CENTER FOR THE UTILIZATION OF FEDERAL TECHNOLOGY (CUFT) FYT MIR-

PUTTING FEDERAL TECHNOLOGY TO WORK FOR INDUSTRY...

U.S. industry has a great opportunity to use the technology developed by the Federal Government. Each year, the Government spends billions of dollars on research and engineering activities. Although most of the results are announced in tens of thousands of technical reports and papers issued by the Government, other results may never be formally issued or may be delayed until final completion of a project years after its conception. Because of this vast amount of Federal R&D and the difficulty in locating specific useful items, the Government has been making special efforts to identify that technology having commercial or practical potential and then alerting industry to its availability.

In 1980, the Stevenson-Wydler Technology Innovation Act was enacted requiring Federal agencies and their laboratories to provide a way to make outside users aware of Federal Technology. Although the law covers a variety of efforts which the Government should undertake, one of its elements included the creation of a Center for the Utilization of Federal Technology (CUFT). This center now has been established at the National Technical Information Service (NTIS) of the U.S. Department of Commerce. NTIS will use its resources as a national information clearinghouse to alert industry to that Federal technology with the highest potential for commercial or practical use. The center will serve as a catalyst to encourage agencies to evaluate and selectively highlight their technology. CUFT will be expanding upon the announcement of Government inventions, developing sources of technology fact sheets for its Tech Note program, and preparing new special current awareness catalogs, directories, and services.

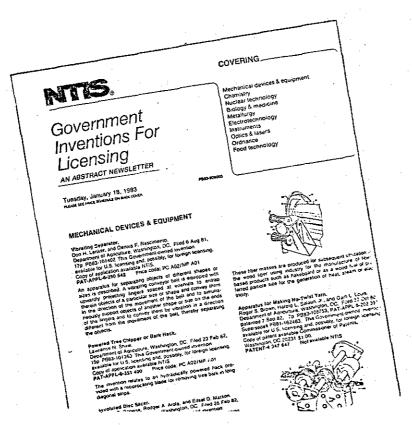
CUFT Products & Services will:

- o Develop means of introducing industry to appropriate technology
- o Encourage agency technology evaluation efforts
- o Create online access to this selected technology
- o Promote Federal laboratory technology
- o Encourage the licensing of Government inventions



3. Government Inventions Catalog

Government inventions are based on technology meeting patent office requirements of novelty and utility. This catalog provides easy access to the technology covered by these inventions. Therefore, it serves two functions: (1) to encourage the licensing of Government inventions (often on an exclusive basis) and (2) to present the technology of these inventions in an easy to use format. Each annual catalog will contain more than 1,300 summaries of both patents and patent applications arranged into broad application categories for easy browsing. An author, agency, and subject index is included. (Check Government Inventions Catalog)



4. Government Inventions for Licensing Abstract Newsletter

A weekly subscription bulletin summarizes more than 1,300 Government owned inventions annually. Each issue divides inventions into eleven subject disciplines and provides a summary of each. When appropriate, a drawing, of the invention is also included. Since many of these inventions are available for licensing, often on an exclusive basis, this bulletin offers a valuable service for transfering Federal technology to industry. The previously mentioned Government Inventions Catalog is provided free to subscribers of this abstract newsletter. (Check Government Inventions Abstract Newsletter)

FOR FURTHER INFORMATION

CHECK ITEMS OF INTEREST BELOW: Center for the Utilization of Federal Technology U.S. Department of Commerce Comme NTIS Room 8R Springfield, VA 22161 61 Phone (703) 487-4838 Name (Please Print) lea: Title - W. W. & Address Company City State/Zip Phone (Size of company [] Under 100 [] 100-Un000 [] over 1,000 employees Your areas of interest:
[] Biotechnology [] Energy st: [] Transportation [] Chemical processes [] Manufacturing [] Other [] Communication [] Materials [] Optics [] Computers [] Testing [] Electronics YES, I WOULD LIKE MORE INFORMATION REP ABOUT THE FOLLOWING [] Tech Notes (PR-375) $a \in \mathcal{P}$ [] Federal Technology Catalog achie [] Government Inventions Catalog In [] Government Inventions AbstractINewsletter

7.12.1

Gua.

[] Resource Guide

[] Data Base Guide (PR-725)

(2-76) hy

File WI NTIS

Objectives are to develop a leadership role for coordinating, implementing, managing and monitoring improved Federal technology transfer and patent licensing activities.

NTIS has granted exculsive licenses to the following companies:

--Seton Medical Products (Chaddsford, Pennsylvania) for a process to produce granular and fibrous collagen products (from livestock hides and skins) for incorporation into a variety if animal and human foodstuffs;

--Bend Research, Inc. (Bend, Oregon) for extracting selected ions of metals from aqueous feed solutions; and

--P.C. Inc. (Potomac, Maryland) for a new flow-through coil planet centrifuge which provided an efficient chromatographic separation of solutes.

REV			6					-	ľ	•	Į,	1		#			
REMAKS	Coordination	Comment	etemon()	As Requested	topicus.	10.15						Dr. W	building	2	8 01		
	ion			e) e)								Dr. Merrifjeld	Renc	omes s			14000
												jeld -	/Post)	mbol 7	i di		A SECTION ASSESSMENT
	Justiny	Investigate	For Y	1010	For C	FILE							building Agency/Post)		ROUTING AND TRANSMITTAL SLIP		" 火 经营
	y supplied the	igate	For Your Information	For Correction	For Clearance									Day.	M		
			mation														
		S	5	Pr	7	N										2	
		Signature	See Me	Propare Reply	Par Conversation	More price and								1			
				gy		taun.									ner i venu		
														7	101		

以外的特别 。 2	A Company of the Company
LEE JAN O	(1) 20 A 10 A
	18 C 4 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
35. 10	rom: Wame, og s orma¶∕natker
Charles -	
A POST OF THE REAL PROPERTY.	· 旅 · · · · · · · · · · · · · · · · · ·
2.028 Sec. 101	200
	Company of the same
大学 "	W. C.
2 March 200	
	国际公司
	建筑的
0 02 1 5 33	
	治秘》至第一个诗次
Barrier Committee	
Maria Maria	· · · · · · · · · · · · · · · · · · ·
100	为是为别于特别的现在分
MARKET SANCTOR	A CONTRACTOR OF THE SECOND
10 20 1	强化等的发现
1000	是 160 Km (100 CM)
DAYS THE STATE OF	企業的基本經濟學的
加州市场 电	
(1858), 635-198- O 1864, Odo), e	经验的特别的
	国际通过设计
10000000000000000000000000000000000000	位为1955年
五個的問題	FROM: (Name, org. symbol, Agency/Post) Norman/ Matker
经代表的企业	2. 数据数据数据数据数据数据数据数据数据数据数据数据数据数据数据数据数据数据数据
C 25 1 (2)	通知的证明 25. 元二十二
	是一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个
建筑	STATE OF THE STATE
主流和 的系统	第四条
4 3 S 3 S 3 S 3 S	(1) 中国 (1) 中国 (1) 中国 (1)
5 A THE 2014 A	15 Ann ann an 1
	THE PERSON NAMED IN
28.50	2. S. C.
"阿尔尔克斯	建设施设施
建设等的 参加的	Marie Control of the
	37% 建约10°00 10°000000
	48 10 17 17 17
3 C 4 4	THE SECTION AND SECTION
V-12 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
	CASE STATE
没有包含	经验的证据
	1650年1650年1650年1650年1
	15.10 140 15.00 14.0 14.0 16.0 16.0 16.0 16.0 16.0 16.0 16.0 16
AL-44-AL-48	THE PARTY OF THE P
	Room No.—Bidg H4324 Phone No. 377-0659
	A STATE OF THE STA
20 M	
	AND SECURITION OF THE PARTY OF
医肠腔内型 特	
	CONTRACT TO SERVICE
38 V 12 (4)	
	CU (A / LD) (2)
Service Service	
S 2 3 14	
建工作的	
200 P. S. S. S.	
经本种的	
经数数	110000
A COMPANY	
公司	
5.00	
8 4 K X	
建 2000年	
新加州	
1. S. 1864. S.	
1. 10. 10. 10.	CONTRACT CONTRACT
	CONTRACTOR TRANSPORTATION OF THE PROPERTY OF

Lan &



UNITED STATES DEPARTMENT OF COMMERCE The Assistant Secretary for Productivity, Technology and Innovation

Washington, D.C. 20230

(202) 377-1984

OCT1 0 1984

MEMORANDUM FOR Dave Mowry

SUBJECT:

Letter from Niels Reimers of Stanford University dated September 24, 1984

The attached letter from Niels Reimers deals with an invention that is apparently owned by NIH and which, according to the letter, has been or will be turned over to NTIS for licensing. Stanford has clearly established an equity in this invention through its facilitator efforts, its additional research and because the inventors are now employed by Stanford and the University of California. To expedite matters please treat the Reimers' letter as a "plan" and issue a notice of a proposed exclusive license. If NIH has not yet formally transferred the invention to us, you should contact them and ask them to expedite matters since there appears to be a potential bar on foreign filing. In the meantime you might talk to Stanford about filling in the details of their plan.

There is an obvious possibility that Stanford's potential licensee will seek a license. In the event a decision is eventually made to license them directly rather than to allow Stanford to manage this invention, as a minimum we should require the licensee to reimburse Stanford for its out of pocket costs for filing on the invention.

(signed)
Bruce Merrifield

D. Bruce Merrifield

Attachment

STANFORD UNIVERSITY

STANFORD, CALIFORNIA 94305

Area Code (415) 497-0651 Telex: 348402 STANFRD STNU

OFFICE OF TECHNOLOGY LICENSING 105 Encina Hall

September 24, 1984

Mr. H. Bruce Merrifield
Assistant Secretary for
Productivity, Technology,
and Innovation
U.S. Department of Commerce
Washington, D.C. 20230

Re: Request for Policy Guidance

- Ref. (1) Stanford Invention Disclosure Docket S83-193,
 "T Cell Receptor-Specific Polypeptides and Related Polynucleotides"
 PI: Davis and Hedrick
 (NIH Case E-307-84)
- Ref. (2) NIH Letter dated September 11, 1984, Responding to Stanford's Request that the Subject Invention be Administered under Public Law 96-517

Dear Mr. Merrifield:

There is, happily, a great deal of interaction between scientists in universities, industry, and government. These interactions often give rise to significant discoveries. An example is the gene splicing discovery that resulted from the discussions of Stan Cohen of Stanford and Herbert Boyer of the University of California.

These interactions, while often very productive in terms of science and discovery, frequently produce tangled rights situations. When one situation such as this arises with another university, we usually discuss the circumstances and agree as to which university shall undertake management of the invention. The problem occurs when such interactions occur with the Government, since there appears to be no set policy. Hence, we are communicating the circumstances of a specific case to you and making recommendations for your consideration as policy in this area.

Background

The technology in question has two inventors — one from Stanford and one from the University of California. But both were also working at NIH during a good portion of the development of this technology. For example, Dr. Hedrick was a Government employee for a period, a University of California employee but also "guest worker" at NIH for the second period, and then a UC employee at UC. Dr. Davis was a staff fellow at NIH, also a guest worker at NIH, and then came to Stanford.

SEP 27 1984

Mr. D. Bruce Merrifield Page Two September 24, 1984

These circumstances were presented to NIH. While the significant contributions to the technology were made while Hedrick and Davis were under Government patent agreements, we asked that we be allowed to administer the invention under PL 96-517 in view of the fact that the inventors were now here and we could more efficiently license the invention with their support, and in view of the future research work and reduction to practice that occurred after the two scientists had been in California. To avoid loss of patent rights before the rights situation could be determined, we filed a U.S. patent application.

By the enclosed letter of September 11 (Reference 2), our request was denied.

The Present Situation

We have discussed the September 11 determination with the NIH Patent Office to explore what are the alternatives available to us at this point. We are advised the case will now be turned over to the NTIS for administration and licensing. Stanford will be required to assign the patent to the Government, and there is no provision for reimbursement of the patent expenses incurred by Stanford. It was suggested we explore with NTIS the possibility of their "licensing" Stanford so that we then could sublicense industry.

In exploring this latter possibility, we understand that even if NTIS should agree, notification would need to be published in the federal register and that considerable time might elapse before a final determination.

The Patent and Licensing Situation

The decision with respect to the foreign filing must be made well in advance of the absolute bar to occur on March 1, 1985, preferably by this December.

We found that prospective Davis/Hedrick patent rights may not be able to be practiced without the licensee having access to other related patent rights. These related patent rights are held by a relatively new company formed to exploit this technological area -- T Cell Sciences.

