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Jacob (Jesse) Erlich is a partner in the firm of Perkins, Smith & Cohen, LLP and a member of the firm's E- Commerce & Communications, Intellectual Property and Government Relations Groups. He is admitted to practice law in Massachusetts, the District of Columbia and is admitted to practice before the Supreme Court of the United States. He is a registered patent attorney with the U.S. Patent & Trademark Office and the Canadian Patent Office.

A graduate of Worcester Polytechnic Institute, Mr. Erlich earned his J.D. from Georgetown Law School in 1966. Prior to joining the firm, Mr. Erlich served as Chief Patent Advisor for the United States Air Force.

Jesse has contributed to numerous publications in the field of intellectual property and technology transfer, in addition to co-authoring a book entitled <u>Technology Development and Transfer - The Transaction and Legal Environment</u>, Quorum Books, 1997 and being a contributing author to <u>Licensing Update</u>, Aspen Law & Business - a division of Aspen Publications, Inc., 2000, 2001, 2002, 2003 and <u>Valuation of Intangible Assets in Global Operations</u>, Quorum Books, 2001. He sat on the faculty of The National Intellectual Property Law Institute, Postgraduate Program in Intellectual Property and The Intellectual Property Institute for Corporate Counsel, both in Washington, DC. A frequent lecturer and speaker, Mr. Erlich has been asked to appear before groups including, but not limited to the WPI Venture Forum, Government Patent Law Association Conferences, Franklin Pierce Law School Annual Licensing Program and the American Association of State Colleges and Universities.

Mr. Erlich has been appointed to the U.S.-Israel Science and Technology Commission Task Force: Legal, Patent and Intellectual Property Rights, serves on the Advisory Council of the National Institute of Justice, a research agency of the U.S. Justice Department and has recently been elected to serve on the Board of Directors of the New England Chapter of the National Defense Industrial Association (NDIA). He is a member and past President of the Boston Patent Law Association, and an active member of the Technology Transfer Society, the Licensing Executive Society and the American Intellectual Property Law Association as well as being listed in "Who's Who in American Law" "Who's Who in Intellectual Property.".

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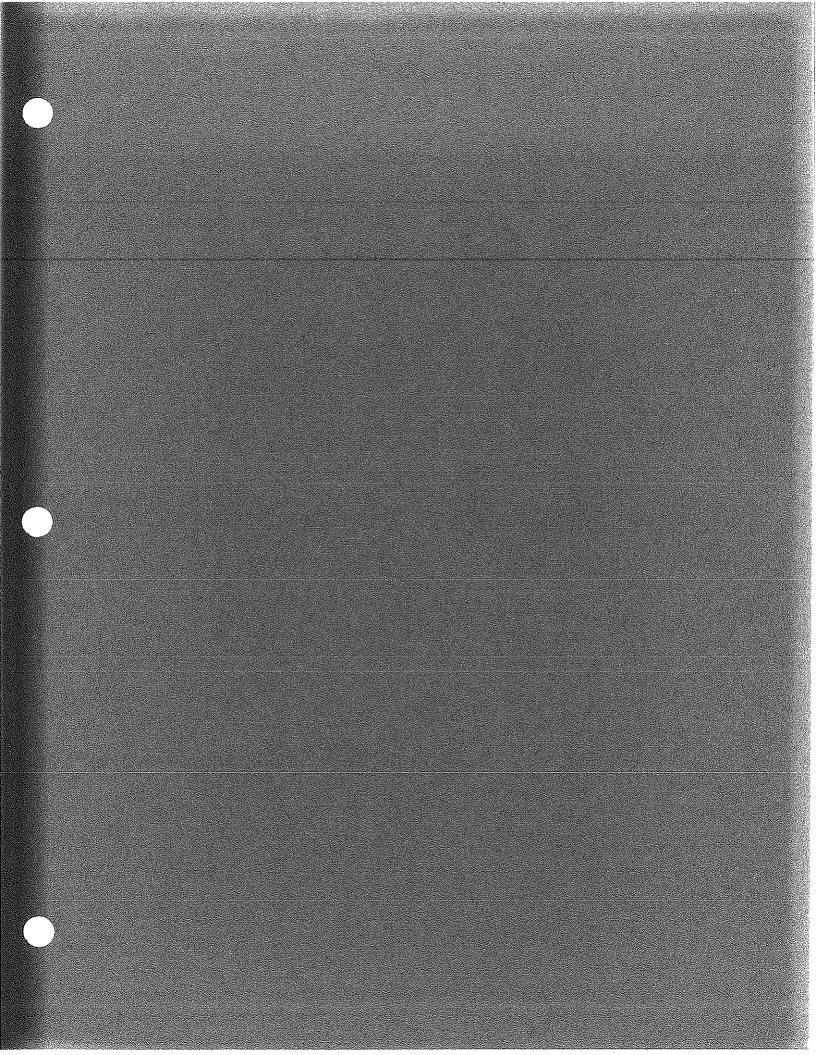
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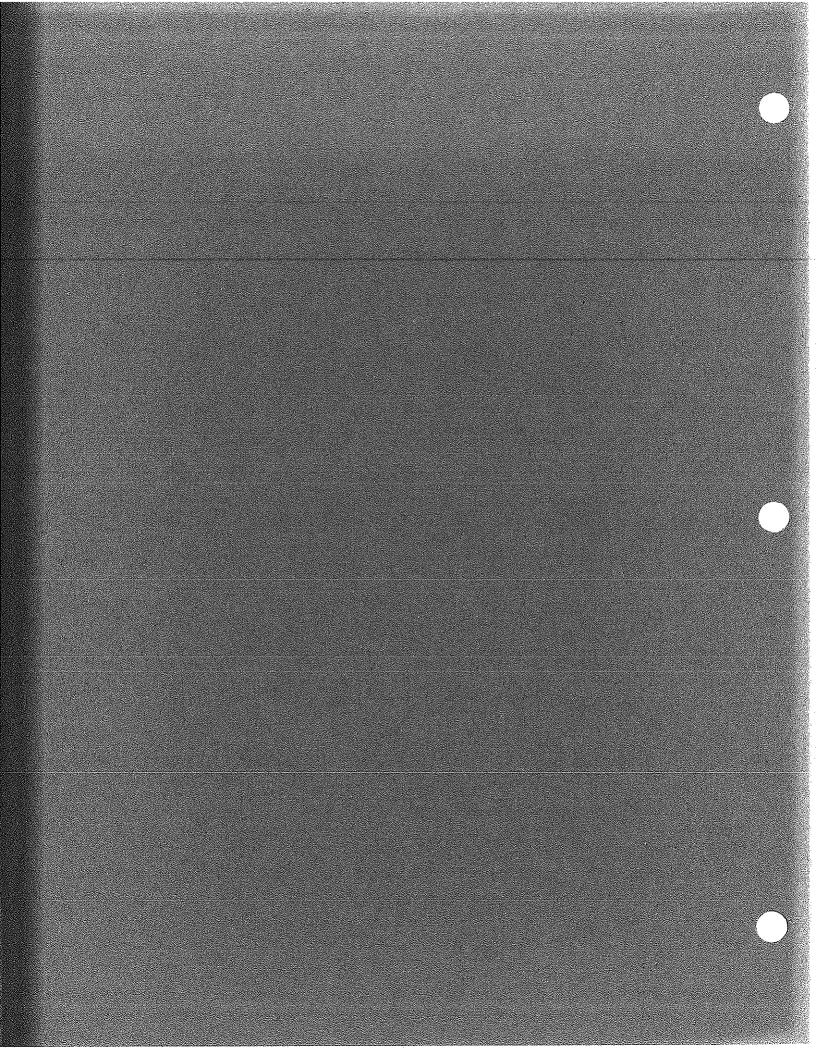
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THE FEDERAL TECHNOLOGY TRANSFER PROCESS LICENSES AND COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

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BACKGROUND

Recent studies by the National Science Foundation have provided evidence of a substantial drop in spending and consequent reduction in the research and development capability of U.S. corporations. During this same period of private sector decline in research and development, money spent on research and development by several foreign countries, particularly, Japan, Germany, the United Kingdom and France has substantially increased.

