Tab D

Analysis of Statutory and Administrative Roles of Agencies

Section 6 of P.L. 96-517 is composed of 35 U.S.C. 200 through 211. Sections 202 through 204 cover disposition of inventions to universities, small business and non-profit organizations. Sections 207 through 209 cover the licensing of government-owned inventions.

OFPP is designated under 35 U.S.C. 206 as the office responsible for establishing standard funding agreement provisions called for by 35 U.S.C. 202 through 204. OFPP is also designated under 35 U.S.C. 206 as the office responsible for determining the need to issue regulations implementing 35 U.S.C. 202 through 204 after receiving recommendations from OSTP. While it is unclear from 35 U.S.C. 206 whether OFPP needs to obtain the advice of OSTP in drafting the standard funding agreement provision, it is presumed they do since the conditions of the provision are set out in 35 U.S.C. 202 through 204

GSA is designated under 35 U.S.C. 208 as the office responsible for promulgating regulations for the licensing of government owned inventions under 35 U.S.C. 207 through 209. OSTP and OFPP are not given a role by 35 U.S.C. 208 in advising on these regulations.

OSTP, as noted, serves in an advisory capacity in drafting the standard funding agreement and regulations provided for in 35 U.S.C. 202 through 204. No input is required of OSTP in the drafting of regulations to implement 35 U.S.C. 207 through 209, the sections of the Act pertaining to licensing of government-owned inventions.

OMB has assistance policy development and coordination responsibilities but is not designated a specific role in the Act. However, clearly basic science assistance policies, productivity and innovation, the absence of an ongoing focal point for assuring implementation, and no provision for OSTP to be involved in advice on the licensing agreement provisions suggests at least an initial coordination responsibility and advice to the President on the implications of this Act in promoting a national policy on innovation. Also see Sec. 102(c)4 of P.L.94-282.

GAO is designated under 35 U.S.C. 202(b)(1)-3 to receive agency determinations involving exceptional circumstances which require the use of provisions other than the standard funding agreement provision; to advise agencies of patterns of determinations contrary to the policy and objectives of chapter 38 or that an agency's policies or practices are otherwise not in conformance with the Chapter; and at least once each year, transmit a report to the Committee on the Judiciary of the Senate and House on the manner in which Chapter 38 is being implemented and on such other aspects of government patent policies deemed appropriate.

SBA is designated under 35 U.S.C. 202(b)(1) to receive agency determinations involving exceptional circumstances which require the use of a provision other than the standard funding provision in funding agreements with small business firms.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

MAY 12 1981

MEMORANDUM TO: FRED DIETRICH

From: Tom Hadd

Subject: Revised Patent Amendments Draft Regulations (P.L. 96-517)

In accord with the agreements made between you and my staff on April 28th attached is the proposed revised draft regulation and funding agreement clause for P.L. 96-517.

Because of the late date and necessity to use these draft regulations as interim regulations for a specific period beyond July 1, 1981, I feel it is essential that any problems you may possibly have with our revisions be resolved prior to publishing the regulations in the Federal Register. In that connection we have added a few items regarding the lead agency and appeals issues, and have still remaining the unresolved issues of alternatives to Section 11 (Patent Rights Follow-up). Also, a "road map" has been provided to indicate areas where changes have been made.

Finally, I would like to propose that in the preamble we include a statement concerning when OMB will publish final regulations, and in this way indicate that revisions/refinements will be made quickly based on public comments. This will help defuse any concerns that a lengthy period will transpire in which the law will be implemented under regulations without benefit of public comment. In this regard I propose designating on or about September 15, 1981 as the date we will publish final regulations.

Please call me if you have any questions.

cc: Jim Kelly
William Mathis
Hal Steinberg
Dennis Prager

Draft Preamble to Federal Register Notice on P.L. 96-517

(a) Background

After many years of public debate on means to enhance the utilization of the results of government funded research, the last Congress enacted P.L. 96-517, "The Patent and Trademark Amendments of 1980". Sections 202-204 of the Act gives universities, non-profit organizations and small businesses a first right of refusal to title in inventions they have made in performance of government grants and contracts subject to some limited exceptions. In creating this right to ownership, the Act abolishes approximately 26 conflicting statutory and administrative policies.