Because of the early stage of development of this technology and these related patent rights, it may not be in the best public interest to license other companies, even if they agree to diligently pursue development. We were in the process of negotiating a license agreement with T Cell Sciences which will require diligence and the earliest availability of the technology to other companies.

We will be pleased to send you a copy of this license agreement on a confidential basis. It is now under consideration by the prospective licensee, but all discussions have been stopped because we are no longer able to enter into the license in view of the NIH decision.

Mr. D. Bruce Merrifield Page Three September 24, 1984

The license agreement requires one sublicense be issued by January 1, 1985, and, after August 1, 1987, sublicenses be issued to any applicant. The license further provides that a licensed product must be available for commercial sale prior to August 1, 1986, or Stanford may terminate the Agreement.

Please note that final agreement to these terms has not yet been reached, but they illustrate where we are at this stage of negotiation.

Policy Alternatives

1. In a situation of mixed technology rights between the Government and a third party, the determination of who will administer the case as far as patenting and licensing (and bearing all risk of loss and reward) should be made based on which party will be more likely to bring about the earliest development of the technology for public use and benefit.

A factor in this determination would be availability of the inventors. That is, bare patent rights are very difficult to license, particularly before the patent issues. Generally, we find the enthusiasm (and agreement to provide consulting support) of inventors is necessary to conclude a successful collaboration with industry. The prospective patent rights, while a factor, are not as critical to early innovation as the availability and support of the technology creators.

- 2. This policy alternative proposes that when NTIS receives an invention for which the other party has the technology creators, the will and the competence to undertake licensing in the public interest, the invention be exclusively licensed to that entity without requirement for Federal Register notice.
- 3. This policy alternative proposes that if NTIS undertakes licensing in a situation such as described herein, it reimburses the entity which created the property (without which property they would otherwise not be able to license) for its patent expenses.

If in such situations there is no possibility of reimbursement, given the time that is necessary to have the facts sifted out and the Government agency to come to a decision as to whether it or another party has rights, then the other party will not invest its resources either in patent filing or licensing efforts until the decision is made. In a fast moving science, such as biotechnology, with the pressure to publish, foreign, if not U.S. patent rights, generally will be lost. And the window in time in which one quickly must conclude a high technology collaboration may have been closed, regardless of patent rights.

Mr. D. Bruce Merrifield Page Four September 24, 1984

I think the Government would be protected against expenses of frivolous filing by the fact that it could choose not to accept the case if it didn't feel that it was worth the patent expenses and turn it back to the other party.

Conclusion

We will be pleased to provide all the information that we have regarding this case, including the copy of the draft license agreement, the steps taken to qualify the licensee and to understand the market.

If Policy Alternative 1 is not selected, then NTIS needs to be brought into this case as soon as possible in order that it may make an informed decision with respect to whether or not to invest in foreign patent filing expenses, which are not insignificant expenses.

I would like to say that we have had the utmost cooperation and helpful interchange with the DHHS patent staff. They empathize with the situation, but circumstances and the law led them to conclude that they could not allow this invention to be administered under PL 96-517.

Sincerely,

Niels Reimers

Director, Technology Licensing

cc: Leroy B. Randall
Chief Patent Branch
Department of Health and Human Services
Office of the General Counsel
Washington, DC 20201

Roger Ditzel University of California Patent, Copyright & Trademark Office

Mark Davis Stephen Hedrick

NJR:kla



DEPARTMENT OF HEALTH & HUMAN SERVICES

Attachinest to 9/24/84 /c/fee Olice of the Secretary 20 H.B. Merrineld

Office of the General Counsel Washington, D.C. 20201

Our Ref: E-307-84

c/o National Institutes of Health Westwood Building, Room 5A03 Bethesda, Maryland 20205 (301) 496-7056

September 11, 1984

STANFORD UNIVERSITY

SEP 17 1984

TECHNOLOGY LIFTING

Ms. Katharine Ku Associate Director Office of Technology Licensing Stanford University 105 Encina Hall Stanford, CA 94305

Re: DAVIS/HEDRICK, "T Cell Receptor-Specific Polypeptides and Related

Polynucleotides"

Dear Ms. Ku:

This refers to your letters dated March 30, 1984, April 2, 1984 and August 3, 1984, advising that Stanford University would like to administer the invention under Public Law 96-517 and providing information in support of that request.

We have reviewed this matter with officials of the Laboratory of Immunology, National Institute of Allergy and Infectious Diseases. Based upon that review, we conclude that the first actual reduction to practice of the subject invention occurred at the Laboratory of Immunology on August 2, 1983 when the inventors had finished sequencing enough of the gene to determine that they had isolated the T cell receptor. The work on this project that continued after that date merely verified that conclusion. The Chief of the Laboratory of Immunology has advised that if "reduction to practice" is taken to mean the isolation and sequencing of the gene, there can be no doubt that such reduction to practice occurred at the National Institutes of Health where the isolation of the cDNA clone, the sequencing of that clone, and its comparison to the nucleotide data bank led to the recognition of its homology to immunoglobulin were carried out.

At the time of the first actual reduction to practice on August 2, 1983, Dr. Hedrick was still a Government employee. His Federal employment terminated on August 6, 1983, but he remained in the Laboratory of Immunology as a "Guest Worker" until he left the National Institutes of Health on October 20, 1983. As a Guest Worker, any inventions made by him are subject to administration under the provisions of Executive Order 10096. Dr. Davis had been a Staff Fellow in the Laboratory of Immunology until April 1, 1983, but had continued to work in the laboratory as a Guest Worker until July 23, 1983. He left the laboratory only ten days prior to the date of first actual reduction to practice and it appears clear that most of the sequencing had been completed while Dr. Davis was still a Guest Worker.

In view of the foregoing, we are lead to conclude that the invention is subject to report and administration under the terms of Executive Order 10096 and that Public Law 96-517 is not applicable in this case. Accordingly, we would make a formal disposition of rights in this case in accordance with the requirements of the Executive Order. Please give us the benefit of any facts in your file contrary to any of the above.

Sincerely yours,

Leroy B. Randall Chief, Patent Branch

STANFORD UNIVERSITY

STANFORD, CALIFORNIA 94305

Area Code (415) 497-0651 Telex: 348402 STANFRD STNU

OFFICE OF TECHNOLOGY LICENSING 105 Encina Hall

September 24, 1984

Mr. H. Bruce Merrifield Assistant Secretary for Productivity, Technology, and Innovation U.S. Department of Commerce Washington, D.C. 20230

Re: Request for Policy Guidance

- Ref. (1) Stanford Invention Disclosure Docket S83-193,
 "T Cell Receptor-Specific Polypeptides and Related
 Polynucleotides"
 PI: Davis and Hedrick
 (NIH Case E-307-84)
- Ref. (2) NIH Letter dated September 11, 1984, Responding to Stanford's Request that the Subject Invention be Administered under Public Law 96-517

Dear Mr. Merrifield:

There is, happily, a great deal of interaction between scientists in universities, industry, and government. These interactions often give rise to significant discoveries. An example is the gene splicing discovery that resulted from the discussions of Stan Cohen of Stanford and Herbert Boyer of the University of California.

These interactions, while often very productive in terms of science and discovery, frequently produce tangled rights situations. When one situation such as this arises with another university, we usually discuss the circumstances and agree as to which university shall undertake management of the invention. The problem occurs when such interactions occur with the Government, since there appears to be no set policy. Hence, we are communicating the circumstances of a specific case to you and making recommendations for your consideration as policy in this area.

Background

The technology in question has two inventors — one from Stanford and one from the University of California. But both were also working at NIH during a good portion of the development of this technology. For example, Dr. Hedrick was a Government employee for a period, a University of California employee but also "guest worker" at NIH for the second period, and then a UC employee at UC. Dr. Davis was a staff fellow at NIH, also a guest worker at NIH, and then came to Stanford.

SEP 27 1984

D. BRUCE MERRIFIELD

Mr. D. Bruce Merrifield Page Two September 24, 1984

These circumstances were presented to NIH. While the significant contributions to the technology were made while Hedrick and Davis were under Government patent agreements, we asked that we be allowed to administer the invention under PL 96-517 in view of the fact that the inventors were now here and we could more efficiently license the invention with their support, and in view of the future research work and reduction to practice that occurred after the two scientists had been in California. To avoid loss of patent rights before the rights situation could be determined, we filed a U.S. patent application.

By the enclosed letter of September 11 (Reference 2), our request was denied.

The Present Situation

We have discussed the September 11 determination with the NIH Patent Office to explore what are the alternatives available to us at this point. We are advised the case will now be turned over to the NTIS for administration and licensing. Stanford will be required to assign the patent to the Government, and there is no provision for reimbursement of the patent expenses incurred by Stanford. It was suggested we explore with NTIS the possibility of their "licensing" Stanford so that we then could sublicense industry.

In exploring this latter possibility, we understand that even if NTIS should agree, notification would need to be published in the federal register and that considerable time might elapse before a final determination.

The Patent and Licensing Situation

The decision with respect to the foreign filing must be made well in advance of the absolute bar to occur on March 1, 1985, preferably by this December.

We found that prospective Davis/Hedrick patent rights may not be able to be practiced without the licensee having access to other related patent rights. These related patent rights are held by a relatively new company formed to exploit this technological area -- T Cell Sciences.

Because of the early stage of development of this technology and these related patent rights, it may not be in the best public interest to license other companies, even if they agree to diligently pursue development. We were in the process of negotiating a license agreement with T Cell Sciences which will require diligence and the earliest availability of the technology to other companies.

We will be pleased to send you a copy of this license agreement on a confidential basis. It is now under consideration by the prospective licensee, but all discussions have been stopped because we are no longer able to enter into the license in view of the NIH decision.

Mr. D. Bruce Merrifield Page Three September 24, 1984

The license agreement requires one sublicense be issued by January 1, 1985, and, after August 1, 1987, sublicenses be issued to any applicant. The license further provides that a licensed product must be available for commercial sale prior to August 1, 1986, or Stanford may terminate the Agreement.

Please note that final agreement to these terms has not yet been reached, but they illustrate where we are at this stage of negotiation.

Policy Alternatives

1. In a situation of mixed technology rights between the Government and a third party, the determination of who will administer the case as far as patenting and licensing (and bearing all risk of loss and reward) should be made based on which party will be more likely to bring about the earliest development of the technology for public use and benefit.

A factor in this determination would be availability of the inventors. That is, bare patent rights are very difficult to license, particularly before the patent issues. Generally, we find the enthusiasm (and agreement to provide consulting support) of inventors is necessary to conclude a successful collaboration with industry. The prospective patent rights, while a factor, are not as critical to early innovation as the availability and support of the technology creators.

- 2. This policy alternative proposes that when NTIS receives an invention for which the other party has the technology creators, the will and the competence to undertake licensing in the public interest, the invention be exclusively licensed to that entity without requirement for Federal Register notice.
- 3. This policy alternative proposes that if NTIS undertakes licensing in a situation such as described herein, it reimburses the entity which created the property (without which property they would otherwise not be able to license) for its patent expenses.

If in such situations there is no possibility of reimbursement, given the time that is necessary to have the facts sifted out and the Government agency to come to a decision as to whether it or another party has rights, then the other party will not invest its resources either in patent filing or licensing efforts until the decision is made. In a fast moving science, such as biotechnology, with the pressure to publish, foreign, if not U.S. patent rights, generally will be lost. And the window in time in which one quickly must conclude a high technology collaboration may have been closed, regardless of patent rights.

Mr. D. Bruce Merrifield Page Four September 24, 1984

I think the Government would be protected against expenses of frivolous filing by the fact that it could choose not to accept the case if it didn't feel that it was worth the patent expenses and turn it back to the other party.

Conclusion

We will be pleased to provide all the information that we have regarding this case, including the copy of the draft license agreement, the steps taken to qualify the licensee and to understand the market.

If Policy Alternative 1 is not selected, then NTIS needs to be brought into this case as soon as possible in order that it may make an informed decision with respect to whether or not to invest in foreign patent filing expenses, which are not insignificant expenses.

I would like to say that we have had the utmost cooperation and helpful interchange with the DHHS patent staff. They empathize with the situation, but circumstances and the law led them to conclude that they could not allow this invention to be administered under PL 96-517.

