensee to be privileged or confidential and is so marked, the Agency agrees that, to the extent permitted by law, it will not disclose such information to persons outside the Government." 43 Fed. Reg. 4426-7.

Thus, the institution, as a condition to the Institutional Patent Agreement, agrees to disclosure of invention disclosures made pursuant to section (e) of the Proposed Agreement, at least prior to a patient application being made. Once a patent application is made, the information contained in the application is protected by statute, 35 U.S.C. 122 (1970), and would be exempt under Exemption Three of the FOIA. *See, Irons* v. *Gottschalk*, 548 F. 2d 992, 994 n. 3. (D.C. Cir. 1976). In the case where the institution iutends to file a patent application, the Agency agrees "to use its best efforts to withhold publication of such invention disclosures until a patent application is filed thereon . . ." As far as other reports and papers furnished pursuant to the Agreement are concerned, the institution may designate those it deems "privileged or confidential" and the Agency agrees, "to the extent permitted by law", not to disclose such information.

Throughout the procedures by which an institution (including universities and nonprofit organizations) enters into Institutional Patient Agreement and develops a patented invention pursuant to Government grant or contract commercial use and marketing of the invention is a primary consideration. Prior to qualifying for an Institutional Patent Agreement a nonprofit organization must supply the contracting or granting agency with, among other things, a description of "the plans and intentions of the organization to hring inventions to the market place to which it retains title, including a descripion of the efforts typically undertaken by the organization to license its inventions." Proposed 41 C.F.R. 1-9.109-7(a) (8); 43 Fed. Reg. 4427. Before entering into an Agreement, the nonprofit organization must have a technology transfer program which shall include an "active and effective promotional program for the licensing and marketing of inventions". Proposed 41 C.F.R. 1-9.109-7(b) (5); 43 Fed. Reg. 4428. Furthermore, under existing regulations, contracts having Patent Rights clauses are to be administered so that "[e]xpeditious commercial utilization of such inventions is achieved." 41 C.F.R. 1-9.109-1(e) (1977). See also, Proposed Institutional Patent Agreement, section (i), 43 Fed. Reg. 4426.

Thns, an important goal of inventions which are disclosed pursuant to the Institutional Patent Agreement would seem to be commercial marketing. The

Government-sponsored research and development—as an implement of Government patent policy. Could the 72 institutions having such agreements with HEW cite that fact on their grant applications as official recognition of the commercial potential of the proposed research.

Finally, there is the basic question of what is patentable. NIH sometimes receives different opinions from its advisers as to what is patentable, as do universities and researchers. It is by no means obvious, perhaps because inventions must be "unobvious" to qualify for patenting.

Mr. President, I ask that the analysis by CRS, consisting of two memorandums, be printed in the Record.

[The material follows:]

THE LIBRARY OF CONGRESS,
CONGRESSIONAL RESEARCH SERVICE,
Washington, D.C., May 8, 1978.

To: Senate Subcommittee on Monopoly and Anticompetitive Act.
From: American Law Division.
Subject: The Applicability of Exemption Four of the Government-In-the-Sunshine Act and the Freedom of Information Act to NIH Peer Review Meetings and Invention Disclosures Pursuant to Institutional Patent Agreements.

This memorandum will analyze the propriety of language used in meetings notices of the National Institutes of Health in light of the Government-in-the Sunshine Act and the applicability of the Freedom of Information Act to invention and disclosures required by the provisions of the proposed Institutional Patent Agreement.

Meetings of the National Institutes of Health dealing with contract proposals and/or grant applications have been closed to the public on the basis of Exemption 4 of the Government-in-the Sunshine Act, 5 U.S.C. 552b(c)(4) (1976). The Federal Register Notices of such closures have stated:

"These proposals and applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposals and applications."

The question is the propriety of use of the phrase "patentable material" in the agency's justification for closing a meeting to the public. The starting point for analysis is the statutory language—which is identical to Exemption Four of the Freedom of Information Act, 5 U.S.C. 552(b)(4),—and judicial interpretations of that language, which was intended by Congress to be imported into the Government-in-the Sunshine Act provision. See, H. Rept. 94-880, 94th Cong., 2d sess. at 10 (1976).

