GOVERNMENT-OPERATED LABORATORY <u>#</u> 2 RESPONSIBLE PROJECT INITIATORS DITERNINE WHETHER NEW PROJECT SHOULD BE FUNDED AND NAS CONNERCIAL/COOPERATIVE POTENTIAL . LABORATORT. LABORATORY BOLICITS COOPERATORS R & D PROPOSAL 8 & D PROPOSALS COOPERATIVE 2-A R & D PROPOSAL LABORATORY 14 **m**-EMPLOYEE WILL PUND? DONATES ERPLOYEE IDEA INVENTIONS 3 2-8 SEEK DECIDE 13 LABORATORY \bigcirc NON TO FIND 15 (••) EMPLOYEE COOPERATOR? INVENTION PERFORMS PRELIMINARY VALUE SCREEN HORE - 4 SEEK 15-A COOPERATOR CONNERCIAL/ (11) VALUE SEEN? - 5 6 G FIND LABORATORY 15-15 (н) COOPERATOR? CONTINUE (¥ (8) PROJECT? PATENTABLE? END 22 ADDITIONAL DEVELOPMENT NEEDED? ഹ EMPLOYEE INVENTION (N) END 23 COOPERATIVE 16 DEVELOPHENT COORDINATE POTENTIAL? PUBLICATION WITH PATENTING 24 SEER 26 LABORATORY 17 (\mathbf{r}) ገ LICENSEE/ WILL DEVELOP? WORK DEVELOPER RELATED? 25 27 FIND IN DONATED BY LABORATORY Y 19 LICENSEE/ DEVELOPS ഹ LET EMPLOYEE (11 DEVELOPER? EMPLOYEE? REEP 7 28 RESOLVE 21 20 OBTAIN CONFLICTS OF APPLY FOR END , SIGNIFICANT PATENT INTEREST PATENT CONNERCIAL VALUE SEEN? B. 29 NEGOTIATE & 1) EMPLOYEE PIND EXECUTE LICENSEE AGREEMENT WANTS? 9 30 RESOLVE COMPLICTS OF INTEREST CONDUCT 38 34 COOPERATIVE GOVERNMENT GOVERMENT PROTECTION (Y PROJECT PROTECTION Ŧ NEEDED? NEEDED? 10 31 NEGOTIATE 6 NAKE INVENTIONS 39 END 35 LET EMPLOYEE PUBLICATION 7 LICENSE ADEQUATE? REEP L] DISTRIBUTE 12 RECEIVE & DISTRIBUTE 32 BELP DEVELOP 40 41 37 36 HELP PATENT NITH GOVT. STATUTORY TECHNOLOGY PER AGREEMENT LET EMPLOYEE PER LICENSE PUBLISE INVENTION ROYALTIES KEEP REGISTRATION USE LICENSE END END END END END.

MANAGING TECHNOLOGY IN A

PROPOSED SYSTEM FOR MANAGING TECHNOLOGY IN FEDERAL LABORATORIES

PART 1

Part la.

While there are many forms of technology transfer, the schematic chart titled, "Managing Technology in a Government-Operated Laboratory," concentrates on the two identified in Section 11 of the Federal Technology Transfer Act of 1986--collaboration with other organizations and management of patentable inventions by Government-operated laboratories. The proposed system of actions and decisions has been developed as a basis for discussion. This determination will establish a "laboratory" within the meaning of the Technology Transfer Act of 1986.

The schematic is a generalized presentation that considers domestic patents only, applies to unclassified work only, and omits some details. The system emphasizes laboratory/industry cooperation and patent licensing because of the new Section 11 authorities. It is not intended to substantially impact on the wide range of other typical laboratory interactions such as publication of papers, consultation, and personnel exchanges.