Some understanding of the relative importance of the Act can be determined from the amount of research and development funding impacted. Based on fiscal year 1980's rate of government R&D funding of small business, universities, and non-profit organizations, the Act covers the disposition of the invention results from approximately 1.2 billion dollars of grant and contract awards to small business and approximately 5 billion dollars to universities and non-profit organizations. The 5 billion dollars utilized by universities and non-profits covers approximately 65% of the total cost of all the basic research

conducted in the U.S. This large investment coupled for the first time with the incentive of invention ownership in small businesses, non-profits and universities across all government research and development programs could initiate a significant increase in the commercialization of inventions resulting from these programs.

(b) Responsibilities Undertaken to Draft Implementing Regulations

Under the Act, OFPP is responsible for issuance of the regulations implementing sections 202-204 after consultation with OSTP. In order to expedite the drafting of these regulations and obtain the advice of agency personnel familiar with patent matters, OFPP relied on a GSA interagency committee for a preliminary draft of the implementing regulations for sections 202-204. This committee was formed through an invitation to all departments and agencies affected by the Act to participate in the drafting of the regulations.

During the drafting period a meeting was held between the Council on Governmednt Relations (COGR), OMB, and GSA representatives to discuss the concerns of the university community and solicit their views in writing. The draft regulations and funding agreement clause of Section 5 represents a reflection of many of the views expressed by COGR and other interested groups.

Notwithstanding the above, not all issues are entirely resolved

as reflected by alternative language incorporated into the text (at Section II of the Regulations) and ongoing reviews intended to ensure proper and uniform implementation, oversight, evaluation, and adjudication of appeals.

In particular, commentors attention and views are invited on the following important elements of the draft regulations:

A. Issues of Uniformity

- Will the provisions prepared ensure maximum consistency of application of of the laws and regulations on a governmentwide basis and provide minimum regulatory and reporting requirements burden?

- What appeals and disputes resolution policy and procedures should be applied governmentwide to ensure equity, fairness and expeditious handling of cases?

- Under what conditions should a government agency entertian an appeal of a decision affecting ownership rights?

- Are the utilization reporting requirements sufficient to provide both the private sector and federal government adequate information with which to determine proper utilization of inventions?

- Should a single set of uniform requirements for assistance (grants, cooperative agreements) and procurement be issued by OMB, or one for assistance and one for procurement?

B. Issues of Coordination and Monitoring of the Act

- Which department or agency, if any, should be accorded governmentwide responsibility as lead agency for coordination, evaluation, correlation of department and agency reports, liaison with the Comptroller General, etc.?

- In assessing what kinds of information shall be collected by the lead agency, what should be considered in evaluating the benefits of the Act?

The above are illustrative of the type of issues which OMB is considering in preparing the regulations for issuance. Commentors views are encouraged on these and all other issues contained in the following. Where possible, revised language suggesting improvements and the rationale for changes is invited.

DRAFT

Subject: Implementing the Patent and Trademark Act Amendments of 1980

I. Issues Requiring Decision:

- Should the Administration authorize the drafting of implementing regulations?
- Should the Administration assign a governmentwide focus of responsibility for implementing, coordinating, and evaluating the results of this legislation?
- What ongoing role, if any, should OMB play in implementing this legislation?

II. Background

In the last decade the U. S. economy has been badly damaged by the increasing cost of imported energy, the decline of available domestic natural resources and the stranglehold of competition from imported goods due largely to low cost labor, increased productivity or innovative improvements. While assessing our economic problems it has become clear that other nations - Japan in particular — have maintained a high level of employment and productivity, and a favorable balance of payments despite more severe short falls of native energy and other natural resources. The favorable trade conditions of these nations are attributed, in part, to their reliance on high technology in the manufacture of products for both domestic and foreign consumption. It is now considered nearly an axiom among many opinion leaders that technological innovation is crucial to the continued economic vitality of all nations, including our own. Clearly "invention", and its application as "innovation" are again fashionable.