Sincerely,

Niels Reimers

Director, Technology Licensing

cc: Leroy B. Randall
Chief Patent Branch
Department of Health and Human Services
Office of the General Counsel
Washington, DC 20201

Roger Ditzel University of California Patent, Copyright & Trademark Office

Mark Davis Stephen Hedrick

NJR:kla



DEPARTMENT OF HEALTH & HUMAN SERVICES

Attachment to 9/24/84 letter Ollice of the Secretary to H.B. Herrifield

Office of the General Counsel
Washington, D.C. 20201

Our Ref: E-307-84

c/o National Institutes of Health Westwood Building, Room 5A03 Bethesda, Maryland 20205 (301) 496-7056

September 11, 1984

STANFORD UNIVERSITY

SEP 17 1984

TECHNOLOGY LIFT SING

Ms. Katharine Ku Associate Director Office of Technology Licensing Stanford University 105 Encina Hall Stanford, CA 94305

Re: DAVIS/HEDRICK, "T Cell Receptor-Specific Polypeptides and Related

Polynucleotides"

Dear Ms. Ku:

This refers to your letters dated March 30, 1984, April 2, 1984 and August 3, 1984, advising that Stanford University would like to administer the invention under Public Law 96-517 and providing information in support of that request.

We have reviewed this matter with officials of the Laboratory of Immunology, National Institute of Allergy and Infectious Diseases. Based upon that review, we conclude that the first actual reduction to practice of the subject invention occurred at the Laboratory of Immunology on August 2, 1983 when the inventors had finished sequencing enough of the gene to determine that they had isolated the T cell receptor. The work on this project that continued after that date merely verified that conclusion. The Chief of the Laboratory of Immunology has advised that if "reduction to practice" is taken to mean the isolation and sequencing of the gene, there can be no doubt that such reduction to practice occurred at the National Institutes of Health where the isolation of the cDNA clone, the sequencing of that clone, and its comparison to the nucleotide data bank led to the recognition of its homology to immunoglobulin were carried out.

At the time of the first actual reduction to practice on August 2, 1983, Dr. Hedrick was still a Government employee. His Federal employment terminated on August 6, 1983, but he remained in the Laboratory of Immunology as a "Guest Worker" until he left the National Institutes of Health on October 20, 1983. As a Guest Worker, any inventions made by him are subject to administration under the provisions of Executive Order 10096. Dr. Davis had been a Staff Fellow in the Laboratory of Immunology until April 1, 1983, but had continued to work in the laboratory as a Guest Worker until July 23, 1983. He left the laboratory only ten days prior to the date of first actual reduction to practice and it appears clear that most of the sequencing had been completed while Dr. Davis was still a Guest Worker.

In view of the foregoing, we are lead to conclude that the invention is subject to report and administration under the terms of Executive Order 10096 and that Public Law 96-517 is not applicable in this case. Accordingly, we would make a formal disposition of rights in this case in accordance with the requirements of the Executive Order. Please give us the benefit of any facts in your file contrary to any of the above.

Sincerely yours,

Leroy B. Randall Chief, Patent Branch



UNITED STATES DEPARTMENT OF COMMERCE The Assistant Secretary for Productivity, Technology and Innovation

Washington, D.C. 20230

(202) 377-1984

NOV 1 61984

MEMORANDUM FOR Dr. David Mowry

SUBJECT:

Stanford University Letter of November 2, 1984

I received a copy of the subject letter and attachments. I think Stanford's argument concerning the need for life-of-the patent exclusivity makes good sense. Similarly, I would be inclined to waive royalties. Hopefully we can put the royalties back into the National Institute of Health (NIH), if we get our laboratory legislation passed next year. Then I think royalty sharing with the Government would make sense. However, since we can't yet do this, perhaps it would be best to see the income put into the university's research as Stanford indicates will be the case. Moreover, since the inventors are now employed at the University of California and Stanford and will receive a share of the royalties, we have no need to obtain royalties to reward the inventors.

Does this make sense to you?

(Signed)
Bruce Merrifield
D. Bruce Merrifield

OPTI/FTMP/Jesse Lasken/Norm Latker/rh 11/15/84

bc: Dr. Merrifield Dr. Williams Egils Milbergs Chron

Read

STANFORD UNIVERSITY

STANFORD, CALIFORNIA 94305

Area Code (415) 497-0651 Telex: 348402 STANFRD STNU

OFFICE OF TECHNOLOGY LICENSING 105 Encina Hall

November 2, 1984

Mr. George Kudravetz Director Office of Federal Patent Licensing National Technical Information Services P.O. Box 1423 Springfield, VA 22151

Dear Mr. Kudravetz:

Enclosed is Stanford's application for an exclusive patent license for the "T-Cell Receptor-Specific Polypeptides and Related Polynucleotides."

As we have discussed before, we feel that Stanford is in the best position to bring this technology forward for public use and benefit. We have extensive experience in successful technology transfer and have the support of both inventors (Dr. Mark Davis and Dr. Stephen Hedrick) and both universities (Stanford and the University of California).

Some of the requested information in the application appears to be intended for a commercial manufacturing entity, but we have tried to answer them as best we can. In particular, we feel that it is reasonable to request life-of-the-patent exclusivity; otherwise, the licensing situation will become unduly complex as new inventions are developed at our respective universities under PL 96-517. In fact, the alpha-chain of the T-Cell receptor was recently isolated here at Stanford under NIH funding, clearly falling under PL 96-517.

In addition, we are requesting a waiver of royalty sharing with the Government. The net royalties collected by Stanford after sharing with the inventors would go directly for research and education at both universities. Since the GSA regulations do not require royalty-sharing with the Government, we feel the most effective use of the funds is for research and educational purposes.

We therefore feel justified in requesting a waiver of royalty-sharing and a life-of-the-patent exclusive license.

Mr. George Kudravetz Page Two November 2, 1984

I look forward to hearing from you as soon as possible. We do appreciate all the cooperation and encouragement you have given us.

Best regards,

Katharine Ku

Associate Director

Katharine Ku

cc: B. Merrifield (Department of Commerce)

M. Davis (Stanford)

S. Hedrick (University of California)

R. Ditzel (University of California)

Enclosure KK:kla

bcc: Norm Lather

APPLICATION FOR EXCLUSIVE PATENT LICENSE FOR GOVERNMENT INVENTION

IDENTIFICATIO	N OF INVENTION FOR	WHICH LICENSE IS DES	IRED of knowns			
1. TITLE OF INVENTION	2. Agency Patent Case No.					
T Cell Receptor-Specific Pol	· NIH E-307-84					
3. OTHER IDENTIFICATION (Technical brief, maga	•	4. U.S. Patent Application Serial No.				
Nature Vol. 310 Aug 2, 1984,	585 333					
5. SQURCE OF INFORMATION CONCERNING AV	AILABILITY OF A LICE	NSE ON THIS INVENTIO	N	6. U.S. Pátent No.		
Applicant						
		G APPLICANT FOR LICE				
The Board of Trustees of the Stanford Junior University Stanford, CA 94305		Niels J. Reimers Director, Technology Licensing Office of Technology Licensing 105 Encina Hall Stanford CA 94305				
9. STATE OF INCORPORATION (if corporation) OR CITIZENSMIP (if an individual)	10. APPROXIMATE NU	MBER OF PERSONS		MBER OF REPRESENTATIV		
California	Stanford 9 O	00	51			

Stanford is a nonprofit university, dedicated to research and education. The Office of Technology Licensing seeks to bring technologies developed as a result of university research forward, for public use and benefit in an adequate and rapid manner.

13. APPLICANT'S BEST KNOWLEDGE OF EXTENT TO WHICH THE INVENTION IS BEING PRACTICED BY INDUSTRY AND GOVERNMENT

The invention is of great scientific interest but no commercial products have been developed thus far; the discovery is very new. To our knowledge, the invention is not yet being practiced by industry or government.

APPLICANT'S PLANS AND INTENTIONS FOR PRACTICING INVENTION

14. FURPOSE FOR WHICH EXCLUSIVE LICENSE IS DESIRED

The attached letter to Mr. Merrifield explains our reasons for requesting an exclusive license. In summary:

- 1.) Dr. Mark Davis & Dr. Stephen Hedrick are faculty members of Stanford & University of California (UC) respectively;
- 2.) Stanford took the financial risk of filing a patent application;
- 3.) Stanford & UC are in Agreement, subject to government approval, for Stanford to

administer the invention on behalf of the two universities.

- 4.) Stanford has a potential sublicensee, with whom negotiations have been progressing smoothly toward a License Agreement;
- 5.) Both the Stanford & UC inventors are continuing research in the area under NIH funding; any new inventions will be administered under PL96-517.

15.	DESCRIBE HOW	APPLICANT PLANS TO	UNDERTAKE THE USE.	DEVELOPMENT & MARK	ETING OF INVENTION.

Stanford plans to sublicense the technology in the public interest in order to encourage diligent development of the invention. The License would include a requirement for furthe sublicensing of the invention and that a licensed product be available for commercial sale prior to Aug. 1, 1986. Stanford has had extensive experience in licensing inventions (since 1969)

16. SPECIFIC FIELDS OF TECHNOLOGY IN WHICH APPLICANT INTENDS TO USE INVENTION

A11

17. GEOGRAPHIC AREAS IN WHICH APPLICANT INTENDS TO PRACTICE INVENTION

18. MINIMUM NO. OF YEARS FOR WHICH APPLICANT SEEKS EXCLUSIVE LICENSE

A11

Life of the patent

19. IS APPLICANT WILLING TO ACCEPT EXCLUSIVE LICENSE FOR LESS THAN ALL FIELDS OF USE OF INVENTION?

YES (If "Yes," please explain)

ON 😰

20. OTHER SPECIAL TERMS OR CONDITIONS OF LICENSE DESIRED BY APPLICANT

In general, we would like a royalty-free license to administer the invention pursuant to PL96-517. Specifically, Stanford requests 1) a royalty free license pursuant to Paragraph 101-4, 104-1 (a) (7) of 41CFR Part 101-4 - "Licenses may be royalty-free" 2) exclusive license for the life of patent in all fields of use so as to simplify the administration of the subject invention & future inventions arising from research at Stanford & UC. 3) the right to grant sublicenses to companies who may also further sublicense.

21. ADDITIONAL INFORMATION IN SUPPORT OF THIS APPLICATION FOR LICENSE

The Net Royalties, if any, generated from the licensing of the subject invention will be divided in accordance with PL96-517. i.e., the inventors will receive a share and the remaining portion will be returned directly to the universities for use in research & education. Such a procedure would appear to be the most efficient way to use the royalty income productively.

22. SIGNATURE OF APPLICANT OR REPRESENTATIVE OF APPLICANT	23. DATE	
	•	

September 24, 1984

Mr. A. Bruce Merrifield Assistant Secretary for Productivity, Technology, and Innovation U.S. Department of Commerce Washington, D.C. 20230

Re: Request for Policy Guidance

- Ref. (1) Stanford Invention Disclosure Docket S83-193,
 "T Cell Receptor-Specific Polypeptides and Related Polynucleotides"
 PI: Davis and Hedrick
 (N1H Case E-307-64)
- Ref. (2) NIH Letter dated September 11, 1984, Responding to Stanford's Request that the Subject Invention be Administered under Public Law 96-517

Dear Mr. Herrifield:

There is, happily, a great deal of interaction between scientists in universities, industry, and government. These interactions often give rise to significant discoveries. An example is the gene splicing discovery that resulted from the discussions of Stan Cohen of Stanford and Herbert Boyer of the University of California.

These interactions, while often very productive in terms of science and discovery, frequently produce tangled rights situations. When one situation such as this arises with another university, we usually discuss the circumstances and agree as to which university shall undertake management of the invention. The problem occurs when such interactions occur with the Government, since there appears to be no set policy. Hence, we are communicating the circumstances of a specific case to you and making recommendations for your consideration as policy in this area.

Background

The technology in question has two inventors — one from Stanford and one from the University of California. But both were also working at NIH during a good portion of the development of this technology. For example, Dr. Hedrick was a Government employee for a period, a University of California employee but also "guest worker" at NIH for the second period, and then a DC employee at UC. Dr. Davis was a staff fellow at NIH, also a guest worker at NIH, and then came to Stanford.

Mr. D. Bruce Merrifield Page Two September 24, 1984

These circumstances were presented to NIi. While the significant contributions to the technology were made while Hedrick and Davis were under Government patent agreements, we asked that we be allowed to administer the invention under PL 96-517 in view of the fact that the inventors were now here and we could more efficiently license the invention with their support, and in view of the future research work and reduction to practice that occurred after the two scientists had been in California. To avoid loss of patent rights before the rights situation could be determined, we filed a U.S. patent application.

By the enclosed letter of September 11 (Reference 2), our request was denied.