Each rectangle in the chart represents a work step or series of actions, while each oval indicates a decision step. While the chart does not indicate who should make each decision, we believe that by identifying and describing them, we will recognize the need to designate who should contribute and who should have the authority to make each decision. Regardless of who makes a decision, the chart assumes the necessary close cooperation among:

- o Laboratory researchers and scientists
- o Research managers
- o Technology transfer officers
- o Attorneys (including Patent Attorneys)

The chart has three points of entry. The first follows Step 1 when a proposal for a cooperative R&D project is received from outside the laboratory. The second is Step 2 when an internal proposal for a laboratory project is being initiated. The third is Step 15 PRELIMINARY VALUE SCREEN, where when the laboratory makes a preliminary decision on whether an employee's discovery or idea may be a valuable and patentable invention.

The chart has ten triangles that say "end." This means the end of what the chart is intended to show -- not the end of activity for the laboratory, an employee, the technology transfer officer, or a patent attorney.

Part lb. <u>Step-by-Step</u> <u>Explanation</u>

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Step 1, LABORATORY SOLICITS COOPERATORS. A laboratory may encourage outside proposals for cooperative R&D projects. The chart shows R&D proposals being received in response to this encouragement but omits the obvious evaluation and decision steps that would preceed a cooperative project.

(Part 2a, <u>Techniques for Finding R&D Cooperators and</u> <u>Licensees</u> discusses ways to publicize a laboratory's interest in undertaking cooperative R&D projects; page 10.)

Step 2, PROJECT INITIATION--CONSIDER MEANS OF COMMUNICATING AND TRANSFERRING RESULTS. This is the first large rectangle. When a new R&D project is being considered, it is normal to think about how the results of a project will be communicated to the sponsor as well as deciding whether or not the project should be funded. With the new authorities, labs should also ask at this stage whether the project may have commercial potential and whether a private sector organization might be interested in helping or cooperating on the project. A related question is whether the project can be modified to meet the original sponsor's needs and increase its interest for a private sector organization. The chart compresses these considerations into two decisions. Step 2-A, LABORATORY WILL FUND? YES leads to Step 2-B, SEEK COOPERATOR? If 2-B is YES, the laboratory will seek a cooperator. If NO, the laboratory will proceed to do the work on its own.

Taking advantage of the commercial potential and possibility of R&D cooperation at an early stage may have several benefits for the laboratory, including:

- o The sooner a commercializing firm becomes involved in developing a technology, the greater the chances of commercial success.
 - The private sector may supplement Federal funds for conducting laboratory R&D.
 - Other parties may bring knowledge and expertise to the project that increase its chances of meeting the Government sponsor's needs.
 - Working with outsiders can enrichen the job of laboratory staff in many ways.

If the R&D project is expected to lead to an item the Government will purchase, there may be an opportunity to expand the market for the item. This can spread both the development and manufacturing costs among private as well as Government users, thus lowering the total cost to the Government.

Step 3, DECIDE HOW TO FIND COOPERATOR. If the project appears to have commercial potential and may be of interest to a cooperator, the next step is to decide how to find one.

(Part 2b. <u>Techniques</u> for <u>Finding</u> <u>R&D</u> <u>Cooperators</u> <u>and</u> <u>Licensees</u> discusses some ways this can be done; page 10.)

Step 4, SEEK COOPERATOR. This involves carrying out the plan for finding a cooperator.

Step 5, FIND COOPERATOR? NO. (If YES, go to Step 7)

Step 6, LABORATORY CONTINUE THE PROJECT? The decision at Step 2-B to proceed may have been conditioned on finding a cooperator. If none is found, the laboratory will have to decide whether or not to proceed on its own.

Step 7, RESOLVE CONFLICTS OF INTEREST. If a cooperator is found, before an agreement is executed, it is necessary to ensure that conditions which might lead to an apparent or real conflict of interest are identified and provided for.

(Part 2a. <u>Conflict of Interest</u> discusses a number of aspects of conflict of interest, including situations where the term is sometimes missused; page 16.)

Step 8, NEGOTIATE AND EXECUTE AGREEMENT. Under the Federal Technology Transfer Act, cooperative R&D agreements are not procurement contracts, grants, or cooperative agreements as these instruments have been established by the Federal Grant and Cooperative Agreement Act. As a result, neither the Federal Acquisition Regulation nor Government-wide assistance policies apply. This gives labs wide latitude to negotiate terms and conditions with cooperators that meet the needs of the particular parties. Model agreements are being developed as a point of departure to assist labs in developing the agreements they may need.