In view of these facts, where can US companies go to enhance their declining technological base? To the Federal Laboratory System of the United States, that is where. The Federal Laboratory System of the United States is a gold mine when it comes to providing a source of the latest and most innovative technical developments. This year, for example, approximately 40 billion dollars is being spent by the United States Government in funding federal research and development. This research and development is taking place at over 600 federal laboratories and centers which employ well over 100,000 scientists and engineers. The research being conducted at these facilities encompass virtually every area of technology and the scientists and engineers employed there are some of the finest and most distinguished found anywhere in the world.

In order to effect a cooperative relationship between the Government and the private industry, over approximately the last ten years, Congress has enacted numerous pieces of legislation (for example, Public Laws 96-480, 96-517, 97-219, 98-462, 98-620, 99-382, 99-502, 100-107, 100-418, 100-519, 100-676, 101-189, 101-510, 102-240, 102-245, 102-564, 102-25, 102-484, 103-160 and 104-113) dealing with enhancing the technological position of the United States in the global marketplace. The most important legislation in this area being the Stevenson-Wydler Technology Innovation Act of 1980 and the Federal Technology Act of 1986 now codified in 15 U.S.C. 3701-3717 ("the Act"). The above legislation has enabled a unique partnership to take place between the Government and private enterprise in which vast stores of Government owned technology, services, and property (including intellectual property) can be transferred to the private sector. The primary objective of this transfer being the commercialization of the latest technological developments by U.S. companies.

The Act has put teeth into an already existing federal licensing program. Prior to the passage of the Act the Government found it extremely difficult to transfer the "know how" associated with an invention being licensed. By combining the already existing licensing program of the Government (authorized under 35 USC 207, 208 and 209 and 37 CFR 404 et seq.) with the use of cooperative research and development agreements (CRDAs or

CRADAs) as authorized under the Act, the Government now has the mechanisms necessary for effectively transferring its vast source of technology to the private sector. The Act by granting federal laboratories authorization to enter into CRDAs, has enabled federal laboratories to transfer the much needed "know-how," essential in a true transfer of technology, to the private sector.

More specifically, under 15 USC 3710a, each federal agency has the authority to permit the director of any of its Government-owned, Government-operated federal laboratories and its Government-owned, contractor-operated laboratories to (1) enter into cooperative research and development agreements (CRDAs) with other federal agencies, units of state or local government, industrial organizations (including corporations, partnerships, and limited partnerships, and industrial development organizations), public and private foundations, non-profit organizations (including universities), or other persons (including licensees of inventions owned by the federal agency); and (2) negotiate licensing agreements under 35 USC 207, or other authorities for inventions made or other intellectual property developed at the laboratory and other inventions or other intellectual property that may be voluntarily assigned to the Government. Furthermore, under 35 USC 207, federal agencies are authorized to grant nonexclusive, exclusive, or partially exclusive licenses under federallyowned patent applications, patents, or other forms of protection obtained. (Note: It is the author's opinion that the phrase "other forms of protection obtained" relates to patent-like protection obtained in foreign countries and not to other forms of intellectual property such as copyrights, trademarks, or trade secrets. Support for this position can be found in 37 CFR 404.2 and 404.3.)

Although the Government has supported the private sector financially through the years by contracts and grants and, more recently, with programs such as the Independent Research and Development Program (IR&D), the Small Business Innovation Research Program (SBIR) and the Technology Reinvestment Program (TRP), it is still clearly evident that money alone cannot solve our nations problems in overcoming the substantial technological decline of U.S. industry. Therefore, it is imperative that private industry take advantage of the vast store of federally funded research and development found in federal laboratories throughout the United States.

ACCESSING FEDERALLY OWNED TECHNOLOGY

In order for the private sector to access federally owned technology, two main issues arise:

(1) How do private companies determine which federal laboratories have the

specific technologies they need, and

(2) Once the appropriate technology is located, what legal mechanisms are available to properly transfer this technology to the private company.

Below are examples of major sources of information available to determine where, within

our federal laboratory system, these technologies are located:

There is the National Technology Transfer Center (NTTC), located in Wheeling, West Virginia, which has an extensive data base on federal laboratories. The NTTC can be reached at (800) 678-NTTC. Additionally, there are a series of Regional Technology Transfer Centers located throughout the United States, staffed by research experts to help your company locate federally owned technology. In Massachusetts, for example, the Regional Technology Transfer Center, namely the Center for Technology Commercialization, is located in Westboro and can be reached at (508) 870-0042.

Further, there is the Federal Laboratory Consortium (FLC) Administrator, located in Cherry Hill New Jersey, which can be reached at (856) 667-7727. The FLC has a data base which continuously updates the technological developments of most laboratories. In addition, the FLC has a web site which can be reached at www.federallabs.org. From this web site many federal laboratory web sites can be reached, as well as the NTTC web site.

Once a company has determined the type of technology it needs and has made contact with the appropriate federal laboratories, there are two primary mechanisms available to legally transfer this technology to your company - the Licensing Agreement and the Cooperative Research and Development Agreement.

LICENSES AS A MECHANISM FOR TRANSFERRING FEDERALLY OWNED TECHNOLOGY

Licensing as a mechanism for transferring federally owned technology is a straight forward process very similar, in many ways, to private sector licensing. Government licensing does, however, fall into two categories (1) licensing of inventions made prior to a cooperative research and development agreement (CRDA or CRADA) and (2) licensing of inventions made under a CRDA. More specifically, the authority for the Government to enter into licenses (exclusive, partially exclusive, and nonexclusive) with nonfederal parties is found in 35 USC 207, 209 and 15 U.S.C. 3710a(b)(1). The regulations implementing the federal licensing program are set forth in 37 CFR 404 et seq. and in individual federal agency implementing instructions. The following discussion of federal licensing will be directed to the licensing of federally owned inventions in the form of patents and patent applications.

A license granted by the Government to a nonfederal party creates a contractual relationship between the Government (licensor) and the nonfederal party (licensee). In this license the licensor grants to the licensee the right to practice the invention claimed in the licensed patent or patent application in consideration for a payment (royalties) made by the licensee to the licensor. In other words, by granting this license, the licensor agrees not to sue the licensee for infringing licensor's patent. Determining appropriate royalty payments under the licensing agreement is a difficult and nonexact system and is discussed in detail later in this paper.

There are different types of licenses that can be obtained from the Government. The Government can grant either an exclusive, partially exclusive, or nonexclusive license. These licenses may be granted for all or less than all fields of use of the invention and for use in specified geographical areas. It is important for the licensee to understand that each license granted by the Government under 35 USC 207 is subject to an irrevocable, royalty-free right of the Government of the United States to practice and have practiced the invention on behalf of the United States and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States. This right left with the Government ensures the Government a royalty free use of the invention for governmental purposes. The license granted by the Government to the licensee is granted for the purpose of commercializing the federally-owned technology and not for the purpose of creating a sole source for future Government contracts. Reference should be made to 37 CFR 404.5 and 404.7 for further restrictions and conditions on licenses granted by the Government.