The Present Situation

We have discussed the September 11 determination with the NIH Patent Office to explore what are the alternatives available to us at this point. We are advised the case will now be turned over to the NTIS for administration and licensing. Stanford will be required to assign the patent to the Government, and there is no provision for reimbursement of the patent expenses incurred by Stanford. It was suggested we explore with NTIS the possibility of their "licensing" Stanford so that we then could sublicense industry.

In exploring this latter possibility, we understand that even if NTIS should agree, notification would need to be published in the federal register and that considerable time might elapse before a final determination.

The Patent and Licensing Situation

The decision with respect to the foreign filing must be made well in advance of the absolute bar to occur on March 1, 1985, preferably by this December.

We found that prospective Davis/Hedrick patent rights may not be able to be practiced without the licensee having access to other related patent rights. These related patent rights are held by a relatively new company formed to exploit this technological area — T Cell Sciences.

Because of the early stage of development of this technology and these related patent rights, it may not be in the best public interest to license other companies, even if they agree to diligently pursue development. We were in the process of negotiating a license agreement with T Cell Sciences which will require diligence and the earliest availability of the technology to other companies.

We will be pleased to send you a copy of this license agreement on a confidential basis. It is now under consideration by the prospective licensee, but all discussions have been stopped because we are no longer able to enter into the license in view of the NIE decision.

Mr. D. Bruce Merrifield Page Three September 24, 1984

The license agreement requires one sublicense be issued by January 1, 1985, and, after August 1, 1987, sublicenses be issued to any applicant. The license further provides that a licensed product must be available for commercial sale prior to August 1, 1986, or Stanford may terminate the Agreement.

Please note that final agreement to these terms has not yet been reached, but they illustrate where we are at this stage of negotiation.

Policy Alternatives

1. In a situation of mixed technology rights between the Government and a third party, the determination of who will administer the case as far as patenting and licensing (and bearing all risk of loss and reward) should be made based on which party will be more likely to bring about the earliest development of the technology for public use and benefit.

A factor in this determination would be availability of the inventors. That is, bare patent rights are very difficult to license, particularly before the patent issues. Generally, we find the enthusiasm (and agreement to provide consulting support) of inventors is necessary to conclude a successful collaboration with industry. The prospective patent rights, while a factor, are not as critical to early innovation as the availability and support of the technology creators.

- 2. This policy alternative proposes that when NTIS receives an invention for which the other party has the technology creators, the will and the competence to undertake licensing in the public interest, the invention be exclusively licensed to that entity without requirement for Federal Register notice.
- 3. This policy alternative proposes that if NTIS undertakes licensing in a situation such as described herein, it reimburses the entity which created the property (without which property they would otherwise not be able to license) for its patent expenses.

If in such situations there is no possibility of reimoursement, given the time that is necessary to have the facts sifted out and the Government agency to come to a decision as to whether it or another party has rights, then the other party will not invest its resources either in patent filing or licensing efforts until the decision is made. In a fast moving science, such as biotechnology, with the pressure to publish, foreign, if not U.S. patent rights, generally will be lost. And the window in time in which one quickly must conclude a high technology collaboration may have been closed, regardless of patent rights.

Hr. D. Bruce Merrifield Page Four September 24, 1984

I think the Government would be protected against expenses of frivolous filing by the fact that it could choose not to accept the case if it didn't feel that it was worth the patent expenses and turn it back to the other party.

Conclusion

We will be pleased to provide all the information that we have regarding this case, including the copy of the draft license agreement, the steps taken to quality the licensee and to understand the market.

If Policy Alternative 1 is not selected, then NTIS needs to be brought into this case as soon as possible in order that it may make an informed decision with respect to whether or not to invest in foreign patent filing expenses, which are not insignificant expenses.

I would like to say that we have had the utmost cooperation and helpful interchange with the DUHS patent staff. They empathize with the situation, but circumstances and the law led them to conclude that they could not allow this invention to be administered under PL 96-517.

Sincerely,

Niels Reimers Director, Technology Licensing

cc: Leroy B. Randall
Chief Patent Branch
Department of Health and Human Services
Office of the General Counsel
Washington, DC 20201

Roger Ditzel University of California Patent, Copyright & Trademark Office

Mark Davis Stephen Hedrick

NJR:kla

THE NTIS LICENSING EXPERIENCE*

Douglas J. Campion**

The National Technical Information Service (NTIS) is an agency of the U.S. Department of Commerce. Unlike most government agencies, NTIS recovers its routine operating costs through the sale of its technical information products and services, not from Congressionally appropriated funds. In other words, NTIS operates as a public enterprise, with \$25 million in annual revenues.

The statutory mission of NTIS is "... to make the results of technical research and development more readily available... as a clearinghouse for technical information which is useful to American business and industry." NTIS continues its 40-year clearinghouse tradition with the technical research report, produced by or for the federal government, as its basic product. Some 70,000 new titles are published annually and thousands of copies of technical reports distributed each day. In recent years, the traditional scope of the NTIS operation has broadened considerably beyond purely informational products and services. Programs for applied technology and patent licensing have put the agency on the leading edge of government technology transfer activities.

Legislation which passed in late 1980 encouraged NTIS' technology transfer efforts. The Stevenson-Wydler Technology Innovation Act resulted from national concern about lagging productivity and innovation and the presumption that the government's R&D investment might be put to better use. Under the Act, agencies with large R&D budgets are required to allocate a fraction of their resources to the identification and spin-off of commercially valuable technology. Technology transfer now enjoys its highest level of consciousness within the government and considerable resources have been claimed for the process. Unfortunately, too few government officials understand or have experience with the process for converting laboratory results into commercial or industrial property rights.

- * Statements of fact or opinion in this paper are solely those of the author and do not necessarily represent the views of NTIS or the Department of Commerce.
- ** Patent Licensing Specialist
 National Technical Information Service
 U.S. Department of Commerce

Government patents and licensing are not specifically mentioned in the Stevenson-Wydler Act. Presumably, Congress did not want to create any confusion between that Act and the Act to Amend the Patent and Trademark Laws, Public Law 96-517, which passed a few weeks later. Public Law 96-517 is best known for providing patent ownership to universities, small businesses, and non-profits for inventions disclosed under federal R&D contracts; but it also provided statutory authority for federal patent licensing. In particular, it gave federal agencies the authority to grant exclusive patent licenses. NTIS has moved aggressively under both pieces of legislation, recognizing the relationship between patent licensing and technology transfer. NTIS views licensing as an extremely potent mechanism for consistent and efficient movement of government-owned technology out of government laboratories to the private sector.

This concept of licensing led to a consolidation of two NTIS programs, the Federal Patent Licensing Program and the Applied Technology Program. The union of these programs produced the NTIS Center for the Utilization of Federal Technology, or CUFT. CUFT was specifically mandated by the Stevenson-Wydler Act to serve as a clearinghouse within the Department of Commerce for the transfer of information on "federally-owned" or originated technologies, language which is remarkably close to the basic NTIS statutory mission. The Applied Technology office of the new CUFT program is working with some 200 federal laboratories to provide information to industry on laboratory projects; 300 additional laboratories have been identified as possible participants. Under this program, laboratories submit short technology assessment reports on projects having near term potential for commercialization and these reports are made available to industry through a monthly NTIS subscription service called Tech Notes. Patent licensing finds a suitable operating environment in the CUFT program because the technology encompassed in government patents is "federally-owned," to use the words of Congress; and the ease of access to CUFT's laboratory technology assessment reports increases the likelihood of finding good, licensable technology.

As many know, patent licensing is not a new activity at NTIS; to some, it has that appearance because the 1980 legis-lation provided greater visibility and the statutory framework within which to operate. In addition, the program has only recently completed its long induction period and achieved a level of accomplishment based on the numbers of licenses being granted, licensees' R&D commitments, and royalties as a function of product sales. The program was officially established in 1974 with specific delegations from the Secretary of Commerce to promote wider private sector use of government inventions and to obtain foreign patents to protect valuable overseas markets for U.S. industry. The program was not very active in licensing at

first, focusing instead on technique and review of private sector and foreign government licensing programs.

Analysis of the few successful licensing operations that existed revealed an important common denominator. A critical mass of good inventions was necessary to sustain a long-term, viable program. Typically, a few hundred new inventions were required each year, inasmuch as only a small percentage would be highly successful commercially. Some programs with a single highly successful invention bringing in substantial royalties prospered for a time but then faded without access to a steady flow of new inventions. NTIS concluded that multi-agency participation in its program was imperative to achieve the necessary critical mass.

It took several years to sell the NTIS licensing concept to a handful of agencies which now provide NTIS with its invention inventory. Individualized, cooperative licensing arrangements have been negotiated with several civilian agencies: NTH, USDA, Interior, the VA, NSF, and DOT; two DoD agencies, the Army and the Air Force, are also represented. Through NTIS, these agencies promote more uniform application of licensing regulations and overcome otherwise fragmented private sector attempts to locate federal technology with specific commercial value.

The current NTIS licensing program consists of a comprehensive set of licensing services. Some services are performed for all agencies, while others are available only to those (client agencies) mentioned earlier which formally transfer custody of inventions to NTIS for the purpose of licensing:

For All Agencies

Invention announcements

Patent application distribution

For Client Agencies

Invention screening

License negotiation

Foreign filing

Royalty collection

Invention promotion

Incentive awards

Applicant-licensee screening

Performance review

Invention Announcements & Distribution

A dozen federal agencies provide NTIS with copies of recently filed patent applications and issued patents which are being made available for licensing. NTIS announces these inventions in weekly, subject oriented newsletters which are distributed to hundreds of industry subscribers; the most comprehensive of these weekly publications is titled Government Inventions for Licensing. Anyone interested in reviewing the technical specifications of published inventions may, of course, purchase patent copies from the Patent & Trademark Office. Patent application copies, less claims, are available directly from NTIS. Parties interested in additional technical or licensing information on any invention are either referred to agency licensing officials or are serviced directly by NTIS, depending on where the licensing will occur.

Invention Screening

NTIS routinely screens client-agencys' recently filed patent applications to attempt to identify those which have better than average potential for commercialization and which are worthy of an investment in direct solicitation of industry interest.

The current NTIS screening approach is flexibly structured. Screening usually starts with the inventor who completes a questionnaire which provides basic technical and market assessments and references to related publications and patents; the inventor also identifies companies which may have already expressed interest in the technology. Additional evidence of possible commercial potential may be obtained from a variety of sources, including other client-agency technical staff, trade publications, trade associations, and the accumulated experience of the NTIS licensing staff. The intensity of staff review will differ for each invention and may be influenced by the current licensing negotiation caseload. Frequently, prospective licensees are quickly contacted to provide early feedback on the commerical worth of selected inventions. A rough equilibrium seems to have been achieved by screening out just enough invention noise from the system and letting enough good inventions through to hold the consistent attention of many industry contacts.

Foreign Filing

The foreign filing activity at NTIS is designed to encourage exports by protecting overseas markets for U.S. industry and to prevent unrestricted and uncompensated foreign use of government technology. Foreign filing decisions are necessarily very

selective and emanate from the screening process and industry assessments. Because of the expense, foreign patent filing is tailored for maximum coverage with a minimum of individual country filings. Inventions are frequently filed in western Europe and Japan where major markets or production capabilities exist. The NTIS foreign patent portfolio consists of about 800 pending and issued foreign patents, approximately 30% of which are licensed. This percentage will continue to increase over time as unlicensed cases are weeded out. One-half of all licenses now being granted by NTIS include foreign patent rights, attesting to the eagerness of U.S. companies to protect their exports and investments outside the U.S.

On occasion, promising technologies can not be protected overseas because of disabling publications. Government R&D management is not well informed about patenting requirements and there is little control over the publication activities of government scientists, to the advantage of the overseas competitors of U.S. industry. Fortunately, some individual government employee-inventors withhold publication voluntarily for a time out of concern for preserving an advantage for U.S. industry. In addition, our Incentive Awards Program is helping as others realize they may be denying themselves a share in future royalties.

Invention Promotion

The importance of securing early assessments from prospective licensees on selected inventions makes the procedure for soliciting licensing interest a principal consideration. Various promotion techniques were the subject of early program experimentation. Selected inventions were highlighted in mass promotional mailings, in newsletters and trade publications, at technology fairs, and through computer-based technology brokerage services. These "shotgun" types of promotions produced little by way of hard licensing interest; the initial response rate was frequently very high but the actual licensing rate low. Some amount of this kind of general exposure is considered useful, however, to maintain general program visibility and to reduce complaints when inventions are licensed exclusively. In contrast to the shotgun approach, the real payoff was revealed in highly targeted promotional efforts. The "rifle" approach is directed to specific individuals in selected companies whose job it is to stay abreast of the latest in product and process developments. Industry contacts are normally made by letter and telephone and, on occasion, inventions may be presented at personal meetings. All contacts are personalized and may be limited to only a handful of prospective licensees for a given invention. Inventions are promoted this way for expeditious licensing to qualified companies, not for maximum exposure of the technology.

