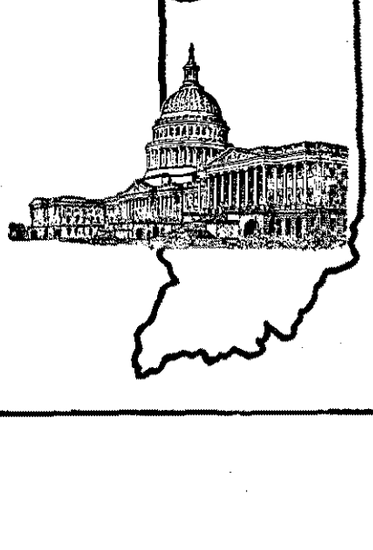


A Special

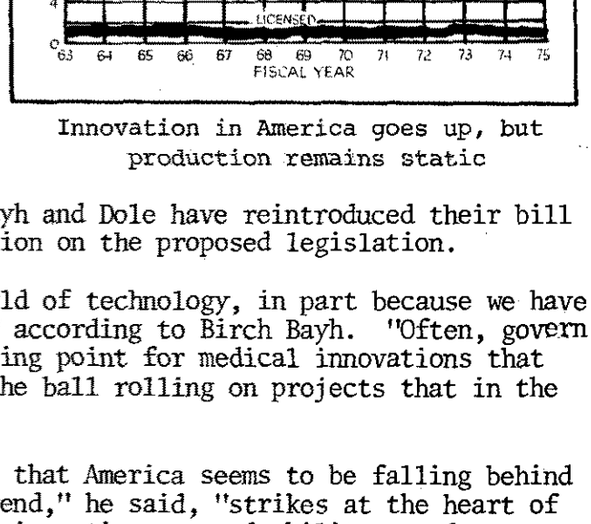
STATUS REPORT

from **BIRCH BAYH**

STREAMLINING FEDERAL PATENT PROCEDURES

WHAT'S HAPPENING TO OUR FEDERAL RESEARCH DOLLARS?

A wealth of scientific talent at American colleges and universities -- talent responsible for the development of numerous innovative breakthroughs in science and medicine each year--is going to waste as a result of bureaucratic red tape and illogical governmental regulations. These regulations which cover procedures governing the issuance of patents for inventions resulting from government-financed research by universities and small businesses have kept new and potentially beneficial ideas from being marketed.



Innovation in America goes up, but production remains static

Last September, Senators Birch Bayh and Bob Dole introduced the University and Small Business Patent Procedures Act, a bill with the purpose of cutting red tape to expedite the granting of patent rights on inventions resulting from federally-financed research. Bayh and Dole have reintroduced their bill in the 96th Congress, and predict favorable action on the proposed legislation.

"Our nation has become a leader in the world of technology, in part because we have not been afraid to move on bold, new concepts," according to Birch Bayh. "Often, government-backed research programs provide the starting point for medical innovations that ultimately save thousands of lives, or starts the ball rolling on projects that in the end result in new sources of energy."

The Hoosier Democrat pointed out, however, that America seems to be falling behind in the development of new technology. "This trend," he said, "strikes at the heart of our traditional American economic strength, our inventiveness and ability to adapt to a changing world."

Approximately 28,000 patents are now sitting on government shelves collecting dust. Untold thousands of other developments have not been patented by the government, but rather have gone unused or underutilized simply because no exclusive rights could be obtained during the critical developmental period.

Shortly after the Bayh-Dole bill was introduced last year, the U.S. Department of Health, Education and Welfare ordered action on 30 pending patent rights petitions. While that action is a step in the right direction, Bayh says, it is "only the tip of the iceberg," and demonstrates more clearly than ever the need for Congressional action.

One of the most attractive features of the bill enables the government to recover some of its research investment from a portion of the profits accruing to inventions that are successfully marketed. The following pages include a Section-by-Section analysis of the bill and some articles of interest.

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PROCEEDINGS AND DEBATES OF THE 96th CONGRESS, FIRST SESSION

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Senate

[From the Washington Post, Nov. 16, 1978]

WANING OF INNOVATION IS SEEN

By Bradley Graham

It is hardly a matter of doubt anymore: America's ability to innovate just isn't what it used to be. And a panel of distinguished researchers and professionals says America herself is to blame.