A prime objective of some cooperative R&D projects may be to produce inventions that can lead to marketable products. In other cases, inventions may be a possible outcome but not an objective or perhaps not even likely. Since it is often impossible to anticipate when an invention will occur, it is best to assume that any R&D project has a chance of producing one, and the rights to a resulting invention should be established in the agreement.

Step 9, CONDUCT COOPERATIVE PROJECT.

(Part 2b. <u>Types of R&D Cooperation</u> suggests different types of shared projects that labs may find beneficial; page 12.)

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Step 10, MAKE INVENTIONS. An oversimplification that includes all of the steps necessary to identify, describe, and protect an invention.

Step 11, TRANSFER TECHNOLOGY PER AGREEMENT. This alludes to the time that responsibilities and rights are undertaken by the original sponsor, the cooperating partner, the lab, and individual investigators in accordance with the agreement in order to initiate commercializing the results of the research. It includes project reports, rights to publish, demonstration models, and patent rights if any.

Step 12, RECEIVE AND DISTRIBUTE ROYALTIES. Agencies must follow the statutory requirements and select among the options for using royalties the Government receives from licensed or assigned inventions.

Step 13, LABORATORY PERFORMS WORK. Going back to Step 2, if a project is not seen as having cooperative R&D potential, or the lab was unable to find a cooperator (Step 6), the lab will consider the merits of the proposal and decide whether or not to do the work on its own just as it has always done. If it goes ahead, a lab employee may report a discovery or an idea that could be an invention.

Step 14, EMPLOYEE DONATES IDEA. Under the new law, a Government employee may voluntarily assign an invention that may be entirely unrelated to his or her job. This is to give employees an opportunity to have their ideas evaluated, patented, and managed by a laboratory if the lab agrees. It also provides an additional source of ideas to laboratories and the Government which might otherwise die for lack of follow-up.

Step 15, PRELIMINARY VALUE SCREEN, Based on experience most employee ideas will not have significant potential. This twopart evaluation step is designed to be a quick and low-cost process for sorting those which may have significant value from those which have little promise. The first question (Step 15-A, COMMERCIAL/GOVERNMENT VALUE SEEN?) involves technological, economic, and managerial questions. The Government may anticipate using the idea and need for defensive protection even if there does not appear to be any commercial potential. Ιf there is reason to believe the idea or discovery may be of commercial value or of use to the Government, the second part (Step 15-B, PATENTIBLE?) should be performed by a patent attorney to provide advice on what type of patent protection may be If this Preliminary Value Screen indicates the idea obtainable. may have commercial potential or value to the Government and be patentable, the employee is considered to have made an invention.

This step will involve the employee, the technology transfer officer, the person designated by the laboratory for conducting the screening process, individuals who may be members of a screening committee, a patent attorney, and perhaps others. Considerable thought should go into how a laboratory will organize and conduct this step which should include the content and flow of invention reports, confidentiality agreements, and controls.

(Part 2c. <u>Determining the Value of a Technology</u> outlines factors and approaches to evaluating technology; page 14.)

Step 16, COORDINATE PUBLICATION WITH PATENTING. It may be desirable to publish a paper on the discovery or idea. Publication is entirely consistent with patenting, but done prematurely, publication can destroy the opportunity to obtain a patent. In addition, "publication" has a special meaning in patent law. The inventor should be advised on how to coordinate the timing of discussions of the technology and publications with domestic and perhaps foreign patent applications.

Step 17, WORK RELATED? Executive Order 10096 sets the policies and the rights of the Government and its employees to employee inventions. A test is whether the invention was work related or made in the course of regular assigned duties. If YES, the invention should be examined more extensively for possible commercial value.

Step 18, DONATED BY EMPLOYEE? NO. (If YES, go to Step 20)

Step 19, LET EMPLOYEE KEEP. If the invention was not work related, and not donated by the employee, and the Government has no interest in it, the employee should normally be allowed to keep it.