This rediscovered axiom has produced competing spokesmen for increased support of high technology. While this competition has already produced some legislative and administrative remedies that further fragment innovation and productivity policies, major legislation intended to clean up this fragmentation through creation of a national policy of supporting entrepreneurs and new high technology enterprises was enacted during the 96th Congress (The Patent and Trademark Act Amendments of 1980, P.L. 96-517).

P.L.96-517 and Its Impact

The Patent and Trademark Amendments Act (P.L. 96-517) gives small businesses, universities, and other non-profit organizations a first right of refusal to title in inventions they have made in performance of government grants and contracts subject only to certain limited exceptions. The Act eliminates approximately 26 conflicting legislative and administrative policies covering the disposition of inventions made by small business, universities and non-profit organizations with government assistance. Essentially, it establishes a crosscutting requirement tied to assistance (grants, cooperative agreements) and procurement programs. (See Tab A for copy of Act)

Based on Fiscal Year 1980's rate of funding of small business, university and non-profit research and development, the Act will cover the disposition of the invention results from approximately 1.2 billion dollars of grant and contract awards to small business and approximately 5 billion dollars to universities and other non-profit organizations. The 5 billion dollars of federal funds utilized by universities and non-profits covers approximately 65% of the total costs of all the basic research conducted in the U.S.

During the past decade, the U.S. experienced the lowest growth in manufacturing

productivity of any of the seven major industrialized nations. All the causes of this lag in productivity cannot be easily identified. However, the major and direct link between productivity growth and innovation requires that every possible effort be made to enhance innovation. Of the many possible explanations for a low level of innovation, one, failure to adequately fund basic research, has been ruled out by some opinion leaders (this position is supported by the business community). This finding could well be based on the single fact that the United States has dominated the Nobel Science prizes with 73 American prizes in physics, chemistry and medicine in the last 20 years. This is in contrast to the award of only one similar prize to the Japanese in a country where science also gets strong financial support. During the same period similar prizes were won by only four Russians, five Frenchmen and eight West Germans.

Thus, one can argue that a serious deficiency in our support of innovation appears at the very next steps beyond basic research in the innovation process: the direct transfer of new basic research advances into the marketplace, and their evolution and application to related products and processes. There is little doubt that the Japanese, with one Nobel Science prize in 20 years, and with little energy resources and a positive balance of payments, is outperforming us in applying the results of research. There is some suspicion that results being applied were derived from U.S. research dedicated to the public through publication in scientific and government journals and reports.

It should be clearly understood that these comments are not an indictment of federal funding of basic research. On the contrary, support of such funding should be sustained based upon the long held fact that sooner or later some important applications of this research will find its way into the marketplace. The issue is to facilitate and encourage such application and measure the results of this effort. Further, if basic research was not undertaken sooner or later the point would be reached where applications trailed off into insignificance. With the passage of P.L. 96-517, it is anticipated that the incentive of invention ownership will significantly increase the technology transfer of scientific results into practical application.

The Drafting of Uniform Regulations and the Effective Date of P.L. 96-517

The Act creates the possibility of a significant university/non-profit licensing program that must be made to work if the full benefits of the nations' investment in basic research are to be achieved. However, the legislative progress made to date could be frustrated if steps are not taken to preclude variation in interpretation and application of the Act by the departments and agencies. In this regard, it is noted that a GSA Task Force made up of the same agencies whose regulations were eliminated by the Act and some who resisted its passage, are now drafting implementing regulations. The Task Force was formed after P.L. 96-517 was enacted on December 12, 1980 but prior to appointment of a Science Advisor, the Administrator of OFPP/OMB and the Director of OMB. Section 206 (35 U.S.C. 206) of the Act provides that the regulations be drafted by OFPP/OMB after obtaining the recommendations of OSTP.

Insert #2

In order to assure the development of uniform assistance guidance this may require, at least initially, a designated office to which the agencies would be responsible and which in turn will produce a climate conducive to innovation. It should be understood that while there has been much advocacy to support basic research within the Executive Branch over the years, there has been virtually no move to generate policies that address the need for a concerted governmentwide effort to take advantage of the results of basic research. In fact, many of the same people who support higher funding levels for basic research are uncomfortable with efforts requiring greater attention to applied research

(or technology transfer). It's this basic conflict to which the Administration must give attention to assure "balance" in implementing the Act.