In a somber forum Tuesday night sponsored by the National Academy of Sciences, six representatives of business, government and academia added their concern to that expressed by others in recent months over the disturbing realization that something's happened to Yankee ingenuity.

Signs of America's innovative spirit on the wane are everywhere, the panelists noted. Among the evidence cited was:

The declining growth rate of the U.S. economy and only minimal gains in productivity.

The worsening U.S. balance of trade caused in part by increasing imports of foreign-manufactured goods.

The decreasing number of U.S. patents issued to U.S. inventors and an increase in patents issued to foreign inventors.

The declining amount of real dollars being spent on research and development by industry and the high degree of concentration of the R&D that is done in a few industries and a few companies.

"These indicators are distressing", said Elmer B. Staats, U.S. comptroller general. Stressing the historical importance of technological innovation in powering America's economic growth, Staats warned that unless specific steps are taken to stimulate innovation, Americans can expect their standard of living to stagnate and their competitive ranking in the world to weaken.

How has the U.S., which once placed a premium on inventiveness and made national heroes out of its pioneers, reached this state of affairs? Although no one could offer a complete explanation, the panelists generally agreed that government actions were largely to blame—specifically, restrictive tax and regulatory policies, along with complex and confused antitrust and patent laws, that together have eliminated financial incentives for industrial innovation and have discouraged investment in R&D.

"Innovations affect the economy, but the reverse is also true," declared Ivar Giaever, a Nobel Laureate who supervises R&D for General Electric and the panel moderator. "The economic climate affects the amount of innovation, and the climate recently has not been encouraging."

In addition to legal impediments and financial disincentives, the waning of U.S. innovation also has been attributed to business managers' defeatist attitude and lessened inclination to take risks.

Business leaders on the panel conceded that U.S. companies are focusing more on short-term results in their planning, preferring to concentrate on innovations that will improve existing processes and reduce costs rather than yield a major breakthrough. But they said this is simply the result of having to cope with a more uncertain marketplace.

"As much as anything, it is uncertainty that affects industry's inclination to invest in innovations," stated N. Bruce Hanay, vice president of Bell Telephone Laboratories.

President Carter appointed a 28-agency task force last spring to spend a year studying the innovation dilemma, and a spokesman for the National Academy said a report on Tuesday's panel would be forwarded to the study group. The panel left no doubt what its major recommendation would be.

"We must restore incentives, or remove disincentives, for entrepeneurs to take risks," concluded Ralph Landau, chairman of Halcon International. "Our industry is good at invention and entrepreneurship if you give it a chance."

ESTABLISHING AN EQUITABLE PATENT POLICY

By Sheldon E. Steinbach

Inventions resulting from federally funded esearch constitute a valuable national resource. The large amount of federal funds supporting research dictates the necessity of examining the government's patent policy in order to ensure that inventions are delivered to the public and that the equities of all parties are protected. Because of their special mission, colleges and universities have unique patent concerns that warrant detailed exploration, particularly with regard to ownership of patent rights on inventions developed on campus under federal contracts and grants.

The federal government sponsors research in universities to expand the boundaries of existing knowledge in areas or on problems deemed to be in the public interest or to be related to national goals. Universities are free to publish research results, which are generally made available to all. The right to publish is normally preserved in the negotiation of grants and contracts, as is the sponsoring agency's right to receive certain reports.

Generating inventions is almost never the main objective of research conducted with federal funds; rather, an invention is generally an incidental by-product of the research activity, largely attributable to serendipity, to the personal creativity of the investigator backed by his years of professional training and experience, and to the scholarly environment and research resources provided by the university. When patentable discoveries are made, the equities to be considered include those of the inventor, the university, and, very properly, the financial sponsors.

When a patentable invention is made by an investigator in an academic institution with the help of federal funds, rarely are the federal funds the sole or even the major element contributing to the invention. Beyond the critical contribution of the investigator, the university itself virtually always helps to finance the laboratories, equipment, and personnel contributing to an invention. It also provides a scholarly atmosphere and often the infusion of funds obtained from nongovernment sources. Accordingly, each of the parties has a claim in equity.