A license may be granted by the Government on inventions made <u>outside</u> of a CRDA only if the prospective licensee has supplied the appropriate federal agency with a license

application containing a satisfactory plan for developing and/or marketing of the invention. The contents of a license application can be found in 37 CFR 404.3 as well as in the agency's implementing instructions, which may be obtained from the agency. If the prospective licensee is applying for an exclusive or partially exclusive license, notification of the prospective license, identifying the invention and the prospective licensee, must be published in the FEDERAL REGISTER for at least 15 days in order to provide an opportunity for objecting parties to file their objection to such a granting of an exclusive or partially exclusive license. If the prospective licensee requests a nonexclusive license, this type of license may be granted without the publication of either the availability of the technology or notice of the prospective license.

Licenses granted on inventions made <u>under</u> a CRDA or CRADA (15 USC 3710a(b)(1)) are not subject to the "publication requirement" set forth above. In addition, if the license is granted under this section of the code, the royalty free license to the Government may be limited to only the federal laboratory associated with the CRDA (35 USC 3710a(b)(A). Inventions made under a CRDA are defined as those inventions which are <u>either</u> conceived <u>or</u> actually reduced to practice under the CRDA.

ESTABLISHING ROYALTY PAYMENTS

In negotiating any patent license, perhaps the most difficult aspect of the license negotiations is in establishing royalty payments satisfactory to both the licensor and the licensee. In cases where the invention to be licensed is owned by the Federal Government, the establishment of a royalty payment or rate is, in many instances, even more difficult. The reasons for this difficulty are as follows:

- 1) The public has an interest in having the invention licensed and commercialized.
 - 2) The Government lacks the ability to manufacture the invention itself. Therefore, the invention would not be commercialized unless the Government licenses the invention.
- 3) Negative public sentiment may be generated if the Government institutes a patent infringement suit against a private company manufacturing a Government owned invention, after having its request for a license turned down by the Government.

Therefore, unlike the private sector where the owner of the invention has an advantage over a potential licensee by simply refusing to license the invention, the Government is at a slight disadvantage. An advantage the Government does have, however, is, if the Government decides to sue for patent infringement, an endless supply of monetary resources are at the disposal of the Government. This asset may be sufficient to make the potential licensee more reasonable in its license negotiations with the Government.

How, then can reasonable royalty payments be established? As stated in Georgia-Pacific Corporation v. U.S. Plywood-Champion Papers Inc. 166 USPQ 239, "Where a willing licensor and a willing licensee are negotiating for a royalty the hypothetical negotiations would not occur in a vacuum of pure logic. They would involve a market place confrontation of the parties, the outcome of which would depend upon such factors as their relative bargaining strength; the anticipated amount of profits that the prospective licensor reasonably thinks he would lose as a result of licensing the patent as compared to the anticipated royalty income; the anticipated amount of net profits that the prospective licensee reasonably thinks he will make; the commercial past performance of the invention in terms of public acceptance and profits; the market to be tapped; and any other economic factor that normally prudent businessmen would, under similar

circumstances, take into consideration in negotiating the hypothetical license."

The most frequently asked question about determining licensing royalties is, "Is there a specific or set percentage charged for the licensing of an invention?"- The answer is NO. Many factors contribute to the establishment of a royalty rate. However, studies have shown many licenses charge a royalty rate between 1-7% of the sales price of the royalty bearing product. Lower rates are charged on nonexclusive licenses and higher rates are charged on exclusive licenses. However, it must be realized that each license requires a separate negotiation of the royalty payment since the royalty is based upon many factors. Furthermore the royalty payment can be assessed in numerous ways as will be shown below.

A reasonable royalty rate is usually considered a fair share of the licensee's profits attributed to the licensed invention. A 5% royalty rate may be reasonable in some circumstances, but unreasonable in others. If, for example in a manufactured product which generates profit margins of 25% of the sales price than one fifth of the profits may be considered an equitable return to the licensor. Of course, the royalty may be reduced or raised based on the importance of the licensed invention. Furthermore, a percentage of sales may be only one aspect of the final royalty payment. In some cases, where the profit margin may be extremely low, for example, a royalty rate of 1% may be excessive, yet a royalty rate in other instances of 25% may be considered reasonable. For example, a royalty rate of 15% may be acceptable for licensing software because the profit margin of the licensee can be very high. Once a computer program is written, it is rapidly recorded on an inexpensive diskette with little labor cost. The profit margin to the licensee could be as much as 90% of the sales price. Consequently, a licensor receiving a 15% royalty would be receiving one sixth of the profits of t he licensee, which could be equitable.

The next most frequently asked question, is, "If there is no set royalty rate, what factors are utilized to set the royalty rate or payment? The first determination that must be made is the establishment of the value of the <u>claimed</u> patented invention to be licensed. It is the claimed invention which determines value since the claims define the scope of the licensed invention. For example, if the claimed patented invention is broad and considered a major breakthrough in the field, the licensee would have a substantial advantage in the marketplace. The royalty would, therefore, be higher than on an invention which is narrowly claimed and considered a minor improvement.

On the other hand, if the Government (licensor) asks a royalty rate that is too high, the potential licensee would have an incentive to use an old or existing device, or even "invent around" the invention. Thus, the strength of the patent to be licensed is an important factor in establishing a royalty rate. Also consider whether the potential licensee must obtain licenses from other parties in order to practice the licensed invention. It may turn out that as many as two or three other licenses may have to be entered into before the potential licensee can manufacture the licensed invention. What good is a license if the licensee is unable to manufacture the royalty bearing product?

Fixed payment fees are generally useful when the royalty base is difficult to ascertain. For example, fixed payments may be used if the claimed invention is a process or a method, or if an apparatus or method is used internally by the licensee. In order to establish royalty payments on software inventions, software inventions should be first broken down into those inventions which pertain to software sold on discs and those developed as chips. The royalty percentage may be higher in licensing software inventions since the expenditure of funds by the licensee may also be low in manufacturing the software.

Another impact on establishing royalty payments is the cost to the licensee to bring the invention to the marketplace. In addition, the market potential or profitability of the licensed invention is

also a critical and important consideration in determining royalty payments. Would it be cheaper for the licensee to "invent around" the patented invention then pay the license fee? Would the licensed invention require substantial post sale maintenance or is the licensed invention a device which, when once manufactured, requires virtually no additional input costs by licensee? Is the market for the licensed invention a long-term market or a short-term market? All of the above questions must be considered when establishing royalty payments.

Another consideration affecting royalty payments are any conditions placed on the potential licensee by the Government. Remember, even in an exclusive license, the Government receives a royalty-free right to use the invention for governmental purposes. Also, a non-exclusive license will generally bring lower royalty payments than an exclusive license. Other conditions, such as field or use, area of use and the length of time the license is in effect also contribute to the establishment of a royalty rate. In some instances, a license may be issued for a specific period of time at a specific royalty rate and after the expiration of that period of time the license may be re-negotiated at a different royalty rate based upon the success of the licensee in commercializing the invention.

Once royalty payments (value) have been established for the licensed invention, the manner in which these payments are to be made becomes important. Generally, the royalty payment is based on a percentage of the sales price (royalty rate) of the royalty bearing product. There are situations, however, when a specific percentage royalty rate is inappropriate. As mentioned above, a lump sum payment may be utilized in lieu of or together with a percentage payment. There may be situations when an up front payment may be made, supplemented with a reduced royalty payment. It is important to recognize, when assessing a royalty payment, the licensee must be left with enough money to manufacture the product. Therefore, up front royalty payments should not put the licensee in such an undesirable financial condition that the subsequent success of manufacturing the royalty bearing product is diminished.

In most cases, if the royalty payment is based on a percentage of sales of a product, the Government generally would like to have the percentage based on gross income. In many situations this is not possible and, therefore, it is customary to base the percentage of royalties on the net sales price. The net sales price generally means the invoice price or lease income of the royalty bearing product sold less any commissions, discounts, refunds, taxes, shipping and insurance costs. The base upon which the royalty is to be paid should be simplistic to ascertain and lacking external factors. Policing of royalty payments can be a nuisance and, therefore, the closer to a fixed price the payments are based, the easier it is to calculate the payments.