Insert #3

Section 8 of the Act makes the relevant sections of the Act effective on July 1, 1981. Issuance of implementing regulations prior to July 1, 1981 would require their initial publication for public comment and possible amendment no later than early April. Failure to issue final regulations prior to July 1 would leave open the possibility of separate agency action based on their interpretation of the Act.

III. Analysis of Administration Issues

Issue: Should the Administration authorize the drafting of implementing regulations?

Discussion:

As previously mentioned P.L. 96-517 legislation eliminates 26 agency statutes and administrative regulations and establishes a single set of statutory guidelines which are tied to assistance and procurement programs. The Act is silent on a number of issues which are considered to be particularly critical to its proper implementation. Attached Tab D describes a number of areas which, if left to agency discretion, would create a patchwork set of interpretations of the Act.

The "march-in" provisions serves as a good example for the need for OFPP/OMB involvement. Page 34 of the Senate Report on the Act indicates that ".....arbitrary exercise of such rights must .....be avoided. The agencies and OFPP should give this question careful and thorough consideration and develop a procedure that carefully balances the considerations on both sides". This crosscutting law is similar in character to some 60 other crosscutting requirements tied to assistance programs, many of which in the past have greatly varied in both interpretation and implementation. A few notable examples are section 504 of the Rehabilitation Act of 1973, and the National Environmental Policy Act. Thus, in order to avoid the problem of non-uniform interpretation and implementation, and to provide for proper oversight, it is suggested the Administration agree to issue implementing regulations. This would be accomplished by OFPP/OMB after consulting with OSTP as required by the Act.

As noted, it is anomalous that notwithstanding the fact that the preponderant portion of the awards affected by the Act are grants to universities and non-profit organizations the Act gives responsibility for drafting the implementing regulations to OFPP alone. It is important that the assistance policy functions support OFPP to assure consistent application of the law across the spectrum of assistance and procurement relationships. If regulations are to be pursued, the July 1 effective date of the Act requires expeditious action.

Decision

Authorize OFPP/OMB to Issue Regulations Implementing P.L. 96-517

Yes———

No———

See me——

Issue: Should the Administration assign a governmentwide focus of responsibility for implementing, coordination, and evaluating P.L. 96-517?

Discussion:

The Act does not assign a governmentwide responsibility to any one agency. OSTP is designated to provide advice to OFPP in implementing regulations governing federal agencies under the Act. GSA has the authority to issue regulations governing the licensing of government-owned inventions. OMB has broad authority over assistance and procurement policy and financial management policy, but has not been designated a specific role in the Act. GAO is designated to review agency reports to assure proper implementation of the Act. (See Tab B)

In the absence of a focus of responsibility no coordination or correlation and analysis of the results of this legislation will be conducted and no vehicle will be available to evaluate whether legislative improvements need to be made, and no accountability will be required in agency implementation. Further, the absence of a focal point in the drafting and later oversight of the implementing regulations will leave individual agencies as the final arbiter of policy matters arising from the Act's implementation. Also, such absence will preclude a comparative analysis of how federal agencies are performing, and thus only a minimum perspective will be available in determining the benefits of the legislation. On the other hand the absence of a focus of responsibility will establish the agencies as the last resort in the area (absent controversy). It can be presumed that each agency will then have a greater incentive to carefully implement the Act.

Responsibilities which a designated governmentwide agency could perform:

- Coordination and exchange of information
- Providing technical advice and assistance to agencies and recipients
- Review of staffing of patent offices in various agencies to determine whether there exists a potential to realize personnel reductions and reallocations which might reduce the agency's budget and increase effectiveness.
- Propose refinements in the Act
- Aid in the development of a national policy on innovation
- Convening conferences/workshops to assist both agencies and universities and small business in implementing the Act

Possible lead agencies include OSTP or OMB in the Executive Office, and Commerce, DOE, NSF, SBA or HHS among the operating departments and agencies.