A policy that assigns patent rights to the government for all federally supported research, however large or small the federal contribution, eliminates the universities' ability to recognize the equities of other sponsors and contributions of the institutions themselves. Because inventions resulting from federally sponsored research involve equities of the government, the contractor (on his own behalf or as the result of inter-

continued page 2

SECTION-BY-SECTION ANALYSIS of the UNIVERSITY AND SMALL BUSINESS PATENT PROCEDURES ACT

Outlined below are the most important features of the bill:

Section 202: Provides that each nonprofit organization (defined in the bill to include universities) and small business shall have a reasonable amount of time to elect to retain title to subject inventions. The federal agency may retain title if the invention is made under a contract for operation of a government owned research or production facility, or in exceptional circumstances when it is determined that restriction or elimination of the right of the contractor to retain title to a subject invention would better promote the policy and objectives of this bill.

Section 202(b): Provides that whenever the funding agency determines that it should retain title to a subject invention a copy of this decision shall be sent to the Comptroller General. The Comptroller General will then review this decision and inform the head of the agency of his determination as to whether or not this retention of title is justified. The Comptroller General will also submit an annual report to the House and Senate Committees on the Judiciary on agency implementation of this bill.

Section 202(c): Provides that each funding agreement shall contain provisions to: (1) insure the right of the federal government to receive title to any subject invention not reported to it within a reasonable time; (2) insure the government's right to receive title to inventions when the inventor does not intend to file for patent rights; (3) guarantee that the agency shall have a nonexclusive, nontransferable, paid-up license to use the invention; and (4) insure the right of the funding agency to require periodic reports on the utilization or efforts at obtaining utilization of the subject invention.

Section 202(c)(7): Prohibits nonprofit organizations from assigning rights without the approval of the federal agency; prohibits granting such rights in excess of the earlier of 5 years from the date of first commercial use, or 8 years from the date of invention, whichever comes first; requires that the organization have some sort of royalty sharing agreement with the inventor; and says that all proceeds shall be used to support scientific research or education.

Section 203: Gives the federal agency the right to require the subject inventor or his assignee to grant additional licenses if the agency feels that sufficient steps are not being taken to achieve commercialization. Additional licensing may also be required to alleviate health and safety needs, or under provisions for public use as specified by federal regulations.

Section 204: Provides that if the patent holder receives $250,000 in after-tax profits from licensing any subject invention during a ten-year period, or receives in excess of $2,000,000 on the sale of products embodying of manufactured by a process employing the subject invention within the ten year period, that the government shall be entitled to collect up to 50 percent of all net income above these figures until such time as the amount of government research money has been repaid.

Section 205: Specifies that any title holder to a subject invention or his assignee shall not grant to any person the exclusive right to use or sell any subject invention in the United States unless that person agrees that any products embodying the subject invention or produced through its use shall be manufactured substantially within the U.S. unless this provision is waived by the funding agency.

Section 208: Will allow federal agencies to grant exclusive, partially exclusive, or nonexclusive licenses on government owned patents to achieve commercialization; the Department of Commerce is authorized to receive patents held by other agencies and to make the necessary steps to determine the market potential of the patent and to receive any fees or royalties due to the government.

Section 211: Says that after public notification of the government patents available for licensing the agency will then require that potential licensees submit plans outlining how the invention will be developed and marketed. If the agency determines that the granting of an exclusive or partially exclusive license will not lessen competition it will give first preference in its licensing to qualified small businesses.

Section 212: States that all contractors not covered under this bill will continue to operate under the existing agency programs

mingled funds derived from other than federal agency sources), and the inventor, many fatcors must be considered in making a decision about where the primary right in such inventions should be vested. In making that decision, however, only one consideration should be paramount—that being in whose hands will the vestiture of primary rights serve to transfer most quickly and economically the invention technology to the public for its use and benefit.

Educational institutions are, of course, not organized to manufacture, produce, or market a patentable invention. Accordingly, if university-generated inventions are to be used, such institutions must interest those in the industrial world who have the commercial capability for invention and marked development, which the university lacks. Interesting the right parties is often a difficult task because few inventions coming out of university research offer readily recognizable prospects of a large market or a high return on investment. University-based inventions, because they most often correlate with the results of basic research, tend to be at best in the early stages of development, and therefore they require a substantial capital in order to develop the invention enough to be marketable.

At the same time, universities are in a unique position objectively to seek the best qualified industrial developer and, under appropriate licensing arrangements, to monitor the diligence of the developmental efforts. If universities cannot furnish, if appropriate, an exclusive license to developers for a limited period and thereby secure the investment of necessary capital, inventions resulting from government contracts are less likely to be developed to the point of marketability, and thus the public is less likely to receive the benefits from such inventions, or at least may not receive them as quickly as otherwise would be the case.