In many instances a minimum, yearly, guaranteed payment is advisable on an exclusive license. This minimum, guaranteed payment provides an incentive to the licensee to bring the licensed invention to the marketplace as soon as possible. If minimum, guaranteed payments are required, these payments generally begin after a certain agreed upon period of time in order to enable the licensee to begin manufacture of the royalty bearing product without a significant financial burden brought on by the license. These minimum payments can increase on a yearly basis thereafter. Payments may also be based on a fixed sum for a unit of sale or a fixed sum for the use of the licensed invention.

In all licenses, it is important to understand exactly how the <u>claimed</u> invention fits into the finished product (royalty bearing product). Is the claimed invention (1) an add-on feature to an already existing product, (2) an insignificant improvement, (3) a significant improvement, (4) a component to an already existing system, (5) a complete system, (6) a method or process, or (7) a major

breakthrough? All of the above factors contribute either positively or negatively to the royalty rate.

The Government generally transfers know-how" to the private company by means of a cooperative research and development agreement (CRDA). Therefore, if the Government is contributing substantial "know-how" in the CRDA, the royalty payment should be increased accordingly in the license.

In conclusion, licensing between the Government and a company in the private sector should be "win-win" situation for all parties. When establishing royalty compensation for the Government, it is suggested that the following guidelines be followed:

- 1) The Government in establishing its royalty rate, should be reasonable. If the Government is unreasonable and the licensee is left with insufficient funds to commercialize the Government owned invention, the license has failed.
 - The licensee must be willing to compensate the Government for its technology. Therefore, if the licensee refuses to negotiate in good faith, the Government should seek a different licensee. However, before rejecting a potential licensee, it is wise for the Government negotiator to seek assurance from the Justice Department that a patent infringement suit will be filed in the event of infringement by the rejected party.
 - 3) It is generally a good idea to minimize up front payments in a license while increasing later payments based upon successful commercialization of the licensed invention.

When fair and reasonable royalty payments are charged and the parties negotiate in good faith, commercialization of the licensed invention has an excellent chance of succeeding. In such a case, the ultimate winners will be the citizens of the United States, whose tax dollars have funded the research and development which led to the development of the licensed invention.

CONTENTS OF A TYPICAL GOVERNMENT LICENSE

The license agreement entered into by the Government, more specifically the federal agency having custody of the patent or patent application being licensed, is very similar to license agreements which are used between parties in the private sector. An analysis of the various sections or articles of a Government license (wherein the terms Government and licensor are used interchangeably) are set forth below:

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1) PREAMBLE

The preamble sets forth the names and addresses of the participants in the license and describes the type of license (exclusive, partially exclusive, or nonexclusive).

2) RECITALS

This section is made up of a series of clauses which explain the background of the license and includes reference to the laws and regulations authorizing the license grant. These clauses aid individuals, who in the future, may have to rule on the interpretation and/or validity of the license agreement.

DEFINITIONS

Having a set of definitions is extremely important. They set forth in clear and concise terms the exact meanings of terminologies used within the license. Examples of terminology which require defining include the makeup of the royalty bearing product or process, the royalty base, the territory covered by the license, as well as any other terms which need explanation and which are used repeatedly throughout the license agreement.

4) LICENSE GRANT

The license grant specifically sets forth the type of license granted (exclusive, partially exclusive or nonexclusive) and any restrictions imposed upon the licensee by the licensor. For example, in the case of a federal license, the license is not assignable by the licensee without the prior written approval of the licensor.

5) ROYALTIES, ROYALTY REPORTS AND PAYMENTS

Although the Government can license an invention without receiving any payments, generally the federal agency in custody of the invention being licensed will require the payment of some form of royalties to the Government (federal laboratory). The manner in which this payment is to be made is set forth in this article. For example, and as pointed out earlier in this paper, payments may be in the form of a lump sum, one-time payment, an upfront payment together with running royalties throughout the length of the license, topping or minimum payments made each year to encourage the commercialization of a licensed technology, and/or sublicensing payments. Determining the actual rate of royalties or payments is difficult and must be given a great deal of consideration and thought by the parties. The amount of the payments are generally arrived at through negotiation. Although it is important that the Government be paid a fair value for its technology, the payment by the licensee should not become such a burden that licensee has little funds left to commercialize the technology. Remember, the greater the commercial use of the licensed technology, the greater the resultant income to the licensor and the greater the benefit to the citizens of the United States.

6) RECORDS, BOOKS AND EXAMINATION

It is important for the licensee to keep accurate records of the number and types of royalty bearing products sold and the amount of income received. These books should be open for inspection by the licensor with the possible stipulation that the information contained therein is to be maintained in confidence by the licensor for a predetermined length of time.

7) LICENSE PERIOD

This article sets forth the effective date of the license and the length of time the license is to remain in effect, generally for the life of the patent.

8) LICENSEE'S PERFORMANCE

The licensee shall abide by the terms of the license agreement and shall carry out the development plans submitted by the licensee when applying for the license. Performance will be on a best efforts basis, and in so doing licensee shall comply with any applicable laws and necessary approvals from the Government, if such approvals are required. In addition, as provided by 37 CFR 404.5(2), the licensee is normally required to agree that any product embodying the licensed invention or produced through the use of the licensed invention will be MANUFACTURED SUBSTANTIALLY IN THE UNITED STATES.

9) SUBLICENSING AND ROYALTY SHARING

This article deals with any sublicensing arrangements the parties have agreed upon and provides for the sharing of royalties which might be obtained by the licensee under such a sublicense. Before any such sublicense can be issued by licensee, written approval must be obtained by the licensee from the federal agency granting the license. Furthermore, the Government could require the licensee to grant a sublicense to any responsible applicant on reasonable terms when necessary to fulfill the health or safety needs of the public to the extent such needs are not being reasonably satisfied by licensee.

10) PATENT MARKING AND NON ENDORSEMENT

In a license granted by the Government, the licensee agrees to mark each royalty bearing product with a notation that the product was "licensed from the United States of America under U.S. Patent No. _____." Licensee also agrees not to create the appearance that the Government endorses the licensee's business or endorses or warrants licensee's products. Furthermore, the Government is not to be connected directly or impliedly with any advertising or promotional program of licensee, except that the licensee may state it has received this license from the Government of the United States.

11) RESERVATION OF RIGHTS

This article points out if the present license is subject to any other licenses granted on the same invention. This clause is necessary if the federally owned invention was developed under a Government contract in which the contractor has relinquished its ownership rights to the Government. In such a case, the contractor has a revocable, royalty-free license from the Government to use the invention. In addition, the license is always expressly made subject to an irrevocable, royalty-free right of the Government of the United States to practice for governmental purposes and have practiced the licensed invention on behalf of the Government of the United States for governmental purposes and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States. Furthermore, if there is a field of use or geographic restriction of the licensed invention, this article will contain reference to such restrictions.

12) REPRESENTATIONS AND WARRANTIES

In this article, the licensor generally provides that it makes no representation or warranty as to the validity of any patent which has been licensed. Furthermore, licensor does not warrant that the exercise of this license will not result in the infringement of any other United States or foreign patent or other intellectual property right. Licensor also sets forth

that it assumes no obligation to bring or prosecute actions or suits against third parties for infringement. Licensor specifically sets forth in this article it has no obligation to furnish any "know-how," however, an arrangement can be made that "know-how" can be furnished under a cooperative research and development agreement (CRDA) at some future time. Additionally, neither the Government nor its employees assume any liability in the exercise of this license, and there are generally no expressed or implied warranties of merchantability or fitness for a particular purpose and use of the licensed invention. It is further set forth in this article that licensee shall hold the licensor harmless from and against all liability, demands, damages, expenses and losses for death, personal injury, illness or property damage arising out of the use by licensee or its customers and any other transferees of any licensed process or out of any use, sale or other disposition of royalty bearing products by the licensee.