Step 20, SIGNIFICANT COMMERCIAL VALUE SEEN? YES. If the invention is work related or has been donated by the employee and it has passed the Preliminary Value Screen, its commercial potential should be evaluated more extensively. Although a small step on the chart, determining commercial value can be a complex process. (If NO, go to Step 33.)

(See Part 2c, <u>"Determining the Value of a Technology";</u> page 14.)

Step 21, APPLY FOR PATENT. The laboratory should apply for a patent on an idea or discovery of an employee to which the Government has rights, that appears to be patentable, and that appears to have significant commercial value. While the Government has obtained thousands of patents, few of them were obtained primarily for commercial use. The laboratory needs to ensure that the application is designed to produce a strong and licensable patent.

Step 22, ADDITIONAL DEVELOPMENT NEEDED? YES. The idea may need additional development, either to meet Government needs or to make it more attractive for promotion and licensing.

Step 23, COOPERATIVE DEVELOPMENT POTENTIAL? YES.

Step 24, SEEK LICENSEE/DEVELOPER. To be done if it appears that a cooperator might be found to help develop the invention.

(See Part 2a. <u>Techniques for Finding R&D Cooperators and</u> <u>Licensees</u>; page 10.)

Step 25, FIND LICENSEE/DEVELOPER? YES. If a licensee/developer is found, the logic of the chart flows back to Step 7 for creating a cooperative R&D project.

Step 26, LABORATORY WILL DEVELOP? YES. If the invention does not appear likely to interest a cooperator, or if one cannot be found, the lab must decide whether to continue development on its own, and continue seeking patent protection and licensees.

Step 27, LABORATORY DEVELOPS.

Step 28, OBTAIN PATENT. Regardless of whether or not the lab continues development, if the idea still appears to have commercial potential, the lab will continue to pursue a patent.

Step 29, FIND LICENSEE.

(See Part 2a. <u>Techniques for Finding R&D Cooperators and</u> <u>Licensees</u>; page 10.)

Step 30, RESOLVE CONFLICTS OF INTEREST. The degree of involvement that a laboratory employee inventor may have in the follow-on development and commercialization of an invention must be decided. This should be considered before the laboratory enters into negotiations with a potential licensee, recognizing that the licensee's wishes must also be considered.

(See Part 2d. Conflicts of Interest; page 16.)

Step 31, NEGOTIATE AND EXECUTE LICENSE. Under the new law, laboratories may be delegated authority to negotiate their own licenses. Once the lab has decided to seek a patent, it should start looking for a licensee. If one is found before the patent is issued, the licensee may wish to amend and the strengthen the patent application in relation to a specific product.

Step 32, HELP DEVELOP PER LICENSE. Extensive development is usually required to convert an invention into a marketable product, and often the inventor or the originating lab can make unique contributions. The new law allows laboratories to include

in their licenses, provisions for the laboratory or the inventor to contribute to further development and commercialization of the invention. Although not shown on the chart, the license might actually be a cooperative R&D agreement which could lead to additional, follow-on inventions. In this case, the logic flow would be from Step 32 back to the cooperative agreement activities beginning at Step 7.

Step 33, EMPLOYEE WANTS? YES. The new law says that an employee will be allowed to keep his or her invention that the Government has a right to own, but has decided not to patent or commercialize. Since the employee may believe the invention has more value than the Government recognizes, this serves as a backstop to prevent destroying the invention's commercial value.

Step 34, GOVERNMENT PROTECTION NEEDED? YES. In the past, the Government obtained most of its patents to protect its royaltyfree right to use inventions it had funded. The Government will continue to need this protection for many inventions regardless of their commercial value.

Step 35, LET EMPLOYEE KEEP. The employee should be allowed to keep the invention on the condition that the Government will retain a royalty free right of use.

Step 36, HELP PATENT WITH GOVT. USE LICENSE. Had the employee not wanted the invention, and had the Government decided to file a Statutory Invention Disclosure, (see Step 40) the Government would have incurred filing and attorney costs. Thus, it is equitable for the lab to help the employee obtain a patent where the Government retains a royalty-free use license. The help could include actual filing of the patent for the employee or paying a fair share of the costs.