WHAT HAPPENS WHEN DELAYS ARE ENCOUNTERED?

When the right to seek patents resides in universities, appropriate patent applications can be filed promptly and negotiations can be begun immediately with prospective developer/licensees with the assistance of the inventor. When this right does not exist at the time of contracting, but must await a determination after the invention has been identified, substantial time is usually required to prepare the necessary documentation for the sponsoring agency and for the agency in turn to make a determination. While awaiting the outcome of such administrative process, the invention lies dormant, with the attendant risks that the inventor's interest in assisting in the development becomes attenuated and that intervening rights of others may foreclose successful transfer of the invention to the public.

Because deadlines for domestic and foreign patent applications are affected by publication of patentable ideas in scientific journals, delays in determining the disposition of rights to an invention can result either in delay of publication of research results or risk of expiration of the time limit in which patent applications can be filed. Neither choice is beneficial to the public interest.

Although the university's primary motivation in filing and prosecuting applications for patents is the timely promotion of actual availability of new products or processes to the general public, if, in the course of such transfer, income to support further research at the institution can be generated, the public benefits a second time.

The public benefits from university-generated patents through the efforts of agencies that offer inducement to those who can recast the fruits of basic research into a useful form. Mere exclusivity in patent rights does not automatically create artificially high prices for related products, and royalties usually represent only a very small fraction of the retail price of marketed goods. Moreover, one must face the inescapable conclusion that the development of inventions under a reasonable government patent policy will benefit the public by making available products that would otherwise not have been available at any price.

Without some degree of exclusivity, private sources are unlikely to have sufficient incentive to develop a product or process. Indeed, the investment required to make a product or process marketable and actually to market it is almost always far greater than the investment in the original research.

To bring an invention to public use, further development or engineering is usually required, such as testing or screening a prototype of the new product or process. Before the efforts and expenses incident to testing or screening are undertaken, investors want to know who has the title to or ownership of the invention (that is, the right secured to inventors and their assignees or licensees, for limited times, as provided in the Constitution). Sometimes, prospective licensees have refused to undertake the testing, screening, or development of inventions unless the licensor granted an exclusive license for commercial sale or use.

In some cases, no alternative has been available, and, in the absence of an exclusive license, the use of the product, process, or machine has been denied to the public. Universities usually do not possess the resources, critical facilities, or controls necessary to bring drug products, for example, through the clinical testing stages to marketability. Thus, it is imperative that universities be able to interest through appropriate licensing arrangements those organizations which have those facilities and control capabilities.

Because government personnel would not be as intimately familiar with an invention as those who have developed it in a university, they would be in a much less favorable position to ascertain or pursue the commercial marketability of an invention. The time that would have to be invested in such activity could well cause a significant reduction in invention disclosures from university researchers, with a consequent reduction in public access to potential fruits of research. Thus, the primary result of the economic stimuli afforded by a realistic licensing policy is a public benefit—the production and introduction of a good or service that otherwise might not become available in the context of our free enterprise system.

Under the policies of some government agencies, the agency, on behalf of the government, normally asserts its rights to ownership of any inventions and patents generated in the course of research sponsored and funded by the agency. But regulations do exist under which such right can be waived to the contractor or grantee. If an institution desires to acquire title to a particular invention, it must request a waiver in accordance with the regulations of such agency. Granting a waiver generally depends on a determination by the agency, based on evidence submitted by the contractor or grantee, that the invention will be more adequately and quickly developed in the public interest if title to the invention is waived to the contractor of grantee. Such waivers are given with a reservation of a license to the government to practice the invention for governmental purposes and with other provisions which adequately protect the public interest.

An alternative to the "waiver" approach is the "Institution Patent Agreement" approach, available since 1968.[1] This approach, endorsed by a 1968 GAO Report,[2] permits the grantee institution to retain title and to administer the principal ownership rights in inventions made under department grants and awards, clearly defines the rights of the parties with respect to such inventions, and sets forth general guidelines governing the licensing of inventions. It includes limitations on the duration of exclusive licenses to be granted; it reserves a royalty-free license to the government for governmental use; and it provides other appropriate safeguards to protect the public interest. These latter safeguards include a reservation to the government of the right to require the granting of additional licenses on a royalty-free basis or on other terms that are reasonable under the circumstances, where such licenses are necessary to fulfill public health, welfare, or safety requirements.