13) PROGRESS REPORTS

The license generally requires written reports showing the progress of the commercialization of a licensed invention. Any data which is supplied within these reports and labeled "proprietary" will be treated on a best-efforts basis as privileged, confidential information and not subject to disclosure under the Freedom of Information Act for a period of, for example, 3 years from the date of receipt of this information.

14) MODIFICATION AND TERMINATION

This article points out that the licensor may modify or terminate the license if the licensor determines that the licensee is not executing the development plan submitted in its application for license and the licensee cannot otherwise demonstrate to the satisfaction of the licensor that it has taken or can be expected to take, within a reasonable time, effective steps to achieve practical application of the licensed invention. In addition, both parties may modify or terminate the license upon written mutual consent of the parties.

15) INFRINGEMENT/LITIGATION

The rights of the parties with respect to infringement of the licensed invention and litigation are discussed herein. More specifically, if the licensee becomes aware of an infringement or has reasonable cause to believe that there has been an infringement, licensee must so notify licensor. After such notification, if the licensee has been granted the power of enforcement of the licensed patent, the licensee at their own expense and pursuant to Chapter 29 of Title 35 of the United States Code may bring suit, enjoin infringement and collect damages, profits and awards of whatever nature recoverable from such infringement, and settle any claim or suit for infringement of the licensed patent. This right, however, is subject to the continuing right of licensor and other Government agencies to intervene. There generally is a sharing of any recoveries made by the licensee with the Government. If the licensee fails to notify the licensor of such infringement within an appropriate time frame, the licensor may elect to terminate or modify the license and take appropriate action on its own to enforce the patent for its own benefit.

16) PATENT MAINTENANCE FEES

This article deals with the payment of maintenance fees either by the licensor or licensee, and the manner of payment.

17) TECHNICAL ASSISTANCE

This article refers to the availability of technical assistance by the licensor to the licensee. This technical assistance is offered in the form of a CRDA as will be explained in greater detail later in this paper. The technical assistance is generally not guaranteed and if furnishing such technical assistance becomes burdensome to the Government, no technical assistance need be provided.

18) GOVERNING LAW

Construction and effect of this license will be governed by the laws applicable to the Government of the United States.

19) EXPORT CONTROLS

It is possible that the licensed invention may be subject to the Arms Control Act (22 USC 2751 et seq.) or the Export Administration Act (50 USC 2401 et seq.). In that event, nothing in the license shall be construed to modify or rescind licensee's obligation under these laws.

20) NOTICE

This article sets forth the addresses of the licensor and licensee to which any notices, communications shall be mailed.

SUMMARY

It is apparent from the above discussion that, with the exception of those clauses mandated by law, license agreements between a nonfederal licensee and the Government licensor follow very closely the terminology found in licenses entered into between private parties. Negotiation is a key ingredient in any license, and except for the clauses mandated by law, most aspects of a Government license agreement can be modified. The Government encourages applicants from the private sector to license federally owned technology and federal laboratories will go out of their way to provide the licensee with the "know-how" necessary to commercialize a product or process based upon the licensed invention. This "know-how" may be transferred from the Government to a private party by a cooperative research and development agreement (CRDA), and which can be entered into directly by a federal laboratory.

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS AS A MECHANISM FOR TRANSFERRING FEDERALLY OWNED TECHNOLOGY

As pointed out in previous portions of this paper, the authority for establishing a CRDA between an agency (laboratory) of the Government and an applicant (collaborator) from the private sector is found in 15 USC 3710a and any implementing instructions issued by the federal agencies.

The Act not only encourages technology transfer, but also makes it the responsibility of each laboratory science and engineering professional employed by the Government, as long as it is consistent with the agency's mission, to transfer technology. The Act provides the authority for the Government laboratory director to enter into CRDAs and negotiate

licenses. It also provides that most funds received under a CRDA or from a license remain within the laboratory providing the technology. In addition, the Act provides that at least 15% of any royalties collected through the licensing of federally owned patents or patent applications will be shared with the inventor(s) if the inventor(s) has assigned his or her ownership rights to the Government. The majority of the remaining balance of these royalty payments will go to the federal laboratory providing the technology.

Under a CRDA, as set forth in 15 USC 3710a, federal laboratories may (1) accept, retain, and use funds, personnel, services, and property received from collaborating parties and provide personnel, services, and property (but not funds) to collaborating parties; and (2) grant or agree to grant in advance to a collaborating party, patent licenses or assignments, or options thereto, in any invention made in whole or in part by a federal employee under the CRDA. Inventions made by the collaborating party under the CRDA are generally owned by the collaborating party and those made by Government employees are owned by the Government.

It is provided under the Act, that a "federal laboratory" means any laboratory, any federally funded research and development center, or any center established under 15 U.S.C. 3705 or 3707 that is owned, leased, or otherwise used by a federal agency and funded by the Government, whether operated by the Government (GOGO) or by a contractor(GOCO). It is emphasized that although the federal laboratory may provide, under a CRDA, personnel, services, and property, it may not provide funding to the collaborating party. There are current laws which may permit such funding under certain circumstances, but the Act does not permit monetary payments to be made from the Government to the collaborating party under a CRDA. Furthermore, the Government may not disclose to others proprietary information and trade secrets (15 U.S.C. 3710a(c)(7)(A)(B)). It should also be noted that this paper is limited to the transfer of federally owned technology, and does not address the transfer of technology owned by contractors and developed in "federal laboratories" operated by contractors (GOCOs). Technology transferred by GOCOs. for example, may include works copyrighted by a GOCO employee.

On March 7, 1996 President Clinton signed into law Public Law 104-113 (see also 15 USC 3710a) which amends the Stevenson-Wydler Technology Innovation Act of 1980 (PL 96-480) and the Federal Technology Transfer Act of 1986 (PL 99-502) (collectively referred to as "the Federal Technology Transfer Act") with respect to inventions made under cooperative research and development agreements ("CRDAs" or "CRADAs"), and for other purposes. Congress, by this amendment to the Federal Technology Transfer Act, has provided industry partners with added incentives for bringing federally owned technology to the marketplace. More specifically, this amendment has removed certain obstacles from the path of technology commercialization.

In summary, Public Law 104-113 provides added incentives to both industry partners and Government personnel to make the federal technology transfer process a more viable tool in the strengthening of the United States industrial base. This law -

1) Ensures collaborating parties, under a CRADA, the right to receive, at a minimum, the option to obtain an exclusive license, in a prenegotiated field of use, in any inventions made by Government employees in exchange for granting a royalty free license to the federal laboratory to use the invention for Governmental purposes;

2) Ensures that the Government, in the exercise of a royalty free license for Governmental use, will not publicly disclose trade secrets or commercial or financial information obtained under a CRDA;

3) Ensures that the Government will not assert their "march-in" rights, except under exceptional circumstances, in inventions licensed or assigned under a CRDA;

4) Ensures collaborating parties under a CRADA that they may retain title to any inventions made solely by their employees, in exchange for <u>normally</u> granting the Government a royalty free license for Government research or other purposes;

5) Permits the Government to hire personnel who are not subject to full-time-equivalent

restrictions of an agency to carry out functions under a CRADA;

6) Restates the right for current and former employees of the Government to assist in the commercialization of inventions made by these Government employees;

7) Ensures the right of a collaborating party having an exclusive license on an invention

made under a CRADA to enforce the licensed patent;

8) Permits a Government laboratory receiving funds under a CRADA to also use those funds for scientific research;

9) Increases the amount of money paid to Government inventor employees from royalties or other income received by the Government as a result of licensing their patents;

10) Permits payments to Government noninventor employees who have substantially

increased the value of a licensed invention;

11) Restates and clarifies the law that a federal employee inventor can obtain or retain title to his or her invention in the event the Government does not choose to patent the invention or commercialize it.