Step 37, LET THE EMPLOYEE KEEP. If the Government sees no use of its own to protect, the employee should be allowed to keep the invention without giving the Government a license.

Step 38, GOVERNMENT PROTECTION NEEDED? YES. If the employee does not want an invention that the Government does not intend to patent, then the Government should decide whether it needs to protect its royalty-free right of use. This is the same decision as Step 34, but the actions taken are different.

Step 39, PUBLICATION ADEQUATE? YES. Once an idea or discovery has been published, statutory bars to patenting take effect. After prescribed periods, the bars prevent anyone from obtaining a patent, and the idea or discovery can be used freely. Thus, publication may provide the use protection the Government needs, and where adequate, publication is also the cheapest form of protection.

Step 40, STATUTORY INVENTION REGISTRATION. P.L. 98-622 allows an inventor or the Government to register an invention with the Patent Office without obtaining a regular patent. By this process (called a SIR), the invention is put into the public domain for anyone to use freely. It serves the Government's purpose of protecting the right of free use. It takes effect sooner than a publication, which may be important for rapidly moving fields of technology. A SIR costs less than a patent but is more than a simple publication.

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Step 41, PUBLISH.

PART 2

Part 2a. <u>Techniques for Finding R&D Cooperators and Licensees</u>

Close cooperation between a Federal laboratory and a commercial firm is new to the culture of most Government employees and managers. Laboratories have legitimate concerns that relationships with the private sector both be fair and appear fair. An attribute of the industrial culture, however, is to maintain secrecy around actions that may affect future products. To be effective it is clear that cooperative R&D agreements and patent licenses must bridge the two cultures. The way a laboratory decides whom to accept as a cooperating party is important to both the appearance and actuality of fairness. This is particularly true where the industry partner will obtain a degree of exclusivity in the results. Labortories will have to exercise some ingenuity in meeting this test. The following are suggestions on how that might be done.

A. If the cooperation stems from an existing laboratory invention, the primary methods to ensure fairness are:

(1) Advertising the invention as available for licensing through NTIS publications, agency fliers, and industry contacts, or use of intermediaries, and other dissemination techniques that expose the invention to possible licensees.

(2) The Federal patent licensing regulation (37 C.F.R. Ch. IV based on 35 U.S.C.208), establishes a process for determining the best potential licensee for a Governmentowned invention and includes a <u>Federal Register</u> publication requirement for exclusive and partially exclusive licenses. While cumbersome and at times, resulting in disputes that end in less than desirable results, the regulation provides for a selection process that is perceived as fair.

(3) Use of a technology management intermediary (such as NTIS, Reseach Corporation, or for-profit technology brokers) to approach industry for the laboratory. In general, these services work best for inventions that have an obvious market value and require relatively little additional development.

B. If the laboratory tries to find a collaborator to help conduct research or develop a technology for which no property rights have yet been established, there are several factors and approaches to consider.

(1) While procurement rules do not apply to cooperative R&D agreements, the feeling of need for an open process comes from the requirement for competitive procurements. There is, however, provision for sole source procurement of R&D that involves unique ideas and when it makes sense to deal directly with those who have the ideas. This view might guide entering into cooperative R&D agreements but labs should be sure to have recorded justifications of their actions.

(2) A lab could publish notices that it is seeking a cooperating party or use intermediaries to do this. It could use the <u>Federal Register</u> as a formality, but scientific, professional, and trade journals and associations would probably be more effective.

(3) Depending on the structure of the industry, the lab could contact the firms it believes most likely to be interested and negotiate with those that respond.

(4) The lab could organize the project in conjunction with a university or unit of State or local government as a partner or intermediary. Allowing the partner or intermediary to select the company or companies could remove the choice from the laboratory. This may be useful where lower levels of government or universities are more able to establish relationships with industry that are closer than arms-length. The partner or intermediary may not, however, be able or willing to evaluate the technical capabilities of a potential R&D cooperator, however.

