JACOB N. ERLICH, J.D.
Partner
E-Commerce & Communications Group, Emerging Business Group, Government Relations Group, Intellectual Property Group, Science & Technology Group
617.854.4281 Direct
jerlich@pscboston.com

Jacob (Jesse) N. Erlich 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 United States Patent & Trademark Office and the Canadian Patent Office.

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

Mr. Erlich represents a wide array of clients such as universities and small and large technology companies in diverse technological fields. He provides advice on patents and other forms of intellectual property, licensing and government related matters as well as is involved with the preparation and prosecution of patent applications (U.S. and foreign). In a representative case, Mr. Erlich obtained intellectual property protection for a client and thereafter was instrumental in negotiating and preparing agreements transferring a substantial portion of the intellectual property to a major company.

He has contributed to numerous publications in the fields of intellectual property and technology transfer, and Mr. Erlich has co-authored a book entitled, *Technology Development and Transfer - The Transaction and Legal Environment,* Quorum Books, 1997. He is a contributing author to *2000, 2001, 2002* and *2003 Licensing Update,* Aspen Law & Business - a division of Aspen Publications, Inc. and *Valuation of Intangible Assets in Global Operations,* 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, D.C. A frequent lecturer and speaker, Mr. Erlich has been asked to appear before groups ranging from the WPI Venture Forum to Government Patent Law Association Conferences and the Franklin Pierce Law School Annual Licensing Program to the American Association of State Colleges and Universities.

Mr. Erlich has been appointed to the United States - Israel Science and Technology Commission Task Force: Legal, Patent and Intellectual Property Rights and serves on the Board of Directors of the National Defense Industrial Association (NDIA), New England Chapter as well as on the Advisory Council of the National Institute of Justice, a research agency of the United States Justice Department. 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. Mr. Erlich is listed in *Who's Who in American Law* and *Who's Who in Intellectual Property.*

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

Jacob N. (Jesse) Erlich
Partner
Perkins, Smith & Cohen, LLP
Boston, MA
(617) 854-4000 jerlich@pscboston.com

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, 104-113 and 106-404) 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

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 outside of a CRDA only if the prospective licensee has supplied the appropriate federal agency with a license

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 claimed 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

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.
2) 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:

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).

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

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

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 normally 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

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.

5) TERM

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

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

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

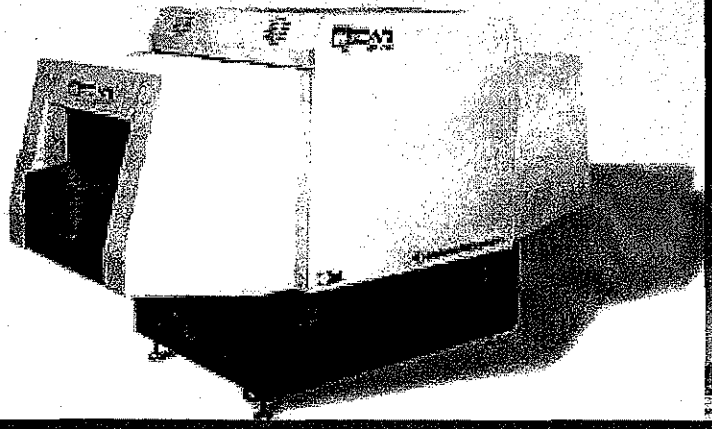
Technology transfer between federal laboratories and the nonfederal sector should be a "win-win" situation for all parties if the following suggestions are followed:

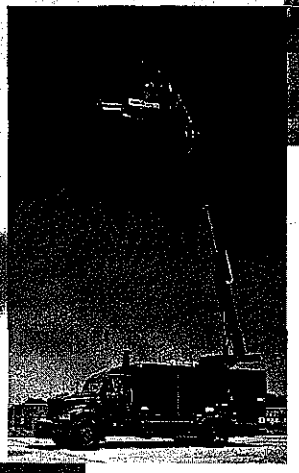
(1) The Government is reasonable in its request for financial compensation. If the licensee or collaborating party is left with insufficient funds to commercialize the Government owned technology, technology transfer has failed.