12) Deletes previous section of the Federal Technology Transfer Act (15 USC 3710a(b)(4)) dealing with the Government laboratory's right to determine rights in other

intellectual property developed under a CRADA.

The two major changes brought about by enactment of Public Law 104-113 are amendments 1 and 4 above relating to ensuring a collaborating party the right, at a minimum, to an option for an exclusive license in a Government employees' invention under a CRADA and providing the Government with a more flexible position with respect to royalty free licenses to the Government when a collaborating party retains title to their employee's inventions under a CRADA.

Specifically -

(1) the Federal Technology Transfer Act ensures a collaborating party, at a minimum, an exclusive license in a prenegotiated field of use for inventions made in whole or in part by a federal laboratory employee under a CRADA. In consideration for the Government's contribution under a CRADA, the Government will be entitled to a non-exclusive, non-transferable, irrevocable, paid-up license from the collaborating party to the laboratory to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. In exercise of such license, the Government shall not publicly disclose trade secrets of commercial or financial information that is privileged or confidential within the meaning of Section 5.52(b) (4) of Title V, United States Code, or which would be considered as such if it had been obtained from a non-federal party. It is interesting to note that the royalty-free use by the Government may be limited only to Governmental use by the federal laboratory where the invention was made.

(2) The collaborating party may retain title to any invention made solely by its employee under a cooperative research and development agreement in exchange for normally granting the Government a non-exclusive, non-transferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other government purposes. It is interesting to

note this royalty-free license is no longer mandatory.

These two major changes along with the other changes to the Federal Technology Transfer Act, places the industry partner or collaborating party in an excellent position to commercialize federally owned technology. The collaborating party now knows that, at a minimum, they will receive an exclusive license for a prenegotiated field of use on an invention made in whole or in part by a federal laboratory employee. Furthermore, on inventions made solely by employees of a collaborating party, the Government is not required to receive, but may <u>normally</u> be granted a royalty-free license. Furthermore, if this royalty-free license is granted, the royalty-free license may be limited to Government <u>research</u> purposes only.

The enactment of Public Law 104-113 clearly illustrates that both the Congress and the President are overwhelmingly in favor of the transfer of federally owned technology to the private sector for commercialization. Overall, the changes brought about by this Law are a giant step in the direction of continued utilization of federally owned technology by the private sector.

It is important to understand that a CRDA is not a procurement contract or a cooperative agreement as these terms are used in Section 6303 et seq. of Title 31 of the United States Code. Consequently, in awarding a CRDA to a collaborating party, the laboratory director is not required to comply with the "competition requirements" set out in Part 6 of the Federal Acquisition Regulations (FARs), nor with any other part of the FAR. Thus the CRDA does not normally include the terms and conditions used in procurement contracts, nor the clauses required in the FAR. Similarly, since the CRDA is not a procurement contract, the Contract Disputes Act does not apply to the resolution of disputes that arise out of or related to CRDAs. Furthermore, as pointed out in the comments section of a recent amendment to the Act, since the CRDA is defined to be different from procurement contracts, cooperative agreements and grants, the CRDA can be executed without triggering the many legal conditions that are placed on these three other statutory methods under which the Government enters into legal agreements. It is further noted therein that technology transfer is most successful when agencies handle their own affairs and when Government officials, technology transfer experts, and scientists at the local level have latitude in designing and carrying out the CRDAs.

CONTENTS OF A TYPICAL CRDA

1) DEFINITIONS

As in licenses, definitions are extremely important in a CRDA. The definition of many of the terms used repetitively throughout the CRDA such as "invention," "royalties or other income," and "proprietary information," etc. are set forth in this article.

2) OBLIGATIONS OF THE PARTIES

The most important article of a CRDA deals with the specific obligations (work plan) which the federal laboratory personnel and the collaborating party must perform during the term of the CRDA. In addition, this article sets forth that any modifications of this obligation of the parties shall be by mutual agreement of the parties and incorporated within the CRDA by a formally executed written amendment. This article also includes the names of individuals performing work under the CRDA and includes specific references to the review of such

work to be performed by the parties. The details of these obligations may be set forth in an appendix.

3) REPORTS

This article refers to the use of written progress reports when applicable, and the time frame in which these progress reports are due.

4) EQUIPMENT, MAINTENANCE AND OTHER SUPPORT

If specific equipment or other support is required for the completion of the CRDA, a list of such equipment would appear in this section. The Government usually makes no warranty, express or implied, with respect to property contributed by the Government.

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This article sets forth the period of time the CRDA is in effect.

6) FINANCIAL OBLIGATION

If the collaborating party is to provide a payment to the Government, the terms of billings, as well as where and how payments are to be made by the collaborating party to the federal laboratory, are set forth in this article. Under the Act, no payments can be made by the federal laboratory to the collaborating party under a CRDA.

7) PUBLICITY/USE OF NAME ENDORSEMENT

The Government and the federal laboratory will not directly or indirectly endorse any product or service provided or to be provided by the collaborating party as a result of the CRDA.

8) PUBLICATIONS TO A SECOND TO A SECOND TRANSPORT OF THE SECOND TO A SECOND TO

The parties to the CRDA must confer and consult with each other prior to any publications or public disclosures of any work which results from the performance of the CRDA. Such a restriction on publication protects the parties from loss of rights for failure to file patent applications on time. In addition, this publication restriction requirement is utilized to ensure that no proprietary information or military critical technology will be released.

9) PATENTS

This is a very important article in a CRDA. It sets forth the rights to inventions made by the collaborating party and employees of the federal laboratory. As a general rule any inventions made solely by a collaborating party will be owned by the collaborating party; any inventions made solely by the federal employees will be owned solely by the Government; and any jointly made inventions will be owned jointly by the collaborating party and the Government. The Government can grant or agree to grant in advance to a collaborating party, patent licenses or assignments, or options thereto, in any inventions made under the CRDA by federal employees (see recent changes to the Technology Transfer Act set forth earlier in this paper). Since the Act permits licensing of inventions made under a CRDA, the publication requirement for exclusively licensing federally owned

inventions under 35 USC 209 does not apply. The specific requirements for disclosure of inventions, filing of patent applications, transfer of ownership of inventions, costs involved in patenting are also provided in this article.

10) COPYRIGHTS

Under federal law, works created by employees of the Government (except in rare instances) cannot be copyrighted. Works created under this agreement solely by the collaborating party or jointly with employees of the federal laboratory may be copyrighted and owned by the collaborating party. Although not required under the Act, the Government may request a non-exclusive, irrevocable, paid-up, worldwide license in all copyrighted software or other works developed under the CRDA. This would enable the Government to use, duplicate or disclose the copyrighted works for governmental purposes only. There is legislation currently before Congress which will permit the Government to copyright software created under the CRDA by employees of the federal laboratory. GOCO employees already have the right to copyright their works since they are not Government employees.

11) COPYRIGHT PAYMENTS

In certain instances, the Government may require the collaborating party to share with the federal laboratory income received as a result of the sale or use of copyrighted works created under the CRDA. The length of time such payments remain in effect is negotiable, and in most instances these payments continue even after the termination of the CRDA.