C. Handling cases where a firm approaches the laboratory with a request to collaborate in research or in developing a technology on which the Government holds no patents, can be divided into two time periods.

Requests received before the lab makes a general announcement of its willingness to enter into cooperative R&D agreements, and

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Requests received after the lab has made an announcement.

(1) It appears that a laboratory can announce its willingness to consider cooperative R&D agreement proposals in fields of science or technology, to be acted on at the lab's convenience. The announcement can provide for a first-come, first-considered selection process, or one that accumulates proposals for a while and then picks the most desirable. The announcement could offer confidentiality for the proposals and present the general agreement terms the lab would offer and require. Once a lab makes this sort of announcement, and follows a rational selection process,

it would probably have met the requirements for both actual and apparent fairness. With the general announcement made in advance, no additional publication should be needed for a specific agreement.

(2) The problem may be greater if a proposal is received that leads to a cooperative R&D agreement before an announcement is made. This may be primarily a start-up problem, but it could occur any time a firm offers a proposal in a field not covered by a lab's announcement. It would be good if the company would agree to a public notice of the proposed agreement. But possibilities of delays, actions by competitors, and publicity may lead a company to reject the idea. Many labs have service for others programs that make lab facilities available to companies for proprietary work. The policies on deciding who can participate in these programs may be a useful and realistic precedent. It may also be possible to work though a university or local government intermediary to remove the selection onus from the laboratory. Finally, the view discussed above (2(a)), that R&D aggreements don't fit the normal openness mold of procurement might be applied.

Part 2b. Types of R&D Cooperation

The range of different types of cooperative R&D projects, in order of increasing complexity includes the following.

A. <u>Parallel Efforts</u>. Probably the simplest type of cooperative R&D project that a laboratory may undertake would consist of parallel but separate work by the lab and the cooperator, with agreement to exchange results. This would not involve joint or shared management, mingling of resources, or the likelihood of inventions made jointly by laboratory employees and non-Federal co-inventors. Since the cooperator would not be a party to the work done by the lab, there would be no provision under existing law to restrict public access to the results produced by the lab. If restricted access is important to some aspects of the project, such as creation of computer software that the non-Federal party desires to Copyright, the work should be divided so that the non-Federal party develops and controls those aspects.

B. <u>Facilities Sharing</u>. Either party might agree to provide the use of equipment or facilities to a joint project. For example, either party might provide an environment to test equipment developed by the other party under the agreement. Under such agreements, there would be minimal mingling of resources, but there may need to be provisions covering damage to and disposition of the shared facilities and the equipment being tested. C. <u>Personnel Sharing</u>. Next on the complexity scale, would be where either the laboratory or the cooperator would provide the services of personnel to pursue an agreed program of work, perhaps at the other's site. This could occur under a patent license where the lab agrees to allow the inventor to assist the licensee with advice or other types of assistance in transforming the invention into a product. Or, it could result from a company requesting the opportunity for one or more of its employees to assist a particular Federal laboratory employee in the conduct of a particular line of work. Under these situations, there would be little or no mingling of resources other than personnel time, but co-inventions involving the non-Federal employees might be a distinct possibility.

D. <u>Industry Funding</u>. A firm might be willing supplement the funding of work undertaken by the laboratory. In their simpler forms, these agreements would include an explicit and predetermined statement of work that is not likely to change, so there would be minimal sharing of decision-making responsibility. Industry funding agreements may require provisions listing the types of laboratory costs that will be allowable and how the costs will be reported. In laboratories whose accounting systems are slow to report, special records may have to be kept to track the use of non-Federal funds.

E. <u>Shared Management</u>. Probably the most complex type of cooperative R&D arrangement would involve a project with significant unknowns and where it is necessary to provide for mutual sharing of the project direction responsibilities. The agreements for these projects need to provide for the management and decision making process. Perhaps the best approach to developing such a project is for the lab and cooperator to work out in technical terms, the initial direction of work, the preliminary decision points, the possible alternatives that may be followed as a result of the decisions, and other significant anticipated or possible events. The formal agreement for the project would then be drafted after the strategy for conducting the project has been outlined.