With the assistance of inventors, the universities are in a better position than the federal government to transfer technology to the public through the economy. A government "title" policy, however, would preclude the university from recognizing the equities of others, including inventors and nongovernmental sponsors, and would fail to acknowledge the benefits that now accrue to the tax-paying public for its contribution to the institutions' research efforts.

Consequently, qualified universities that have developed a technology transfer capability should be given, with the award of a contract or grant, a first option to title in inventions generated with federal funds on their respective campuses with appropriate safeguards to prevent abuse of patent rights retained by any such institution and to minimize any anticompetitive effects.

SMALL FIRMS AND FEDERAL RESEARCH AND DEVELOPMENT

INTRODUCTION

There is increasing concern that the capability of the United States to continue its historic successes in technology is in a serious decline. While astonishing achievements have occurred since World War II, there is now considerable evidence that product innovation has either leveled off or declined in many industries. Predictions of a weakened military posture and a less favorable economic position in world trade are associated with analyses showing that the U.S. is losing a significant part of its capability to invent new products essential for the country's defense and for its international sales market.

Analysis of technological capability is an exceptionally complex matter affected by many diverse factors involving individual and organizational motivations, economics, and governmental actions. Since the Federal Government is the biggest source of research and development (R&D) ($26.3 billion proposed for expenditure in 1978), Government acquisition procedures have a large impact on the country's utilization of its best technical and management talents.[1] One part of this problem—the role and difficulties of the small firm in selling R&D to the Government—was given particular attention by an ad hoc interagency panel under Mr. Jacob Rabinow, nationally known inventor, lecturer and writer, in 1976. The Panel was composed of representatives from the National Science Foundation, Department of Defense, National Space and Aeronautics Administration, Energy Research and Development Administration, Small Business Administration, and the Office of Federal Procurement Policy.

To assist the Rabinow Panel in its inquiry, the services of Mr. William K. Scheirer, an economist, were obtained to perform a literature search and analysis of the role of small firms in fulfilling Government contractual requirements for research and development. Significant findings of Mr. Scheirer are summarized below. His report, with an extensive bibliography, is available for inspection at the National Technical Information Service, Department of Commerce, as Report Number OMB/OFPP/CA-77/1 and in the Office of Federal Procurement Policy.

SUMMARY OF REPORT OF WILLIAM K. SCHEIRER

Importance of small R&D firms

Many analysts believe that small firms have a better record for innovation than large firms. Richard Morse recently wrote that "a disproportionate number of innovative ideas emanate from our smaller technically based companies."[2] The reasons for this phenomenon are varied. Some believe that managers of small R&D firms have a greater incentive to innovate while conversely, in some cases, the marketing plans of large firms dictate that technical improvements to their products be held to a minimum. There also is a possibility that researchers in large firms tend to overspecialize to a greater extent than researchers in small firms. Mr. Rabinow has observed that, "when one narrows his specialization, he probably comes up with fewer ideas. If one loads the dice in favor of a certain art, one cuts off analogous arts, which I think are important. The more an inventor can pull out of related and unrelated arts, the more original his ideas are likely to be."

Empirical evidence indicates that in a comparison of firms with less than 1,000 employees and those with over 1,000 employees:

Firms with less than 1,000 employees accounted for almost one-half of major U.S. innovations during 1953–73.

The ratio of innovations to sales is about one-third greater in firms with less than 1,000 employees.

Firms of less than 1,000 employees have a ratio of innovations to R&D employment which is approximately four times greater.

The cost per R&D scientist or engineer is almost twice as great in firms of over 1,000 employees.

Federal Government utilization of small firm capabilities

A striking disparity appears to exist between the capabilities of small technology based firms and their utilization by Federal agencies. Data collected by the National Science Foundation and supplemented by the Office of Federal Procurement Policy shows that only eight percent of Federal R&D contract awards to industry and only about three and one-half percent of obligations to all R&D performers[3] were made to small firms in FY 1975; that Government R&D obligations to industrial firms vary from less than one-half of one percent for the Department of Agriculture to 62 percent for the Department of Defense; and that reliance on industry for Federal R&D has declined from 59.6% in 1966 to 50.7% in 1976 in current dollars.