12) PROPRIETARY INFORMATION

This article sets forth the ownership rights of proprietary information developed under the CRDA as well as the markings which are required in order to keep this proprietary information from public disclosure. The basis for ensuring the confidentiality of proprietary information developed under a CRDA can be found in 15 USC 3710a(c)7(A) and (B). This section of the Act prevents the disclosure of trade secrets of commercial or financial information that is privileged or confidential under the meaning of Section 552(b)(4) of Title 5, United States Code obtained from a non-federal party while conducting research or other activities while participating in a CRDA. In addition, the Government may protect against dissemination, for up to 5 years, information developed as a result of research and development activities conducted under the CRDA if that information would be a trade secret or commercial or financial information that is considered privileged or confidential if the information had been obtained from a non-federal party participating in a CRDA.

13) EXTENSION, TERMINATION AND DISPUTES

Information dealing with extensions of time, termination of the agreement by the parties, and dispute resolution in case of disagreement as to the terms of the CRDA are found in this article. Generally, the federal laboratory and/or the collaborating party may terminate the CRDA without affecting the rights and obligations of the parties accrued prior to the effective date of termination. Certain obligations, such as, for example, prior payments owed, return of loaned equipment and rights with respect to intellectual property remain in effect even after termination of the CRDA.

14) REPRESENTATIONS AND WARRANTIES

All representations and warranties made by the federal laboratory and the collaborating party are set forth in this article. For example, the federal laboratory represents that, prior to entering into the agreement, it has given special consideration to small business firms and consortia involving small business firms, and has given preferences to businesses located within the United States which agree that products embodying inventions made under the CRDA will be manufactured substantially in the United States. In the event the agreement is made with an industrial organization or other persons subject to the control of a foreign company or government, the Government must take into consideration whether or not such foreign government permits United States' agencies, organizations or other persons to enter into cooperative research and development agreements and licensing agreements with such foreign countries. In addition, the collaborating party sets forth in this article that it has ownership of all rights, title and interest in all inventions made by their employees.

15) LIABILITY

The Government and the collaborator are generally not responsible for property of the collaborating party which is consumed, damaged or destroyed in the performance of the CRDA. The collaborating party generally agrees to hold the Government harmless for any loss, claim, damage, or liability arising out of the CRDA. Furthermore, both the Government and the collaborating party make no expressed or implied warranty to any matter including the condition of the research or any invention or product, whether tangible or intangible, made, or developed under this agreement, or the ownership, merchantability, or fitness for a particular purpose of the research or any invention or product. Additionally, the parties make no warranty that the use of any invention or other intellectual property or product contributed, made or developed under this agreement will not infringe any other United States or foreign patent or other intellectual property right. All research, intellectual property or products provided by the parties pursuant to the CRDA are provided "as is" and the neither party will be liable to the other for punitive, exemplary or consequential damages, even if notified in advance of such possibility.

16) EXPORT CONTROLS

As in a license entered into by the Government, information and/or products developed pursuant to a CRDA may contain information for which export is restricted by the Arms Control Act or the Export Administration Act. Nothing in the CRDA shall be construed to permit any disclosure and violation of those restrictions.

CONCLUSION

Technology transfer between federal laboratories and the nonfederal sector should be a "win-win" situation for all parties if the following suggestions are followed:

(1) The Government is reasonable in its request for financial compensation. If the licensee or collaborating party is left with insufficient funds to commercialize the Government owned technology, technology transfer has failed.

(2) The licensee or collaborating party must be willing to compensate the Government for its technology and input. Unless the federal laboratory receives fair compensation, the incentive necessary to help commercialize the Government owned technology will be lacking. (3) As a general rule, commercialization of federally owned technology might be best effected if up front payments to the Government were minimized in order leave enough funds in the hands of the collaborator to commercialize the technology.

Technology transfer, either by licensing a Government owned invention or engaging in a CRDA, can be considered a true success if all parties (federal and non-federal) receive a benefit from the transfer. The Government should end up with beneficial technical information, a royalty-free license, and/or monetary compensation, while the non-federal party should be in a better position to commercialize the technology.

When technology transfer from federal laboratories to the private sector is successful, the ultimate winners are the citizens of the United States, whose tax dollars have funded Government research and development.

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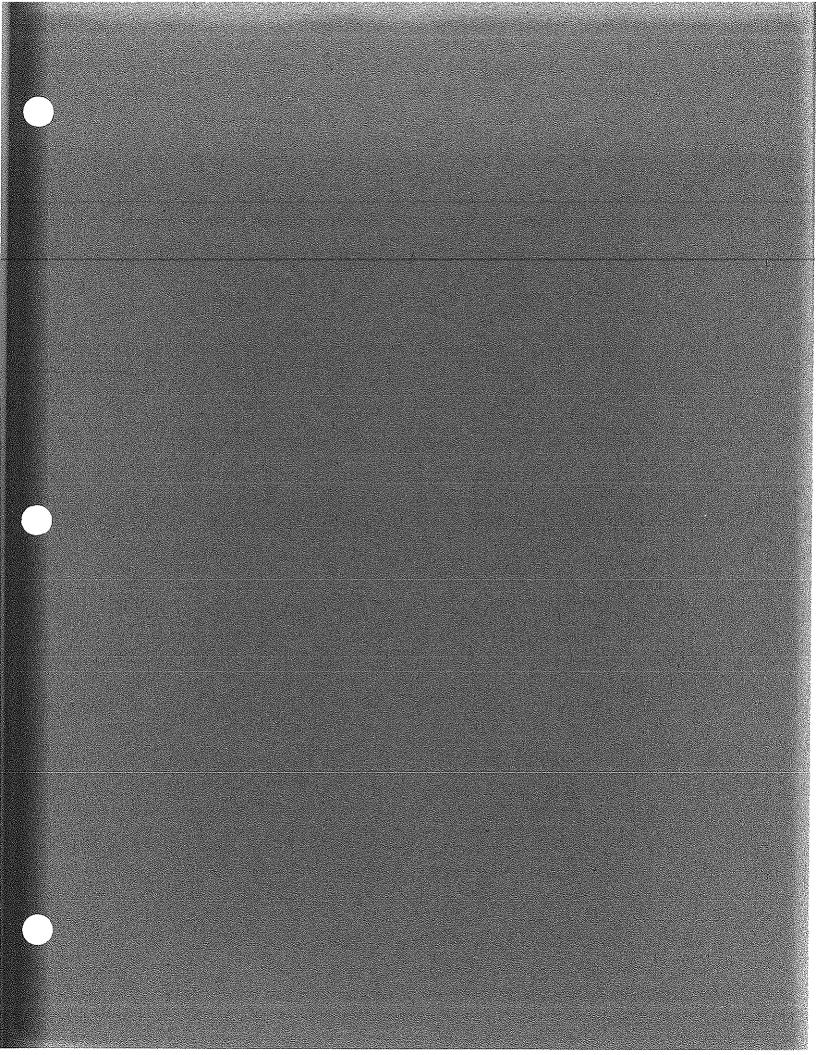
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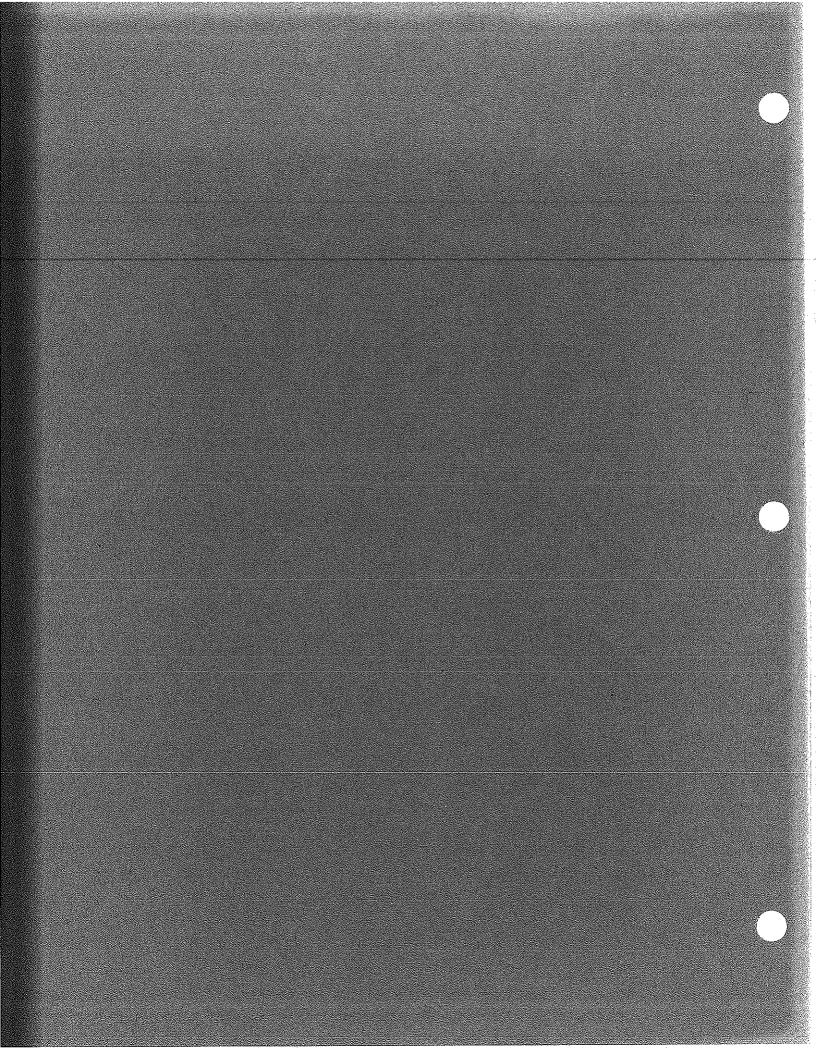
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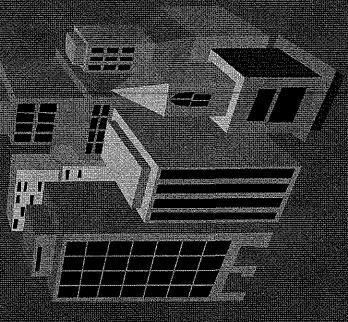
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Mechanisms for Transferring Rederally Owned Technology