Part 2c. Determining the Value of a Technology

This paper will not attempt to replicate the many books and articles in print and being written about evaluating technologies, but there are some points of particular relevance to Federal laboratories.

A. <u>Basis for a Technology's Value</u>. For our purposes, technology is knowledge resulting from R&D, of how to achieve a desired physical result. The value of the technology is basically the value of the result minus the cost of achieving the result.

Sometimes, the value of a technology is <u>directly</u> related to the number of people or firms who have access to it and can use it. To achieve its greatest value, such technology should be put into the public domain through publications, meetings, etc., and distributed through technology dissemination programs, consultants such as Agricultural Extension Agents, and education programs.

At the other extreme, the value of a technology may be <u>inversely</u> related to the number of people or firms that have access to it and can use it. This is often the case with an invention, where a significant capital investment is needed to bring the invention to market by the first firm to use it, but where other firms if allowed, might bring similar or improved products to market without having to repeat the investment. In this situation it is important to protect the first firm's capital investment by restricting other firms' ability to copy. Simply put, this is what a patent does.

Perhaps the clearest example is a potential therapeutic product, where millions of dollars must be spent by the developing firm on testing and obtaining pre-market approvals. A firm making a direct copy would be spared much of this investment, would have lower costs to recover, and could sell at a lower cost. Without confidence that copying would be restricted, no firm would make the initial investment, and the therapeutic would not come to market. Thus if anyone were allowed to use the technology necessary to make the therapeutic, the therapeutic would never be made and its practical value to the public and the economy would be zero.

A body of technology might include elements with both types of value. This could occur, for example in a field of measurement, where an part of the technology consists of data that should be widely publicized. Another part of the technology might be needed to make special measurement equipment and would require a significant developmental investment before the equipment becomes available to those who need to make the actual measurements.

Finally, the value of a technology may stem primarily from its usefulness to the Government. In such cases, the Government may need to protect its right to use the technology it created without having to pay royalties to others who may claim it as their invention. In the past, most Government patents were obtained to gain this protection.

Step 2 on the system chart requires a prediction of the value of the technology that a new project is most likely to produce. Step 15 requires a preliminary evaluation of a discovery or idea. In both steps, the distinctions just described must be applied to each particular case.

B. <u>Intellectual Property</u>. The way to protect the rights of one party to use a technology while controlling the opportunity for others to use it is through identifying and protecting the technology as intellectual property. Normally this is done today to protect an investment in developing the technology and bringing it to market. It is done primarily through:

- o Patents,
- o Copyrights, and
- o Technical data kept in confidence.

Conversely, the way to ensure that anyone including the Government can use a technology is to destroy any intellectual property value it might have by putting it in the public domain through publication or some other means. Unfortunately, it is easy to accidentially destroy the intellectual property value of a technology that should be protected. In part, Steps 2 and 15 should lead to a deliberate decision on protection, publication, or a combination of the two.

C. <u>Commodities vs. Differentiated Products</u> The goods traded by the world's economies tend to be either commodities or differentiated products. The markets for commodities (e.g. iron, wheat, and oil) are usually very competitive and there is little a single producer can do to increase his profitability. The markets for differentiated products (e.g. therapeutics, special devices, and computer programs) allow a single producer much more opportunity to influence his profitability.

Technology is used by producers of both commodities and differentiated products. However, technology in the form of intellectual property is often the basic ingredient necessary to create a differentiated product. If many producers could use a new technology, the product would soon become a commodity.

This distinction is important when evaluating a technology. An objective of most nations that have or aspire to have modern industrial economies is to increase the portion of their economy dedicated to differentiated products, while reducing dependence on commodities.

D. <u>The Evaluation Process</u>. Evaluating an idea or discovery can be time consuming and costly. A laboratory can conserve its resources by using a multi-step evaluation process, highlighted on the system chart as Steps 15 and 20. Step 15, the PRELIMINARY VALUE SCREEN, is intended to be a weeding process to reduce the number of ideas under consideration to those which appear to have the best potential. The three primary purposes of this Step are to obtain preliminary indications of:

- What the technology will actually do and how well it will do it from a technical standpoint,
- Identify what the market or markets may be for the technology, including its ability to meet a Government need, and
- Whether it can and should be protected as intellectual property.