Some companies are consistently more aggressive in their search for technology and those companies are most likely to be regular contacts and repeat licensees.

Applicant-Licensee Screening

Prospective licensees must, by regulation, formally apply for a license and indicate specifically what it is they would do to bring the product or process to the point of commercial application. Applicants are required to submit a plan which details the time, nature, and amount of resources which will be dedicated to the development project. This exercise is rarely a burden on prospective licensees, inasmuch as product development plans are normally prepared, perhaps in even greater detail, for internal management review. Plans are treated as confidential business information and are not released under the Freedom of Information Act.

The architects of the current licensing law and regulations probably did not anticipate keen competition for licenses, inasmuch as the utilization rate of government patents was normally perceived to be very low. Basically, the guidelines for selecting licensees are to pick the best company for the job, and to consider whether the license grant would tend to lessen competition. This is easy enough to do if the license applicants and their licensing interests can be neatly pigeonholed. In actuality, the decision is quite subjective and varies considerably in degree of complexity depending on the technology involved, the kind of license requested (the request is frequently conditional), the development plans, and the number and kind of applicants for the license. If there is a single applicant who is a large company, there is a tendency to assume that resources are available to do the necessary developmental work. Questions of capability or intent may only arise if the invention lies on the periphery of the company's usual area of business endeavor or if it is likely to be one of a stable of many related projects which will have to compete for internal resources. If the applicant is a small business or, perhaps, a brand new business without a track record, the licensing decision is more difficult. Occasionally, a Dunn and Bradstreet report is obtained to verify information in the license application. Bank and investor letters of credit have been requested as well as resumes of key technical staff to be assigned to the project.

The applicant screening process really becomes interesting when there is more than one good candidate for an exclusive license. Competition for the license can be aggressive with personal visits by technical and management staff and company attorneys. As many as seven companies, five of them Fortune 500 firms, have competed for an exclusive license on the same

invention. NTIS allows the companies themselves to largely direct the licensing decision process. They make most of the key licensing decisions by bidding up the levels of resource commitments under their development plans or by opting for a less-than-total exclusive position in preference to the risk of being excluded from use of the technology. However, the likelihood of interest in some kind of a shared licensing arrangement decreases in direct proportion to the aniticpated size of the market and in inverse proportion to the requirements for development capital.

An interesting twist has developed on more than one occasion when one of the candidates for the exclusive license has been a large company and another competing candidate a small firm. large firm has argued that their experience, corporate resources, and track record will ensure most expeditious commercialization of the technology; the small firm has touted their flexibility, aggressiveness, level of corporate commitment, degree of specialization, and, perhaps, substantial investor support as their significant edge over the large, over-managed company. ensure its licensing position, the small company has claimed the statutory small business preference for awarding the exclusive license. In retaliation, the large company has threatened to convert their request for an exclusive license to a nonexclusive license application, asserting a statutory preference for nonexclusive licensing. Fortunately, a compromise has usually been reached with co-exclusive or field of use licenses elected by both companies in order to avoid potentally protracted deliberations, formal administrative appeals, and, perhaps, even litigation.

License Negotiation

Occasionally, NTIS is confronted with the concern that licensing negotiations are not being conducted close to the point of invention and, therefore, are not as productive as they could be. While well intentioned, this notion assumes a greater role for the inventor and, perhaps, for the attorney who prosecutes the patent application than normally occurs in standard licensing practice. The expertise necessary to create intellectual property is not the same as that necessary to promote commercial and industrial development. License negotiation is principally a process of business considerations: economic, financial, legal, and product marketing. Inventor expertise is usually limited to technical subject matter and they do not always have a clear view from the laboratory bench of the commercial value of their discoveries. Scientists, particularly in large companies, are rarely involved in licensing. Inventor involvement does tend to occur more frequently at small companies and universities where there is less separation between technical and business

orientation and responsibility. Early in the licensing process, NTIS provides prospective licensees with access to pertinent technical information and know how, including discussions with inventors or other qualified client-agency staff, as is necessary to satisfy technical questions. NTIS will not represent an agency which does not first guarantee reasonable access to inventors. After the technical considerations have been satisfied, the inventor is usually uninvolved but is kept apprised of continuing discussions and negotiations.

In industry, the licensing role of the patent attorney who prosecutes a patent is also influenced by the size and structure of an organization and the location of the business expertise. In many large companies, patent attorneys play an advisory role with most of the licensing being conducted by a separate licensing staff. At companies where patent attorneys do have major responsibility for licensing, they are usually not the attorneys who file and prosecute patent applications. NTIS usually relies on client agency attorneys to advise on matters relating to patent status but not for significant input in the licensing negotiations.

Implicit in the business orientation of licensing is the necessity for flexibility and compromise. Companies which seek technology are more concerned about the terms and conditions of acquisition than about the source of the technology. Flexibility and compromise are necessary to keep prospective licensees in the negotiation process; and they are essential in this instance to offset some of the uncertainties of doing business with the government. There are some things the government is currently unprepared to do, such as submit licensing disputes to arbitration; but by being imaginative, the present licensing regulations have proved to be considerably accommodating. NTIS has no pro forma license agreement, although there is a preferred format; and many licensing provisions are the subject of negotiation, the most common of which are the royalty base, the royalty rates, and the duration of the license grant.

Royalties

When negotiating royalties, influencing factors include whether the license is exclusive or nonexclusive, the extent of the government's continuing contribution, the strength of patent claims and extent of patent coverage, the necessary development work, and estimated markets. Almost all licenses granted by NTIS do include some royalty requirements; however, if a patent becomes the subject of an industry or government standard, it may be essentially dedicated at little or no cost to licensees. Royalty consideration usually includes an execution fee, annual minimums, and a percentage of sales. Up-front payments have

ranged from \$500 to \$50,000 with running royalties varying from a fraction of a percent to seven percent. Once a license is signed, NTIS assumes the administrative burden of ensuring compliance with the royalty terms of the license, making cash payments to inventors under an Incentive Awards Program, and returning royalties to the Department of Treasury.

Incentive Awards

The NTIS Incentive Awards Program for Federal Inventors was developed to compensate and recognize government employeeinventors, to encourage disclosure of commercially promising inventions, and to facilitate the technology transfer process. Under this program, inventors receive cash awards which are not dependent upon subjective judgments of benefits to the government or the public. The grant of a royalty bearing license is a prima facie justification for an award; the award merely requires routine concurrence of the employee's agency which, to this point, has always been received. When a license has been granted, the inventor receives an automatic \$300 cash award or 15% of the up-front payment received by NTIS, whichever is greater. For each year the license is in effect, regardless of whether commercial sales are ever realized, the inventor receives a \$300 minimum cash payment. If royalties are received, the 15% formula continues to apply and the \$300 annual minimum may be exceeded, depending on the level of product sales. Currently, there is a statutory cap governing all federal incentive programs of \$35,000 which should be reviewed periodically for consistency with university and private sector royalty sharing practices. For calendar year 1983, inventors' cash awards totaled \$34,000, including a single award of \$8,000.

Licensee Performance

All licenses granted contain a projected time by which the licensed invention will be commercially introduced. This target is based on licensees' original development plans submitted with the applications for license. The use of a specific objective avoids relying on a more subjective standard such as "due diligence." Prior to the first commercial sales, licensees must report each year on progress toward completion of the development plan and commercial application of the invention. Failure to submit an annual report or failure to establish sufficient progress against the original plan is grounds for modification or termination of the license. These requirements are applied both to exclusive and nonexclusive licenses; the right to exclude others or block the grant of an exclusive license must be justified by movement toward commercial application. NTIS has revoked licenses for nonperformance and has recently strengthened its reporting requirement with an independent audit provision.

Summary

It is appropriate to conclude this review of NTIS' Federal Patent Licensing Program with a report on last year's (fiscal year 1983) licensing performance, which demonstrates the effectiveness of licensing as a mechanism for greater technology transfer. More than 40 royalty bearing patent licenses were granted, primarily to large and small, high technology companies. Approximately one-third of these were exclusive licenses with an average exclusive term of about nine years. Most of the nonexclusive licenses granted were duplicates of licenses granted in previous years, so the exclusive licensing rate for new inventions was actually about 60%; half of the exclusive licenses were granted on pending patent applications. Under these licenses, licensees anticipate a total of \$92 million of investment in additional R&D and new plant. Royalties for the year (on approximately \$50 million in product sales) were over \$900,000, continuing the upward trend in annual product sales and royalty revenues.

These accomplishments were realized with a clerical and professional staff of six people, which would seem to indicate that effective transfer through licensing need not require substantial subsidy or bureaucracy. At current patenting levels, perhaps no more than a score of people would be required to aggressively manage the government's patent portfolio with potential for many millions of dollars of direct and indirect return to the government.

For maximum effect, government patent licensing should not be conducted on a part-time basis, as it has been at various times and places in the government, competing with other responsibilities and lacking sufficient incentives for high licensing productivity. The NTIS approach is recommended: do it full time and tie job performance evaluations (and pay increases) to actual licensing output. This is a strong incentive to learn the licensing business.

Finally, it might be useful to mention that the government's intramural R&D investment is being vastly under-utilized. Based on current R&D expenditures and patenting rates (and ignoring for the moment the mission orientation of much government research funding), the private sector is about 16 times more likely to secure a patent per unit of R&D expenditure than the government. Indeed, patenting productivity in government is extremely low; and there are many unrecognized, commercially valuable federal employee inventions which are not being developed and exploited through the incentives of exclusive licensing for the creation of new business and jobs to the benefit of the domestic economy and America's international competitiveness.



United States Department of the Interior

GEOLOGICAL SURVEY 345 Middlefield Road Menlo Park, California 94025

May 22, 1984

Mr. D. Bruce Merrifield United States Department of Commerce The Assistant Secretary for Productivity, Technology and Innovation Washington, D. C. 20230

Dear Mr. Merrifield:

Your letter of May 10th addressed to our Director, Dr. Dallas Peck, at Menlo Park was received by this office late on the 11th. I was on my way to Reston, Virginia, where Dr. Peck is located and I took your letter with me. After some discussion and in view of short time available to make a constructive contribution to the May 22-24 meeting, it was decided not to attend. As you probably know, a letter from Mr. Perkins had been received earlier and I had responded on January 26, 1984; a copy of that letter is enclosed for your easy reference. Up to the receipt of your letter we had had no further correspondence on the meeting.

As you probably know, the U.S. Geological Survey's mission, responsibilities, and authorities are concerned with geologic mapping and research, mineral resource assessment, water resources, hydrologic processes and research, topographic mapping and map production, and various combinations of these topics. Laboratories are an integral part of these programs but are not ends in themselves. We are involved in scientific hardware and techniques but only to the extent that they are needed to carry out research surveys or mapping programs. Our major products are maps and reports. The transfer to industry and the public is largely through this medium. You or your staff may be interested in our Circular 777, "A Guide to Obtaining Information from the USGS 1982", enclosed.

We are, of course, aware of the recent emphasis and mandates on transfer technology and we are actively seeking new and better ways to make the results of our work available to the public sector. We would appreciate any further thoughts you have on this subject. Dr. Peck wanted me to extend his thanks for your interest. Should you wish to contact him further, his address is:

> Dr. Dallas L. Peck, Director U.S. Geological Survey National Center, Mail Stop 101 12201 Sunrise Valley Drive Reston, Virginia 22092

> > Sincerely yours

Western Region

Director's Representative RECEIVED

MAY 25 1984

D. BRUCE MERRIFIELD

George Gryc

Enclosures cc: Dallas Peck

Tom Holser



To: 1 our -

8 Please Mendo p coup

OFFICE OF THE ASSISTANT DIRECTOR
FOR RESEARCH
U.S. GEOLOGICAL SURVEY
104 NATIONAL CENTER
RESTON, VIRGINIA 22092
(703) 860-7488



UNITED STATES DEPARTMENT OF COMMERCE

The Assistant Secretary for Productivity,

Technology and Innovation Washington, D.C. 20230

(202) 377-1984

104

May 10, 1984

Dr. Dallas L. Peck Director, U.S. Geological Survey Menlo Park, CA 94025

Dear Dr. Peck:

In the February 15, issue of <u>Chemical Week</u>, an article describes a very effective way of starting the process of technology transfer on a <u>macro basis</u> between industrial companies and universities or with government laboratories. James Wyckoff of the National Bureau of Standards had a very successful meeting. Also, the universities are highly enthusiastic about this process. Unfortunately, many of the government laboratories that are invited are not availing themselves of this opportunity.