Jacob (Jesse) N. Erlich, Esq.

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PERKINS, SMITH & COHEN, LLP

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- technology lead possessed by the United There has been a decline in the
- development departments of U.S. corporations – Deorease in fumding of researoh and
- Sulostantiai ingrease in patentapolications filed by foreign inventors in U.S. Patent and
- 1960's-Approximately 17%
- 1995-Approximately 50%

C.S. Federal Laboratory Systems

- Utilizes newest and most sophisticated technical equipment

PERKINS, SMITH & COHEN, LLP

CS. Federal Laboratory Systems,

cont'd

- Authority to enter licenses

- 35 USC 207
- 37 CFR 404
- 15 USC 3710a (b) (2)
- Agency implementing instructions

Connergiève researe I and develonment agreements

- Attribudity to enter CRDAS

- Public law no. 99-502 (Federal Technology Transfer Act)
- 15 USC 3710a
- Agency Implementing Instructions

Types of Federally Owned Technology/ Protection Afforded Government



Inventions (including software)

- Patents (35 USC 207)

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Invention disclosure patent application (35 USC 205)

Work of U.S. government not protectable by copyright (17 Possible exception under FOIA (5 USC 552 exemption 5b)

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Overview of Governmen J'œnising

Jacob (Jesse) N. Erlich, Esq.

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PERKINS, SMITH & COHEN, LLP

- · Bxclusive
- · Partially exclusive
- · Non-exclusive
- Note: Government makes license subject to the irrevocable royalty-free right of government to practice, for governmental purposes, or have practiced, for governmental purposes, the

Licensing Rederally Owned Inventions Not Made Under a CRDA

- Submita license application to the appropried
- Include a plan for developing and/or marketing
- Nonexclusive license
- Agency grants license
- Bxellisive of partifally exclusive liverise
- Notice published in federal register
- Objections may be filled
- Determination made by agency to gramt license

ASOFOLIUMO, SIROTOLIUMO, INSTITUTOLIUM

- Preamble: type of license, parties, effective date
- Recitals (whereas clauses): Sets forth

background

- Definitions
- License grant
- . Royalties
- Up-front payment
- Running royalty
- Topping payments
- Sub-licensing payments

Typical Licensing Terminology, contid

- Assess the value of the claimed invention
- · Major breakthrough
- Improvement
- Apparatus/method
- Software
- Dstablish impact of royalty payments on TOURSE
- Cost of development
- Market potential (profitability)
- Type of Heense
- Exclusive
- Nonexclusive

Typical Licensing Terminology, contid

· Livense resurivions

Field of Use

. Area of use

Length of time

— Lump sum

- % of sales (profits/net/gross)

Minimum payments

Fixed sum/unit

Fixed sum/use

Iydical Licensing Terminology, cont'd

- Technical assistance
- Use of facilities
- Other intellectual property licenses
- Cooperative agreements



Typical Licensing Terminology, contid

- · License period
- Licensee's performance
- Best effort
- Manufactured substantially in the U.S.
- Sub-freensing and royalty shang
- Patentingrifting and norendorsangut

Lynca I rensing Terminology, cont d

· Reservation of rights

- Subject to other licenses in force at time of agreement
- Subject to irrevocable, royalty-free right of government to practice for governmental purpose or have practiced on behalf of the government the licensed invention

- Licensor does not warrant validity of patent licensed
- Licensor does not warrant that licensed patent will not infringe other patients

Progress reports

Lybical Licensing Terminology, confid

- Licensee may be granted power to enforce
- Sharing of royalties
- Maintenance fees
- Technical assistance
- Under ORDA
- SX DOM: CONTINOLS

Federal Technology Transfer Act of 1986

COOPERITIONS RED A GREETHERIES

- Accept funds, personnel, services, and property from collaborating parties
- Supply any of these, except funds, to collaborating
- assignments or options for inventions of lab employees Grant (or agree to grant in advance) patent licenses,
- Wailve right of ownership, executioning in the license, to inventions made by collaborators

Tederal Technology Transfer Act of 1986, cont'd

- The threator of knowletony may be permitted to:
- I. Enter into cooperative R&D agreements
- 2. Negotiate licensing agreements
- Cooperative R&D agreements may be made with:
- Other federal agencies
- Units of state and local government
- Inclustrial organizations
- Public and priivate foundations
- Non-profits (including universities)
- Officer reasons

Federal Technology Transfer Act of 1986, cont'd

- . The laboratory director shalls
- I. Give special consideration to small businesses and consortia of small
- -2. Give preference to business units located in the U.S. and agree to manufacture in the U.S.

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o Definitions

Obligations of parties

Term

Financial obligation

Protection and ownership of intellectual property

Patents

Copyrights

Proprietary information and trade secrets

Typical CRDA Terninology, contid

- · Licensing options
- · Liability/nowarrantics
- Government not responsible for property
- Government does not warranty
- · Research
- Infringement of existing patents

ACCESSING FOMERAL DECIMONA

- Major Data Bases
- Pederal Baboramony Consortium (PLC)
- Telephone: 856.667.7727
- National Technology Transfer Center (NITTO)
- Telephone: 800.678.NTTC
- Regional Technology Tramsfer Center for Wassachusatts Center for teannogy Onningron izalion
- Telephone: 508.870.0042