If a decision is made to designate a focus of governmentwide responsibility a separate decision memo will be developed to analyze the pros and cons of where to assign this function.

Decision:

Assign a focus of governmentwide responsibility to one agency.

Yes____ (Prepare specific memo describing the options available and advantages and disadvantages)

No_____

See me___

Issue: What ongoing Role, if any, should OMB have in Implementing the legislation?

Discussion:

P.L. 96-517 impacts on three discrete but related OMB interests: procurement policy, assistance policy, and regulatory and reports management policy. OFPP has responsibility, if the Administration desires, to issue overall implementing regulations. The Assistance Policy Branch has responsibility for matters impacting on assistance and in particular policies impacting on the implementation of grants and cooperative agreements under the Federal Grant and Cooperative Agreement Act. As to the latter, as previously noted, the bulk of awards affected by this Act are grants for basic research to universities and non-profit organizations.

The new Office of Information and Regulatory Affairs has an interest in reducing reporting requirements, unnecessary federal intrusion, and paperwork. Although this Act abolishes 26 different statutes and regulations it also creates a new governmentwide set of requirements which could lead to unnecessary reporting requirements, unless management initiative is taken to ensure that the reports required are simple, meaningful as an evaluation tool,and otherwise not burdensome.

Thus, it is suggested that proper implementation which will ensure that the maximum benefits of this crosscutting requirement are realized will warrant dispassionate oversight and involvement by OMB at least as long as it takes to assure the program is off to a good start. This Act is a classic case of legislation having the potential for fragmented effective implementation which in turn will create unending bureaucratic red tape with the attendant risk that the congressional intent may not be realized. On the other hand there is equally a potential opportunity to demonstrate that good regulatory management and EOP oversight at the proper time will help assure both that the Congress and Executive Branch realize the ambitious and high priority goals of the Act - to stimulate innovation and enhance the practical use of knowledge developed through basic research.

Decision:

Commit OMB to an ongoing role to assure proper implementation; prepare briefing memo for the Science Advisor; convene interagency Task Force to prepare regulations. (See Tab C for outline of implementing plan).

Yes_____

No_____

See me___.

"Any exact copies prepared in accordance with the provisions of this section may be leased, sold, or otherwise transferred, along with the copy from which such copies were prepared, only as part of the lease, sale, or other transfer of all rights in the program. Adaptations so prepared may be transferred only with the authorization of the copyright owner.".

Approved December 12, 1980.

LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 96-1307, Pt. I (Comm. on the Judiciary) and No. 96-1307, Pt. 2 (Comm. on Government Operations).
CONGRESSIONAL RECORD, Vol. 126 (1980):
Nov. 17, considered and passed House.
Nov. 20, considered and passed Senate, amended.
Nov. 21, House concurred in Senate amendment.

○

Tab B

Analysis of Statutory and Administrative Roles of Agencies

Section 6 of P.L. 96-517 is composed of 35 U.S.C. 200 through 211. Sections 202 through 204 cover disposition of inventions to universities, small business and non-profit organizations. Sections 207 through 209 cover the licensing of government-owned inventions.

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SBA is designated under 35 U.S.C. 202(b)(1) to receive agency determinations involving exceptional circumstances which require the use of a provision other than the standard funding provision in funding agreements with small business firms.

Tab C

Subject: Implementing the Patent and Trademark Act Amendments of 1980

Introduction

If the decision is made not to issue regulations for the entire Act there will still be a need (we believe) to issue a regulation indicating the circumstances under which the funding agreement clause will be used. However, assuming that the decision is to issue overall implementing regulations the following steps are suggested as one approach to implementing P.L. 96-517.

1. OMB prepares briefing memo for the new Science Advisor informing that person of his role.

2. OFPP, with the support of OMB's Assistance Policy Branch, prepares a memo to departments and agency heads for the Director of OMB's signature, informing them of P.L. 96-517, Administation intent to issue regulations and requesting they designate a liaison person to represent their respective agencies on an interagency task force which would prepare the regulations.