If all three indications are positive, then the laboratory is justified in spending more resources for additional evaluation. This is what Step 20 is to indicate. The continuing evaluation may be analytical or it may be done by an actual market test.

If the invention will be used in a commercial product, the sooner a firm is involved in the development process, the more likely the chances of ultimate success. Once a patent application has been filed, the lab can start to seek a licensee. This is the market test approach. The analytical approach is needed if the lab has to do preliminary market and cost projections to interest a potential licensee.

The point is to work gradually into the evaluation process, committing or not committing additional resources on a controlled basis as knowledge is gained.

Part 2d. Conflict of Interest

Conflict of interest is often mentioned in conjunction with technology management by laboratories. While this paper is not to provide legal advice, there are indications that the term is frequently used incorrectly. Three different situations are often confused, but need to be recognized and handled separately:

A. <u>Conflict</u> of <u>interest</u>. A legal conflict of interest situation is probably one that:

o Is prohibited by Federal statute,

- Allows a Federal employee to commit the Government or Government resources including the employee's work time, without prior approval or subsequent management review, and
- o May lead to personal benefit for the employee.

Most conflict of interest statutes were written before enactment of the Federal Technology Transfer Act and were based on the concepts that a Federal/industry relationship should be arm'slength and a Federal employee could serve only one master. These statutes must be applied in light of the new relationships Congress intended under the Act.

Agency regulations written before the Act that do not provide for Federal employees having relationships with more than one organization may need to be revised. While unheard of in most agencies, such arrangements have long been accepted and promoted by some. In addition, implementation of the Act requires agency regulations to accommodate the technological innovation process as it is used in the United States economy. This means that the public good may best be served by special treatment for innovating firms and restricted access to the technology on which a new product is based.

B. <u>Congruence of interest</u>, is a situation anticipated by the Act, where, for example, a laboratory employee inventor is allowed to contribute to and directly benefit from the commercialization of the invention where the employee can make a unique contribution that is in the interest of both the laboratory and a private firm. Patent licenses, cooperative R&D agreements, and employee ownership of inventions not managed by the laboratory are types of hand-in-hand congruence of interest situations which are fundamentally different from the arms-length relationships toward which the conflict-of-interest statutes were directed.

Congruence of interest situations are more like partnerships than typical Government/private sector, arms-length relationships, and the agreements establishing them should be similar to partnership agreements. In many cases, relationships between firms and laboratory employees that would result in conflict of interest situations if the employees acted on their own, can become congruence of interest through agreements between the laboratories and the firms.

C. <u>Conflict of committment</u>, or the competing demands for resources. This can arise, for example, when the services of an investigator are desired both to aid commercialization of a technology and to perform other laboratory work. If it arises, it is a management problem, not a legal conflict of interest issue. It should be solved on the basis of the laboratory's priorities, including its mission committments, commercialization objectives, desires to accommodate its staff, and the value of the technology.

The most difficult aspect of this for many to accept will probably be the fundamentally new types of relationships the Act permits. The Act was designed to bridge between what have formerly been two entirely separate cultures--industry and Government research. The bridge may involve co-work, comanagement, co-acceptance of risks, and co-enjoyment of rewards. While some employees of a few agencies, particularly Agriculture and the VA have experience in these types of relationships, for most Government people, they will be entirely new. As such, the Act is plastic and waiting to be molded in the wisest and most imaginative ways that can be created.

One way an agency could approach this gradually, would be to develop preliminary policies or a statement of intent for the basic types of inventor participation in commercialization that the agency will normally allow. It could establish a review and approval process for proposals of types of participation that go beyond. The organizational levels that could approve more extensive participation should probably correspond with those that make or approve research project funding decisions for a laboratory. These levels will probably also be involved with decisions to approve cooperative R&D projects.