Exemption Four of both Acts excepts from mandatory disclosure or openness "trade secrets and commercial or financial information obtained from a person and privileged or confidential." Thus, three basic categories of information are exempt from disclosure: 1) trade secrets; 2) commercial information obtained from a person which is privileged or confidential; or, 3) financial information obtained from a person which is privileged or confidential. See *Getman* v. *NLRB*, 450 F. 2d 670 (D.C. Cir. 1971).

The first category, trade secrets, has not occasioned much litigation as it was the intent of Congress to adopt the traditional interpretations of the legal term of art. See, O'Reilly, *Federal Information Disclosure*, 14.06 (1977). A common definition is that of the 2938 Restatement of Torts, § 757:

"A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business and which gives him opportunity to obtain an advantage over competitiors who do not know or use it."

See, *Kewanee Oil Company* v. *Bicron Corporation*, 416 U.S. 470, 474 (1974). A similar and frequently relied on definition is that given in *United States ex rel. Norwegian Nitrogen Prods. Co. v. United States Tariff Comm.*, 6 F 2d. 491 (D.C. Cir. 1925) rev'd on other grounds, 274 U.S. 106 (1927):

"An unpatented, secret, formula, or process, which is used for the making, preparing, compounding, treating, or processing of articles or materials which are trade commodities."

The other categories of information exempt from disclosure are commercial or financial information which is privileged or confidential. Commercial or financial information relates to the business affairs of a person. The interest in nondisclosure must be a commercial or trade interest. Thus, in *Washington Research Proj., Inc.* v. *Department of H.E.W.*, 504 F. 2d (DC. Cir. 1974) cert. denied, 421 U.S. 963 (1975), the court held that research grant applications suhmitted by

[1505-01]

GENERAL SERVICES ADMINISTRATION

Federal Supply Service

INSTITUTIONAL PATENT AGREEMENTS

Observance of New Effective Date

NOTE.—This document was inadvertently omitted from the notices section of the issue of Tuesday, July 25, 1978.

The use of Institutional Patent Agreements was prescribed in Federal Procurement Regulation (FPR) Amendment 187, April 11, 1977 (43 FR 4424, Feb. 2, 1978).

At the request of the Office of Federal Procurement Policy the effective date of the amendment was changed from March 20, 1978, to July 18, 1978 (43 FR 16979, Apr. 21, 1978). The change permitted further consideration of the amendment by Members of Congress and others.

FPR Amendment 187 is effective on July 18, 1977, as previously announced. However, the referenced review will be continued in conjunction with the examination of Government patent policy which is in progress.

JAY H. BOLTON,
Acting Commissioner.

[FR Doc. 78-20740 Filed 7-24-78; 11:28 am]

resulting from research and development work it sponsors, they would refer to the Government's bulging patent portfolio and its poor licensing performance. In discussing university licensing efforts, they would concede that performance has been spotty and not particularly profitable, then stress the principle of technology transfer and urge greater cooperation between Government, academia and industry to move discoveries out of the laboratory into the marketplace.

In his prepared statement for that House Appropriations subcommittee on March 10, Dr. Baruch said:

> Government laboratories and Government R&D contractors generate over 2,000 new patentable inventions each year for a total portfolio in excess of 27,000 inventions to which the Government has title and which are available for licensing. Fewer than 1,700 of these patents have been licensed and fewer still have actually been used. This program (of the NTIS) provides the mechanism for greater utilization of this tremendous technology resource.

A decade ago, according to NTIS, Government inventions generally were not evaluated for commercial potential and were not actively promoted. The condition of the Government's patent portfolio is not of itself a reason to suppose that universities could do better.

2. When it began a study of the department's patent policy last August, the HEW Office of General Counsel stopped processing requests from non-IPA holders for retention of patent rights, and there is a backlog of between 25 and 30 cases (1). No similar restriction has been placed on IPA holders, which appears to place non-IPA universities at a distinct disadvantage. Releasing the GSA patent regulation at this time would underscore that inequity.

Again, I appreciate your participation in our hearings, your cooperation and your willingness to receive these recommendations. Thank you.

Sincerely,

GAYLORD NELSON
Chairman

GN/gsy
Encl.

2. The standard IPA contained in the GSA provides that when a university decides to retain the rights to inventions resulting from Government-sponsored research, it shall "make them available through licensing on a nonexclusive, royalty-free, or reasonable royalty basis to all qualified applicants," except that:

> The institution may license a subject invention on an exclusive basis if it determines that an exclusive license is required in the public interest because (A) it is necessary as an incentive for development of the invention or (B) market conditions are such as to require licensing on an exclusive basis in order to bring the invention to the point of practical application.