3. OMB staff prepares decision memo for the President to select a lead agency.

4. The designated lead agency would, once designated, chair the drafting Task Force, OMB would then serve as Vice Chairman.

5. Once draft regulations were prepared they would be published in the Federal Register for public comment.

6. Public comments would be reviewed and where appropriate reflected in revised draft regulations. Where necessary impact analyses would be developed to ensure reasonableness of the requirements.

It is estimated the entire process would be completed by June, 1981, in advance of the statutory date when the Act becomes effective (July, 1981).

Tab D

Some examples of areas where the Act is either silent or leaves the choice of implementation to broad interpretation

1. The Act requires that inventions be reported "within a reasonable time." No definition for reasonable time is provided.

2. The Act permits the agencies to retain title to inventions at the time of grant or contract "under exceptional circumstances." While the legislative history indicates that the exceptional circumstances provision be narrowly applied, a precise definition can not be provided without sufficient operating experience. If the definition is left to interpretation by the agencies there will probably be as many definitions or precedents as there are agencies. Sensitivity, balance, and uniformity can only be assured through Executive Office guidance.

3. The Act permits the agencies to retrieve or "march-in" on invention rights elected by a grantee or contractor in four broadly defined areas. Here again precise definitions beyond the statutory language cannot be provided without operating experience. Implementation of the march-in rights without proper guidance could virtually render the Act useless if agencies take arbitrary positions on "march-in."

4. The Act requires that grantees and contractors submit "invention reports" when inventions are made and "utilization reports" to determine whether elected inventions are being worked. The Act does not prescribe the form and frequency for these reports. the regulations should set out the minimum information and frequency of reporting. Most agencies presently have utilization and invention reports requirements but they all differ to the point that information on them cannot be correlated nor is any single unit of government evaluating them.

5. The Act provides for utilization reports as a means of determining whether the premise of the Act is correct and whether policy changes should be made on the basis of information obtained, i.e., should the first right of refusal to government funded inventions be extended to businesses other than small business? However, without a central focus to analyze the information obtained by the agencies the reports could be considered merely a regulatory burden.

   The value of utilization information coordinated and correlated through a single focus should not be underestimated. It could provide a snapshot of one aspect of what is occurring in technology-transfer from universities to industry across the entire nation. Conceivably we could know how many inventions generated by university/non-profit research reach the marketplace every year; how much royalty return is generated by these inventions; the trend in areas of technology; the needs for support in various areas of technology; areas of disappointment; etc., etc.

6. The agencies are permitted under the Act to extend the life of a exclusive license granted by universities or non-profits to industry on a case-by-case basis. No criteria for such extensions are set out in the Act and probably could not be generated without case-by-case experience.

7. The Act is also silent on the handling of disputes or appeals that might arise in implementing the Act. It is debatable whether the Administrative Procedures Act or Grant Appeals Boards could adequately handle such disputes or appeals in light of the highly technical nature of patents and in the absence of governmentwide guidance. In this regard, it should be noted that a bill withdrawing the jurisdiction of federal district courts over patents and locating patent problems in a new single federal court specializing in patents will be re-introduced this session. The bill had strong support last session and will probably pass. Thus, the special concern for these types of disputes has been recognized by Congress and the Executive Branch should also.

8. The Act requires that universities and non-profits share royalty returns with inventors. No cap or floor is suggested by the Act. However, there is a strong implication and legislative history suggesting that no cap is intended. This flies in the face of some agencies who wish to continue the use of caps on royalties.

Other Implementing Considerations

A. Conduct regional workshops or forums where university/non-profit technology managers could exchange information on techniques and problems which arise from invention licensing and technology-transfer. The need for this type of forum should not be underestimated in light of the short-fall of experienced people in this new profession.

B. In connection with the development of a national policy on innovation require as a condition that each agency conduct an ongoing review of proposed legislation, existing law, and current administrative practices to strengthen the patent system, and ensure that the provisions of the Patent and Trademark amendments of 1980 are properly implemented

C. Recommend needed legislation to enhance technology transfer, strengthen the patent system and innovation in general.