The overwhelming percentage of the dollars in Federal R&D goes to development as opposed to research (basic and applied). Although the industry share of development is substantial, most of this goes to large businesses capable of performing very large development contracts. On the other hand, in the research area where its capability is high, small firms lose awards to colleges and universities, federally funded research and development centers (FFRDCs), as well as to large firms.

Summary conclusions reached are that (i) Federal agencies tend to use sources other than industrial firms for basic and applied research; (ii) a significant portion (64%) of Government R&D is for development normally involving large industrial firms; and (iii) the percentages of both total expenditures for R&D and R&D contract awards to small firms are very low.

[3] Industry, in-house laboratories, educational institutions, and federally financed R&D centers.

Small firm impediments

As indicated above, large firms are favored in the award of development contracts on the basis that they are essential for the production phase of the program. However, this is not the only restriction to a greater use of small firms. Mr. Scheirer found that policies and procedures followed by Federal buying activities also restrict the use of small technology based firms. Following are some of the more significant impediments encountered by small companies:

It is difficult to identify and respond to Government R&D requirements. On a competitive basis, large firms have a greater capability to determine what the Government is interested in researching and to unravel the complexities of "Requests for Proposals" for R&D work.

Preparation of proposals is expensive and time-consuming to a point frequently exceeding the capabilities of small firms.

A bias in favor of large firms can exist when awarding R&D contracts. The tendency is to consider awards to large well-established firms "safer" than to small firms.

Funding for Federal R&D work frequently lacks stability. This condition strains the financial capabilities of small firms.

Submittal of unsolicited proposals is frequently discouraged.

Burdensome administrative requirements for contract solicitation, evaluation, award, and performance impair the ability and desire of small firms to compete for R&D contracts.

Conclusions

Though the responsibility for retention of a high technology capability in the United States is shared by both the private and public sectors, the large annual Federal expenditures for R&D places a unique responsibility on Federal agencies. New techniques must be devised to encourage innovation by all sources, with particular emphasis on small R&D firms. In the placement of R&D work, Government managers should carefully consider the ultimate beneficial effect of using small firms and not give undue consideration the immediate security that may appear to exist by awarding R&D contracts to large firms.

RECOMMENDATIONS OF AD HOC INTERAGENCY PANEL

The interagency panel chaired by Mr. Rabinow developed the following recommendations based on its analysis of this problem:

1. Federal agencies should develop formal programs which encourage the increase of Federal R&D awards to small technology based firms.

2. Large research and technology programs should be divided where feasible into discrete parts to permit solicitation of proposals, and award of contracts to small technology based firms in lieu of making a limited number of awards with consolidated requirements that only large firms can accomplish.

3. Subcontracting to small firms should be encouraged in contract solicitations, source selection criteria, and negotiations for R&D work. A prime contractor's record in subcontracting to small technology based firms should be a factor in fee awarded in award fee and incentive type contracts.

4. Intensive efforts should be made by Federal agencies to reduce or compensate for impediments experienced by small technology based firms. These efforts may include but not be limited to the following:

a. Early identification and publication of agency R&D requirements.

b. Coordination of R&D requirements with Small Business representatives early in the acquisition process.

c. Use of the Commerce Business Daily to provide advance information on anticipated contractual requirements for R&D.

d. Providing methods for small technology based firms to obtain an understanding of requirements which may not be possible through the written solicitation. For example, some buying activities currently provide research and technology libraries, catalogs for technical requirements, and special briefings to explain their research and technology needs.

e. Providing sufficient time for firms to prepare and submit proposals.

f. Reducing to the extent feasible the time and supplemental data required between receipt of proposals and award of contracts.

g. Providing agency R&D points of contact for small firms.

5. Agency policies and procedures should encourage unsolicited proposals. Contracts should be awarded for research and technology efforts based upon the merit of such proposals without converting the requirements to competitive solicitations.

6. The agencies, including the Small Business Administration, should use more technically trained personnel to serve as advocates for and advisors to small technology based firms. Special emphasis should be given by such persons to the advance procurement planning process for R&D requirements.

7. Profit-making firms should not be excluded from making proposals or receiving awards on R&D work that is not assigned to in-house laboratories.

8. Agencies should consider allowing greater amounts of independent research and development and bid and proposal costs than currently authorized when negotiating contracts with small technology based firms.

9. Methods should be developed for collecting and reporting data on small business share of R&D contract awards.

10. Establish small business set-aside programs (similar to those existing for supplies).