As one might have guessed, exclusive licenses are the rule and not the exception under patent rights awarded by EEW pursuant to the IPA -- containing comparable language -- that it has been using for a decade.

Again, the NSF witness (2) said he appreciated that point that had been made

> in this connection about "government by exception." Of course, the unanticipated expansion of exceptions as rules are applied in practice, particularly over many years, is not uncommon in the law. It indeed can be a way of circumventing, or at least modifying, the original expectations held when the rule was promulgated. But it can also, on the other hand, be one of the heal thy ways in which new times, new problems, and new perceptions are accommodated within the old rules.

Several witnesses (7, 11, 12) argued for the need for exclusive rights, raising the prospect that the exceptional use of exclusive licensing permitted in the standard IPA will become the rule just as it has under the HEW IPA.

The grounds (A) and (B) for allowing an exclusive license should be conjunctive instead of disjunctive -- connected by "and," not "or" -- to require both tests to be

contained in the GSA patent regulation if it goes into effect (4, 17). If no other agencies plan to resort to the standard IPA, then the sole -- and insufficient -- short-run result of implementing the GSA patent regulation is standardization of practice between HEW and NSF. If other agencies do plan to resort to it, they and their IPA signatories would run the risk of having their arrangements nullified in a few months as a result of CIPI's recommendations to the President. Given the eagerness of leading research institutions to have the GSA patent regulation implemented (5), a crisis of rising expectations would result which could leave the universities resisting and resentful of the Carter Administration's eventual patent policy.

c. Letting the GSA patent regulation take effect on a frankly interim basis would not square with the rationale underlying the proposal in the President's fiscal year 1979 budget that the Government Patent Program of the National Technical Information Service be converted from a self-sustaining activity -- funded from program revenue -- to one funded entirely from appropriations.

When he appeared before a House Appropriations Committee subcommittee on March 10, 1978, Dr. Baruch said, "The Office of the President made that decision" (to change the funding basis). The following information was subsequently provided for the hearing record:

> There would be more accountability. More specifically, it would facilitate the Administration's monitoring of the program and review its development in accordance with future directions in Federal patent policy. Program revenues are expected to exceed program costs in the future; ...

It would be inconsistent to make that change for that purpose effective October 1 while allowing the use of Institutional Patent Agreements to be expanded on an interim basis.

d. The GSA patent regulation cannot be implemented on an experimental basis. It was not constructed as an experiment, and baseline data do not exist to permit it to be treated as such. With respect to detailed information on its experience with IPAs thus far, the NSF acknowledged (2) that "we do not have the detail we would like to provide."

I can see arguments on both sides for extending the stay, and I can also see arguments for in (sic) the interim, particularly if we are looking at a six to 14 month study period, to establishing an interim uniformity at least.

I want to thank you for your participation, for the cooperation of your office with subcommittee staff in the conduct of the hearings, and for your willingness to receive recommendations by July 18 from me or any members of the subcommittee regarding the patent regulation.

RECOMMENDATION

Based on the testimony and information presented at the subcommittee hearings, and on some relevant factors not disucssed at the hearings, I recommend that the stay of the GSA patent regulation be extended indefinitely.

In the explanation that follows, numbers in parentheses -- keyed to a numbered witness list, which is attached -- will be used to indicate the source of testimony and information cited.

POLICY CONSIDERATIONS

As a matter of policy, it would be premature to allow the GSA patent regulation to go into effect at this time, for these reasons:

1. While the Office of Federal Procurement Policy clearly has the authority to "prescribe policies, regulations, procedures, and forms" to be followed by executive agencies in the procurement of "services, including research and development," President Carter's Executive Order 12039, relating to the transfer of certain science and technology policy functions, published in the Federal Register on February 26, 1978, delegates to the director of the Office of Management and Budget "the responsibility for fostering any policies to facilitate the transfer and utilization of research and development results."

Witnesses at the subcommittee hearings (5, 7, 8, 10, 11, 12) contended that the purpose of the Government-wide IPA contained in the GSA patent regulation is to facilitate the transfer and utilization of research and development results.

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