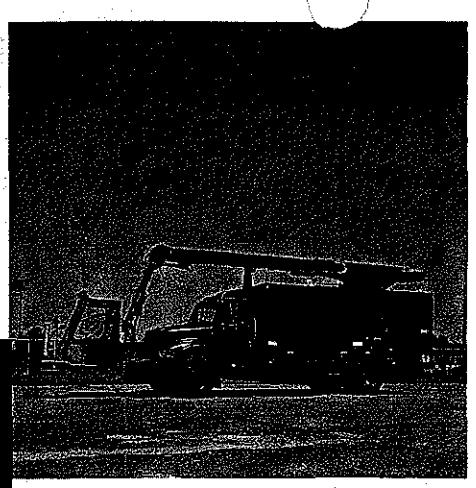
(2) The licensee or collaborating party must be willing to compensate the Government for its technology and input. Unless the federal laboratory receives fair

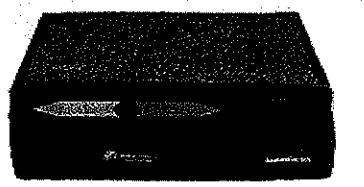
Commercialization Success Stories



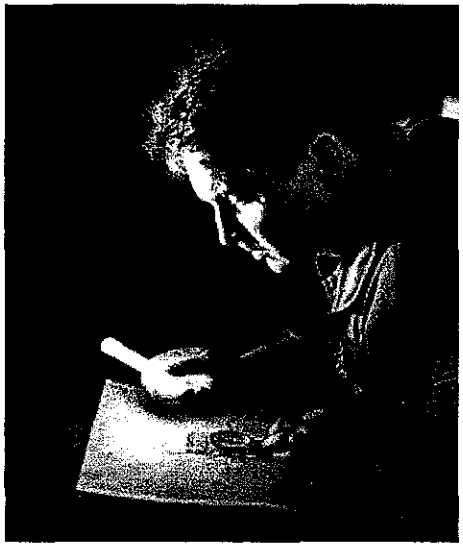


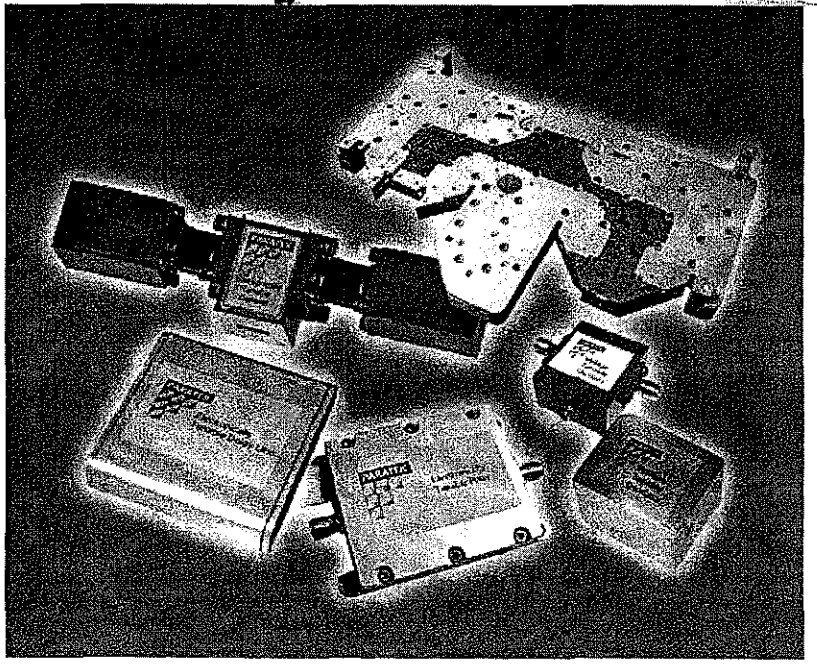


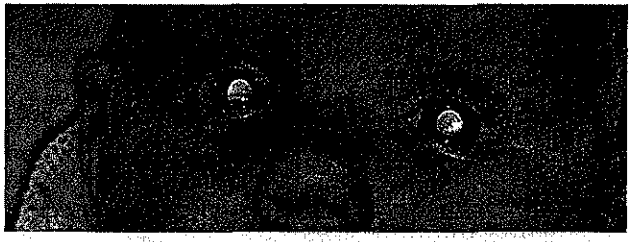


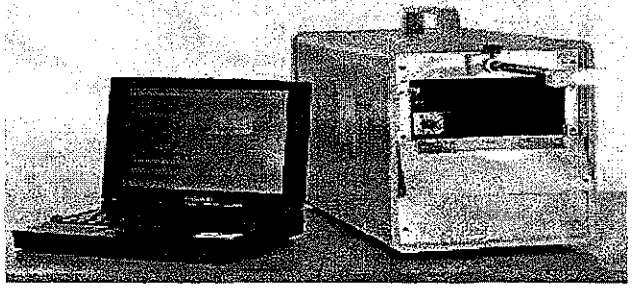




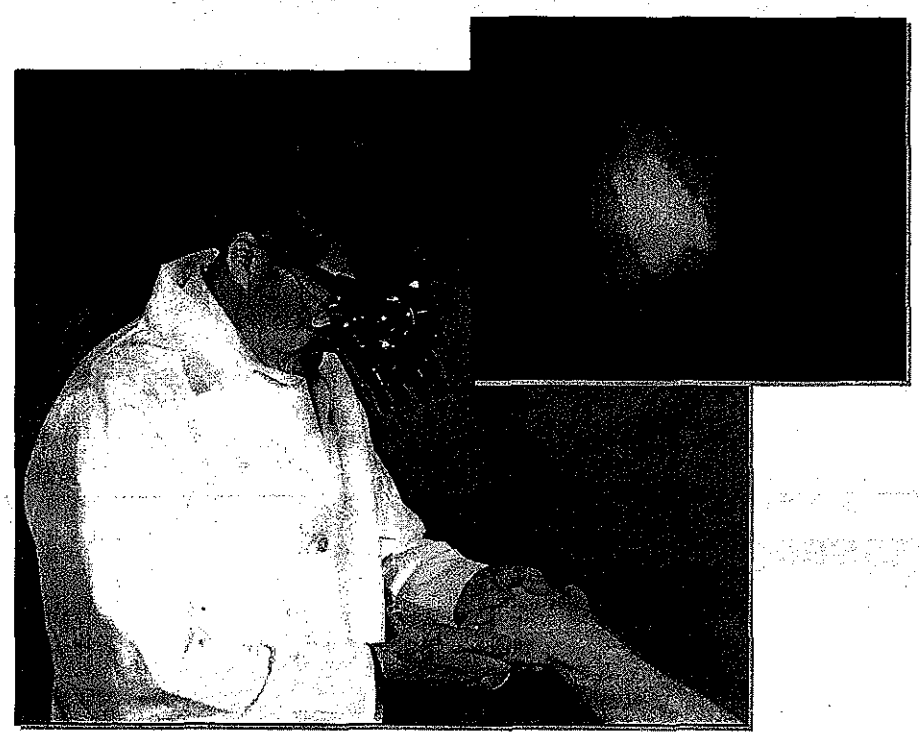








AFRL Materials and Manufacturing Directorate Teams With InfraRed Imaging Systems Inc. To Deliver Life-Saving Vein Viewing Technology To Medical Community



ACCOMPLISHMENT

- Invented, developed, patented and licensed a breakthrough medical device for positive location of under-skin veins in a broad range of lighting conditions

BENEFITS

- ML established a Cooperative Research and Development Agreement with InfraRed Imaging Systems Inc. to manufacture, market, and expand the technology to solve medical industry challenges
- Vein Viewer offers fast, accurate location of veins for timely IV insertion, opportunity to save lives of thousands of wounded soldiers
- Can be used for emergency medical services, pediatric and geriatric care, and for patients who must undergo painful medical procedures that require repeated access to veins, such as chemotherapy or dialysis