There is a meeting in Los Angeles on May 22, 23, and 24 much like the one described in the attached article. Mr. Walter Perkins of the Navy Ocean Systems Center (619/225-6319) is hosting the meeting. I urge you to participate in this meeting. If Mr. Perkins happens to be out of town, call Mr. Al Frye who is coordinating the industrial company's side (615/748-3236).

Also, there will be another meeting in St. Louis hosted by Dr. Andrew Kowden from the Northern Research Center in Peoria on July 31, August 1 and 2, for those laboratories in the Midwest.

I cannot overemphasize the importance of taking advantage of these opportunities. As you know, we are mandated by law to take advantage of all opportunities to transfer technology from our federal laboratories to areas where it can be utilized. Currently, very little of the \$45 billion of federally funded R&D is made available to the private sector. It's a problem we all need to address.

Sincerely,

Blue alevefuld

D. Bruce Merrifield

Enclosure



niversity/industry match

Making a university/industry match

The once warm love affair between academic and industrial research that had proved so fruitful for so long cooled off during the 1960s and 1970s. A number of steps taken to rekindle the romance-such as forming the Chemical Research Council, which is dedicated to strengthening ties between universities and industries—are showing results.

Still, a lot of good, potentially useful academic research is going begging for lack of industrial sponsorship, and there's no single best way of getting

The new gambit: conferences that show a lot of university research to a lot of buyers

such research off the academic shelf and into an industrial setting. A company can accomplish that by using inhouse staff to scout the universities, or it can work with the specialized companies and foundations that facilitate just that sort of technology transfer. Most firms augment their own scouting skills with those of the specialists.

Now, companies have another specialist at their disposal, Technology Transfer Conferences (TTC) of Nashville, a relative newcomer to the technologytransfer field. The company is using an approach that is described at once as both "innovative" and "imitative."

Frye: A varied showcase of university research.



TTC is a nonprofit organization headed by A.L. Frye. It sets up regional conferences by selecting a host university and inviting 9 or 10 other nearby universities to meet near the host's campus. It then invites up to 30 companies, charging each \$400. TTC's last conference was held earlier this month in New York City, with Columbia University as the host. It will be followed in April by a conference in Boston, hosted by the University of Massachusetts.

The conference begins in the evening with brief general presentations by the university representatives, typically the vice-presidents of research. The following morning, each university representative gives a 20-minute summary of the school's applied research programs. The afternoon is devoted to one-on-one discussions between industry and the university representatives.

This approach affords a number of benefits, as Frye sees it. It gives the schools a chance to showcase, and perhaps get some rewards from, their research. It provides an insight for industry on the type of research that is being done in different universities. It also gives industry a chance to find consultants and to discover what patents may be available for licensing.

Double exposure. In fact, the conferences have been working out so well, says Frye, that he has expanded them.

He is using the same format to allow researchers from federal laboratories to address industry. And he is extending the conference into a two-day affair by bringing in a second group of 30 companies for the university representatives to address. That, Frye points out, gives the universi-ties "twice the amount of exposure."

TTC's university-industry conferences do not inspire unalloyed admiration from some in the technology-transfer field. For example, Vladimir Dvorkovitz, president of Dr. Dvorkovitz & Associates, a technologytransfer company in Ormond Beach, Fla., says, "What Frye's doing is a retread of what we did

12 years ago." In the past decade, Dvorkovitz has broadened his operations to allow companies, as well as universities and federal laboratories, to show off their research wares. He has, moreover, gone international in scope; this April, Dvorkovitz will sponsor in Orlando, Fla., TechEx 84, a conference at which he expects delegates from at least 22 countries to report on their technology.

The president of another technologytransfer firm is similarly critical of TTC's conferences. The executive says

Opinions vary from 'innovative and aggressive' all the way to 'imitative and superficial'

that he does not know a single "univer, sity with which we work that can give a 20-minute talk covering even a part of the research it's doing." He cites the University of Illinois, which has "over 3.000 individual research projects ongoing." Frye's conferences, he adds, "sound good as far as they go, but basically they seem superficial."

Other organizations involved in transferring technology from universities to industry take a kinder view of TTC. Comparing his company with TTC, Gordon Howe, director of the invention administration program at Research Corp., a Tucson, Ariz., technology-trans-

Dvorkovitz: A retread of what we did 12 years ago.



fer company says, "We're doing two different things." Frye, as Howe sees it, has a limited objective—"to get universities and companies to discuss things." Research Corp., on the other hand, takes a university invention, patents it, licenses it and "along with a company takes it all the way through development to public use." Howe adds, "I wouldn't say we're competing—we're attacking different problems."

The patent counsel at the Wisconsin Alumni Research Foundation, a non-profit technology-transfer group associated with the University of Wisconsin, echoes Howe. "We take a university invention all the way to industrial development," says Howard W. Bremer, while Frye simply gives universities and industry a forum in which to make contacts. "Frye also gives the smaller schools an opportunity to show what they're doing. And he keeps his group small, so there's better interplay."

Cream. But Frye feels that Research Corp. and other technology-transfer companies "only skim the cream off the top." He concedes that such firms take good inventions and push them. But he does not feel that they "put a lot of effort into pushing everything, so a bottleneck is created." Frye's conclusion: The majority of university research doesn't get enough industry exposure.

Frye's conferences get good marks from some of the chemical majors that have attended them. Dow's manager of cooperative research, Ted E. Tabor, for example, has gone to four conferences. Dow, he says, wants to keep abreast of university research on material sciences, electrical and mechanical engineering, biology and physics. Frye's conferences, Tabor believes, provide a company with a broad overview of a university's research, instead of limiting it to one key area. "We learn," Tabor says, "about expertise that we would not know about, from universities that we would not include in our visitation schedule." The conferences also help Dow decide what research at which schools warrants a more detailed follow-up. Tabor looks on the conferences as an another tool for finding good research. He says it is not the only one by a long shot but does call it "valuable."

Monsanto also thinks well of TTC's conferences. It has been attending them for three years, and T. L. Tolbert, director of external research, says that the company has had input from 100 universities. In follow-up visits, he adds, technology transfer has resulted "a number of times." Such visits have also led to research support and patent licensing in

areas not discussed at the conferences. "But without the conferences," Tolbert says, "we never would have gotten to the university in the first place."

International Minerals and Chemical is another believer in Frye's technique. The firm's coordinator of new product development, Brenda D. Politi, who's been a "regular" at Frye's conferences for two years, looks on the conferences as time-savers, a way of viewing the research programs of several universities at one time. They also, says Politi, enable her to take a more active role in scouting university research than do the specialized technology-transfer companies, such as Research Corp. "It's just a more aggressive way," she says, "for me to go out and beat the bushes."

At least one government research organization found the TTC approach helpful. The National Bureau of Standards (Gaithersburg, Md.) hosted a TTC conference last year, and James M. Wyck-

IMC's Politi: 'It's just a more aggressive way for me to go out and beat the bushes'

off, NBS's liaison officer for state and local governmental affairs, says that of the 23 companies that attended the conference, 15 came back for further data. A pharmaceutical firm, he says, was particularly interested in medical-device research done by one of the bureau's mid-Atlantic regional labs on measuring leaks in pacemakers. "The conference," Wyckoff says, "helped us achieve our legislated requirement to share our information with industry."

Another conference host garnered two research contracts as a direct result of the meeting. Daniel J. Zaffarano, vice-president for research at Iowa State University in Ames, says that Monsanto funded a \$16,000 textile-research project; another firm, a \$30,000 ceramic-research project. In March, says Zaffarano, the state of Iowa will put on its version of Frye's technology-transfer conference. Ten Iowa universities will make presentations to 30 Iowa companies. "Frye's conference worked so well for the region," Zaffarano says, "we want to do it for the state."

The University of Georgia and Georgia Tech have also put on conferences modeled on Frye's gatherings. And although Dow's Tabor is not convinced that such moves portend a trend, he does think they indicate that "universities are becoming more receptive to linking up with industry. They no longer look at industry as adversaries."

1/2×107



DEPARTMENT OF THE NAVY NAVAL OCEAN SYSTEMS CENTER SAN DIEGO, CALIFORNIA 92152

IN REPLY REFER TO

EPC:bhs 3900 Ser 013/24

Mr. George Gryc U S Geological Survey 345 Middlefield Road Menlo Park, CA 94025

Dear Mr. Gryc.

As you may know, the Far Western Region of the Federal Laboratory Consortium (FLC) is co-sponsoring with Industry, a Government/Industry Technology Transfer Conference during the period 22 - 24 May 1984 at the Marriott Hotel located at the Los Angeles Airport.

The Naval Ocean Systems Center (NOSC) will represent the FLC as host laboratory and Aladdin Industries will coordinate the Government/Industry conference as they have successfully done in the past.

You, as the FIC representative for your activity, are requested to determine the desires of your management as to whether or not to participate in this endeavor. I ask that your response, yes or no, be forwarded before 17 February 1984 to:

Mr. Walter W. Perkins, Code 0131 Naval Ocean Systems Center San Diego, Ca 92152 Telephone: (619) 225-2285/2786 or AUTOVON 933-2285/2786

If your activity decides to participate in the conference, please inform Mr. Perkins how the formal invitation is to be addressed.

If no more than eleven acceptances are received, then each participating command will immediately receive a formal invitation from this command and from Dr. Schmid, Far West Regional coordinator for the FLC. Additional information will be requested from you at that time, such as names of personnel who will speak, experts, if any, who will attend and a brief description of topics to be discussed.

If more than eleven activities express a desire to participate, then Dr. Loren Schmid will have to make a decision as to which activities will be given the opportunity to participate.

NOTED JAN 26 1984

CRYC

Participation in the conference is encouraged as such participation represents a unique opportunity for your laboratory to achieve recognition and to effect technology transfer to an important sector of industry. Your committment to participate in this conference will be in accordance with the policy of Congress as expressed in the Stevenson-Wydler Technology Innovation Act of 1980, PL96-480, and also in accordance with the expressed desire of President Reagan to increase interactions between Government and Industry in the R&D area.

Enclosures (1) through (8) provide information and details of interest on this and recent conferences to aid in the participation decision by your management. Other details and requests for information will be provided in a timely manner.

Sincerely,

EUGENE P. COOPER

Director for Science and Technology

By direction of the Commander

Encl:

- (1) List of FLC Far West Region Members
- (2) Brief Summary of Technology Transfer Conference Information for planning purposes
- (3) Sample: Government Laboratory/Transfer Conference Details and Requirements
- (4) U S Dept of Commerce, Nat'l Bureau of Standards, Washington, DC ltr of 28 Jan 1983
- (5) Suggestions on Presentations
- (6) Lists of University/Industry participants at most recent Government/ Industry Conference, Baltimore, MD, 8-9 Feb 1983
- (7) List of Government and Industry participants at most recent Government/ Industry Conference, Baltimore, MD, 8-9 Feb 1983
- (8) Guidelines for FLC participants provided by Aladdin Industries



UNITED STATES DEPARTMENT OF THE INTERIOR

GEOLOGICAL SURVEY
345 Middlefield Road
Menlo Park, California 94025

January 26, 1984

Mr. Walter W. Perkins, Code 0131 Naval Ocean Systems Center San Diego, California 92152

Dear Mr. Perkins:

Mr. Cooper's letter and enclosures describing the Government/Industry Technology Transfer Conference scheduled for May 22-24, 1984, in Los Angeles have been reviewed by this office. Judging by the subject matter likely to be described and the probable attendees, it is unlikely that our participation would contribute much of interest to the group. As you probably know, the U.S. Geological Survey's primary responsibilities and interests are in research in the earth sciences, geology, geophysics, hydrology, topographic mapping, land information, etc. Our activities in instrumentation and "hardware" items that may be of transfer interest are limited. The specific instructions and conference arrangements described in the enclosures do not appear to be directed toward the kind of presentations we might contribute. It also appears that participation in the Conference must be limited to eleven activities.

In view of all these factors and after careful consideration, we feel that we should decline to participate in this particular conference. It is hoped that our prompt reply will be helpful in further planning.

Your efforts on behalf of the Federal Laboratory Consortium are appreciated and we wish you success with the Conference.

Thank you.

Sincerely yours,

George Gryc

Director's Representative

Western Region

cc: Doyle Frederick



UNITED STATES DEPARTMENT OF COMMERCE The Assistant Secretary for Productivity, Technology and Innovation

Washington, D.C. 20230

(202) 377-1984

20

November 15, 1983

MEMORANDUM FOR Jack Williams

From:

Norm Latker

Subject:

Patent Licensing Program

I do not believe that NTIS's patent licensing program has been reviewed to determine its impact on off-balance sheet development of its licensed inventions. I suspect that at best the program is neutral - neither ruling out or favoring off-balance sheet funding. But more likely the program is negative - biased away from off-balance sheet funding. This seems the case in light of the program's requirement that prospective licensees submit a development plan which must include;

- (i) A statement of the time, nature and amount of anticipated investment of capital and other resources which applicant believes will be required to bring the invention to practical application; and
- (ii) A statement as to the applicant's capability and intention to fulfill the plan, including information regarding manufacturing, marketing, financial, and technical resources.

If a prospective licensee intended to use a RDLP to finance development, it seems clear that it would have to be set out in its development plan. If the prospective licensee failed to do so, it would be most difficult to permit a RDLP's later use if the licensee's plan resulted in the grant of an exclusive license. This conclusion is based on the fact that the exclusive license is granted (after public comment) on the condition that the licensee follow the submitted plan. If the manner of financing development were to be later altered, this would amount to a major change in the plan that could be argued to require review of the license grant including the possibility of additional public comments.

Since I have not heard of any prospective licensee suggesting in its plan the intention of using a RDLP to fund development and in light of the apparent inability to switch to a RDLP later, it seems clear that Commerce has provided a negative environment for the use of RDLPs as an alternative means of financing development of government-owned inventions.

It seems to me that we should be positively encouraging the alternative use of RDLPs for financing the funding of the NTIS's portfolio (either in the development plans or as an alternative to the original plan). If we do not, it appears that only the traditional means of financing will be used which in theory limits the number of such inventions reaching the marketplace.

If you agree, I would like to meet with you and Lanse to discuss means of changing our policy in this area.

cc: Lanse Felker

LEGISLATION: H.R. 2965 included appropriations of \$300,000 for the Center for Utilization of Federal Technology (CUFT) to:

- establish a training and education program for the designated technology transfer agents at Federal laboratories to recognize those types of research data, technologies and processes which have the most potential for commercial application,
- 2. identify "growth" industries which would have the most interest in obtaining this information; and,
- 3. maintain a computerized data base of research and technology developed by the Federal laboratories.

The U.S. House of Representatives Appropriations Committee reporting out this legislation strongly suggests that CUFT contract out this education and training program, preferably with a non-profit organization. (Attachment #1)

CUFT has developed a preliminary plan to implement the activities above. Detailed work statements will be developed pending resolution of the recommended disallowance of the \$300,000 by the Senate Committee on Appropriations. (Attachment #2)

* Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Bill, 1986.

OVERVIEW OF PLANNED RESPONSE TO LEGISLATION

1. Training and Education

The training needs of Federal laboratory personnel span the ability to identify useful know-how for application in commercial processes to the understanding of patent licensing procedures to transfer commercially marketable technologies. Implicit in creating this capability, technology transfer agents must understand and master awareness and communication techniques so to establish ongoing relationships between laboratory personnel and U.S. industries as appropriate. Contract(s) with non-profit organizations already involved in industrial innovation and technology transfer would call for three training modules specific to different types of laboratory and agency personnel:

a. training for identifying, evaluating, and internal monitoring of technologies (i.e., proposed technology evaluation scheme at Federal laboratories developed by the Center for the Utilization of Federal Technology (CUFT), National Technical Information Service. (Attachments #3, 4, 5, and 6). An ongoing system needs to be established, with initial emphasis on developing training tools, visual aids, videotapes, manuals and texts. Representatives from agencies and major ORTAs

would attend a "teacher training course" in Washington, and be provided with tools for use at laboratories throughout the country. Techniques for both technical and commercial assessment based on access to market research are essential.

- b. developing understanding of the patent process and the incentives that can be provided to industry through exclusive licensing (e.g., The model for Managing and Transferring Intellectual Property Forms of Government Technology, developed by the Office of Federal Technology Management Policy, Office of Productivity, Technology and Innovation)
- c. designing methods of promoting technology to and interacting with industry. Special emphasis will be to use trade and professional organizations to act as a link to U.S. businesses. Part of this effort will be to identify techniques to "push" technologies as well as ways to locate and identify technology "needs". Input and assistance will be solicited from the Federal Laboratory Consortium, consistent with the Memorandum of Understanding between the CUFT and the FLC. (Attachment #7)

2. <u>Identification of "Growth" Industries</u>

This activity would be undertaken in cooperation with the PTI Innovation Data Analysis Center and other Department of Commerce agencies who would have access to this type of information. A contractor would develop a means for laboratories to reach out to these targeted growth industries.

3. Computerized Data Base

A computer base has been established in the Applied Technology Office, CUFT. This data base contains more than 3,000 new technologies and state-of-the-art advances generated within the past three years by Federal agencies and will be continued. Training to use the data base using online terminals at laboratory ORTAs as part of activities 1.a. and 1.c. can be incorporated provided funds are available.

BACKGROUND:

Technology transfer starts with dissemination of at least a basic amount of technical information. This imperative has caused NTIS to be both subtly entangled and openly involved in various aspects of the technology transfer process since its inception 40 years ago.

One of the most explicit statements of NTIS' broad responsibility for technology transfer is found in the President's Message on Science and Technology to the Congress in 1972. The President stated that "...the Government has a responsibility to transfer

n ne baran engin ber samaki bikan sepertua

the results of its research and development...to further this objective...we created the National Technical Information Service..." In that same message, the President directed the Secretary of Commerce to develop a systematic effort to promote Government invention technology to facilitate its transfer into the civilian economy. This specific responsibility was logically delegated to NTIS.

In the 1970's, NTIS developed new initiatives in response to these mandates. An office of Special Technology Transfer Services was created to insure a high priority for technology transfer and utilization in NTIS program development. During this period, development in NTIS' growth toward a mature technology transfer perspective included interactions and joint activities with the Federal Laboratory Consortium, the Economic Development Administration, and State and local government agencies. In addition, NTIS represented the Department of Commerce on the Federal Council's interagency Committee on Domestic Technology Transfer.

One of the most valuable of NTIS' examinations of the technology transfer process involved experimental programs designed to identify Government technology with potential for commercialization. An initial experiment in the early 1970's involved technologists at two well known research institutes, Battelle and IIT Research Institute. Several hundred Government inventions were evaluated for commercial potential. As a check on the selection process, many of the same inventions were evaluated by both organizations and correlated for consistency of evaluation results. In addition, a subset of these inventions was evaluated by the NBS Patent Evaluation Committee. Correlation of evaluation results between evaluators was extremely low.

In an expanded experiment, four outside contractors, including Bendix Research Laboratories, evaluated a group of Government inventions; in addition, these inventions were evaluated by the Government inventors and the inventors' technical supervisors. Again, there was little consistency among evaluators for what appeared to be the most promising inventions. Government evaluators were less likely to have an opinion of commercial potential and more likely to be optimistic when they did have an opinion than the outside evaluators. Experience in technology evaluation of the extensive ETIP and OERI programs at NBS are available for background.

Recognized as the primary U.S. agency concerned with systematic technology evaluation and transfer, NTIS presented the results of its experiments at two biannual world meetings of National Research and Development Organizations.

The first-hand experience gained by NTIS in operational and experimental programs has been invaluable to development of effective ongoing activities in support of a national technology delivery system.

With the formation of the Center for the Utilization of Federal Technology (CUFT) at NTIS, its Office of Federal Patent Licensing

and the Office of Applied Technology create a unique organization to implement and catalyze technology transfer. CUFT is currently working with the Federal Laboratory Consortium's Federal Laboratory-Industry Interaction Working Group to develop better linkages between laboratories and businesses. It is also working with the U.S. Department of Agriculture in their development of a patent awareness training program for laboratory personnel.

ECONOMIC AND STATISTICAL ANALYSIS

The Committee recommends \$30,543,000 for the Economic and Statistical Analysis programs of the Department. This amount is \$1,024,000 above the President's request and is \$109,000 less than appropriations provided for the current fiscal year, including amounts in the Fiscal Year 1985 Supplemental Appropriations Bill (H.R. 2577) as passed the House. The Committee recommendation provides for uncontrollable cost increases of \$1,763,000, and reductions related to the program freeze (-\$787,000), the Deficit Reduction Act of 1984 (-\$482,000), and the administrative cost reduction (-\$524,000). In addition, the Committee has not restored the \$812,000 related to the five percent pay reduction proposal. If such legislation is not enacted, the Committee understands that the Administration will submit a budget request for the full amount of

the costs related to this appropriation account. The Committee recommendation includes restoration and full funding for fiscal year 1986 for the Office of Productivity, Technology and Innovation (OPTI). The budget request had assumed that this Office would be phased out in fiscal year 1986; however, the Committee felt that the work conducted by this Office was of such importance to the nation's economy that the Office should continue to be funded. In addition, the Committee has included \$300,000 for the Center for Utilization of Federal Technology, as envisioned by the Stevenson-Wydler Technology Act. Section II of that Act established the Center for Utilization of Federal Technology (CUFT) within the Department of Commerce. CUFT was to serve a clearinghouse function, in that all technology assessments prepared by Federal laboratories were to be sent to CUFT for filing. Anyone searching for a particular technology could consult CUFT, which in turn would put the individual in touch with the Federal laboratory which had done research in the field and might be able to provide relevant information or technology. The Committee instructs the Department to establish a training and educational program for the designated technology transfer agents at Federal laboratories. This program would train the technology transfer agents to recog-Onize those types of research data, technologies and processes which have the most potential for commercial application. It would also identify the growth industries which would have the most interest in obtaining this information. The Committee strongly suggests that the Center for Utilization of Federal Technology contract out this education and training program, preferably with a non-profit organization already involved in industrial innovation and technology transfer. As there are more than 300 Federal laboratories of significant size, this should be envisioned as a multi-year program,

which would require a computerized data base of research and technology developed by the Federal laboratories.

		•		
	*			
			•	
•				
	· · · · · · · · · · · · · · · · · · ·			4
•				
		化化化化物 化铁铁矿矿 医二甲草		
				•
				•
× * * * * * * * * * * * * * * * * * * *				
	· 自用的名词复数 表示 医皮肤 医囊腺管			
			•	
				•
and growing the second				

ATTACHMENT

Continued

DIRPATATIVE STATEMENT OF NOW BUDGET REPORTED IN THE BILL FOR FISCAL YEAR 1986

[Amounts in covians]

99TH CONGRESS 1st Session

21.301.60

1241,390,000

-362,243,200

11,922,021,000

11.659.270.000

12,262,903,200

SENATE

REPORT 99-150

DEPARTMENTS OF COMMERCE, JUSTICE, AND STATE, THE JUDICIARY, AND RELATED AGENCIES APPROPRIATION BILL, 1986

OCTOBER 4 (legislative day, SEPTEMBER 30), 1985.—Ordered to be printed

Mr. Rudman, (for Mr. Laxaur), from the Committee on Appropriations, submitted the following

REPORT

[To accompany H.R. 2965]

The Committee on Appropriations, to which was referred the bill (H.R. 2965) making appropriations for the Departments of Commerce. Justice, and State, the Judiciary, and related agencies for the fiscal year ending September 30, 1986, and for other purposes, reports the same to the Senate with various amendments and presents herewith information relative to the changes made.

AMOUNT IN NEW BUDGET (OBLIGATIONAL) AUTHORITY

Amount of bill as passed by the House	\$11,922,021,000 21,361,000
Total bill as reported to Senate	12,265,253,200
Amount of budget estimates, 1986, as amended	11,659,270,000
Under the appropriations for 1985 Over the estimates for 1986	364,593,200 241,390,000

to the day that provides an inference in Estational over the 1985 appropriated level. Finally, the Committee includes \$791,000 in fiscal year 1985 carryover balances.

The Committee has included \$100,000 provided by the House for a

census of horticulture.

The Committee recommendation restores 80 percent (\$2,176,000) of the 5-percent pay reduction originally proposed in the President's budget a reduction of \$545,000.

SERVICE SECTOR CENSUS

The service sector generates 70 percent of GNP and employment, yet accounted for only 40 percent of the Bureau of the Census' budget for the 1982 quinquennial census. In view of this fact, the Committee encourages the Bureau to develop a long-range plan for achieving parity in data collection efforts between the goods and services producing sectors. Accordingly, the Committee directs the Bureau to report to the Congress by February 1, 1986, on its plans to expand the 1987 and 1992 quinquennial censuses to include additional data on the service sector of the economy.

ECONOMIC AND STATISTICAL ANALYSIS

SALARIES AND EXPENSES

1935 appropriations to date	\$30,652,000
1935 appropriations to tale	30,331,000
1986 budget estimate	20 517 000
House allowance	10.149.000
Committee recommendation.	30,100,000

The Committee recommends an appropriation of \$30,168,000, a decrease of \$484,000 from 1985 appropriations to date. The amount recommended is \$163,000 below the budget estimate and is \$375,000 less than the House allowance.

This appropriation provides for the Bureau of Economic Analysis programs to maintain the national income and product accounts includ-

ing GNP, personal income, and foreign investment accounts.

The Committee recommendation includes the program budget request as submitted, which includes the phase out of the Productivity. Technology, and Innovation Program. However, the Department is di- !! rected to maintain the Office of Strategic Resources at the fiscal year 1985 funding level.

The Committee recommendation does not include \$300,000 provided by the House for the Center for Utilization of Federa Technology. In addition, the Committee has restored 80 percent (\$649,000) of the 5-percent pay reduction originally proposed in the President's budget, a reduction of \$163,000.

ECONOMIC DEVILOPMENT ASSISTANCE PROGRAMS

1985 appropriations to date	
1986 budget estimate House allowance	180,000,000
Committee recommendation	160,000,000

The Committee recommends \$160,000,000 in fiscal year 1986, a decrease of \$70,730,000 from 1985 appropriations to date and a reduction of \$20,000,000 from the House level.

The Committee intends that the fiscal year 1986 program components be funded as follows:

Public works grants	\$116,000,000
Planning assistance	
Districts	
Indians	(2,500,000)
Urban,	(4,000,000)
Technical assistance	7,000 000
University centers.	(4,000 FFF)
Economic adjustment grants (title IX sudden and severe projects)	15.500

Consistent with the action of the Congress in approving the fi year 1984 Supplemental Appropriations Act, the Committee directs \$6,000,000 of the funds recommended for public works grants be ma available for a grant to the Institute for Technology Development at Mississippi.

The Committee recommendation includes bill language authorizing a

loan guarantee program of up to \$150,000,000.

The Committee encourages the Economic Development Administration to give consideration to projects in rural and agricultural regions of the country. A good example of such a project is the industrial park development proposed by the Dodge City/Ford County Development Corp., in Kansas, The Committee urges EDA to give every consideration to this proposal.

The Committee recommends that adequate funds from plunning assistance be used in a statewide study in Iowa where an economic emergency has been declared to analyze methods of finding employment for those dislocated and methods of maintaining Government services.

The Committee recommends a proviso in the bill that would prohibit any funds from being used for attorneys fees in connection with EDA grants and contracts. The Committee is concerned that attorneys are. being employed to solicit EDA assistance for proposals. Over the years, an organization of State, local, and Federal officials have developed. projects for EDA assistance. In the Committee's opinion, it is unnecessary for localities and institutions to employ lawyers to develop and expedite projects. It is not the intent of the Committee that this proviso shall interfere with the normal review of projects for legal sufficiency.

TITLE I—DEPARTMENT OF COMMERCE

A total of \$2,112,004,000 is recommended for the Department of Commerce, which is \$178,267,000 less than the amount for 1985, \$396,473,000 more than the budget estimates, and \$7,883,000 under the House allowance. Increases over the budget requests occur primarily in appropriations for the Economic Development Administration and the National Oceanic and Atmospheric Administration.

GENERAL ADMINISTRATION

SALARIES AND EXPENSES

1985 appropriations to date	\$36,483,000
1980 Dudget esumate	16 227 000
riouse allowance	31 600 000
Committee recommendation.	32,343,000

The Committee recommends an appropriation of \$32,343,000, a decrease of \$4,140,000 from 1985 appropriations to date. The amount recommended is \$3,884,000 less than the request and \$734,000 more than the House allowance.

This appropriation provides for the executive direction of the Department of Commerce, including the secretarial officers and their immediate staffs; for departmental staff services for management and administration, including such functions as budget, program evaluation, congressional relations, public information, legal services, organization and management studies, personnel, systems, publications, and security; and for the audit and investigative duties of the inspector general.

The Committee recommendation will provide for the same program level as proposed in the budget request through the use of \$3,700,000 in fiscal year 1985 carryover balances. In addition, the Committee recommendation restores 80 percent (\$734,000) of the 5-percent pay reduction originally proposed in the President's budget, a reduction of \$184,000.

Bureau of the Census

SALARIES AND EXPENSES

1985 appropriations to date	\$85,259,000
1700 Oudget estimate	00 K20 MM
riouse allowance	89 667 000
Committee recommendation.	90,400,000

The Committee recommends an appropriation of \$90,400,000, an increase of \$5,141,000 over 1985 appropriations to date. The amount rec-

This appropriation provides for the Bureau of the Census statistical programs which include the measurement of the Nation's economy and the demographic characteristics of the population. These programs provide a broad base of economic, demographic, and social information used for decisionmaking by governments, private organizations, and individuals.

The Committee recommendation includes \$357,000 as requested to enhance current service trade reports on the transportation, finance, and communications industries, as well as \$500,000 for foreign trade statistics. In addition, the Committee recommendation accepts the House reductions of \$280,000 for demographic reports and \$581,000 for international statistics, as well as a \$3,000 general reduction. However, the Committee has not included \$700,000 provided by the House for general economic statistics, including data on small manufacturers.

The Committee also recommends \$300,000 to allow the Bureau of the Census to conduct a general economic survey of the communications sector which has been affected by deregulation and technological

The Committee wishes to reaffirm the commitment of the Congress, adopted in the Commerce Appropriations Act (Public Law 96–536) for fiscal year 1981, which directed the Secretary of Commerce "to expedite the program of collecting, through appropriate surveys, data on benefits received and data on participation in federally funded, in-kind benefit programs * * ." The Committee further requests that the Department submit a report on its conference on the measurement of noncash benefits scheduled for December 1985.

The Committee recommendation restores 80 percent (\$2,141,000) of the 5-percent pay reduction originally proposed in the President's budget, a reduction of \$536,000.

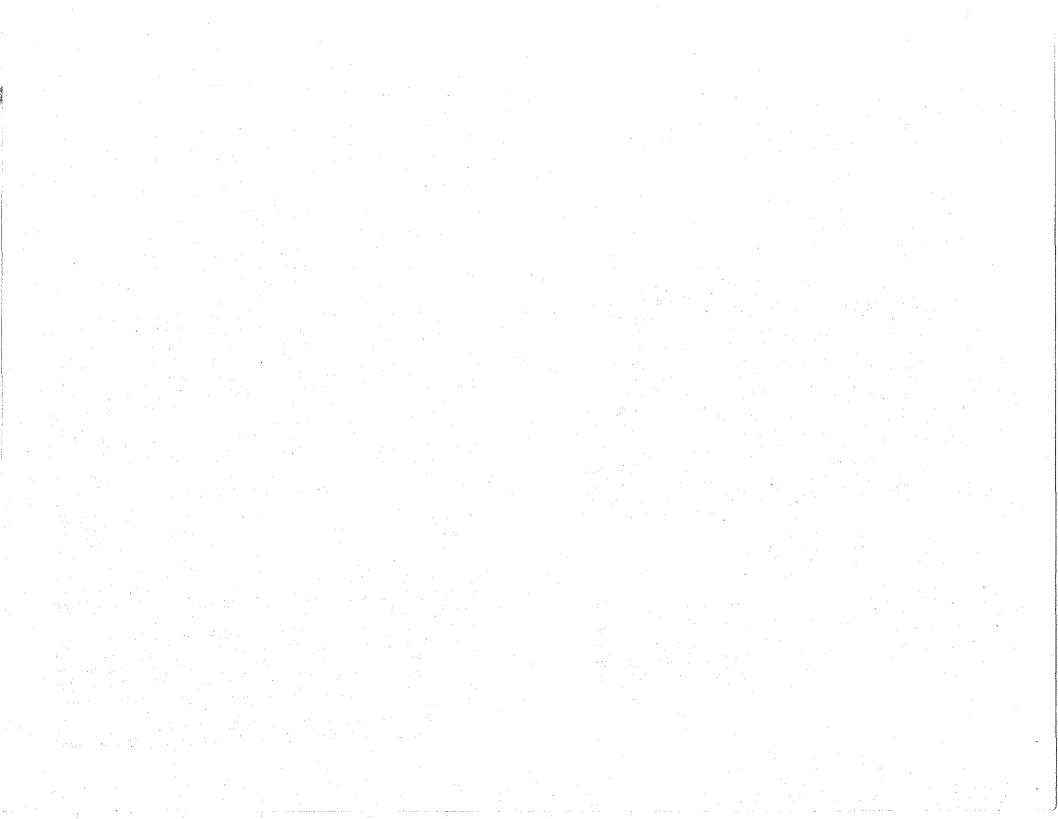
PERIODIC CENSUSES AND PROGRAMS

1985 appropriations to date	\$81,000,000
1986 budget estimate	108,523,000
House allowance	
Committee recommendation	105,687,000

The Committee recommends an appropriation of \$105,687,000, an increase of \$24,687,000 over 1985 appropriations to date. The amount recommended is \$2,836,000 less than the budget estimate and \$576,000 more than the House allowance.

This appropriation funds periodic censuses and surveys covering the major economic and demographic areas once or twice each decade. It also provides for the maintenance of geographic support activities required by the various censuses, the preparation of population and per capita income estimates, and the acquisition of large-scale data processing equipment.

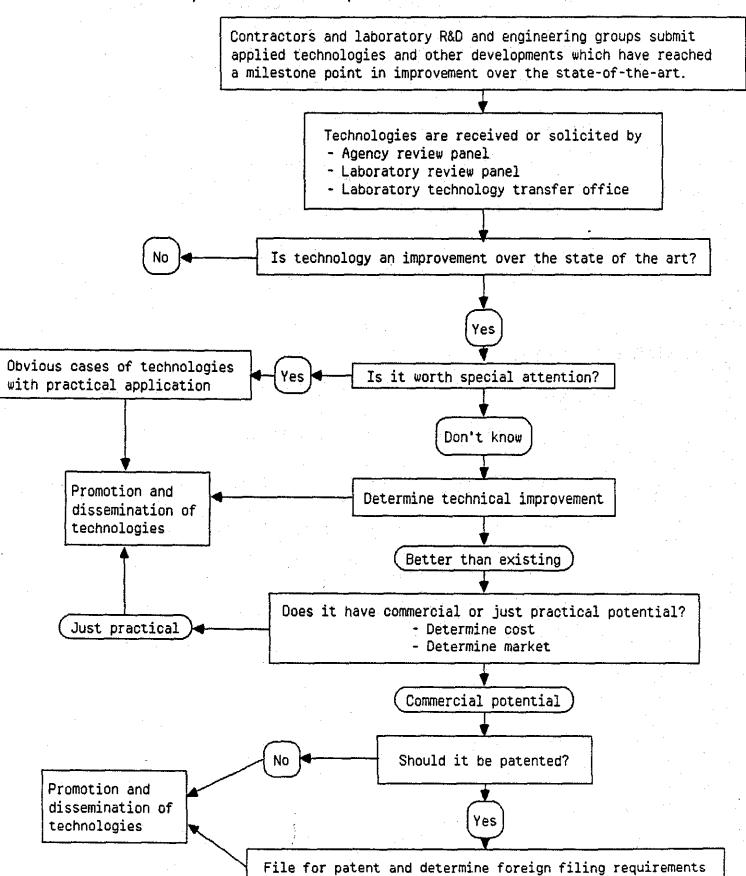
The Committee recommendation includes \$1,178,000 of the requested enhancement of \$2,278,000 for data processing systems. This will pro-



Laboratory Technologies with Commercial or Practical Application (New processes, techniques, equipment, software, or materials)

Definitions: Commercial technologies-Those which can be developed into a marketable product.

Practical technologies-Those which can be used to improve a process or some operation but which cannot be directly developed as a marketable product.



EXAMPLES OF

Commercial technologies-

Portable communicator has been developed for non-vocal people - Veterans Administration

Gamma rays kill moth larva fruit - Dept. of Agr.

Hollow-sphere production line developed - NASA

Portable instrument provides instant blood level carbon monoxide concentrations - Navy

Dosimeter registers radiation dose to sensitive skin layers as well as to deeper layers - Energy

Portable X-Y scanner uses one drive motor for surface scanning - NASA

Heat recovery system designed to recover engine heat for space heating in fishing vessels - NASA

EXAMPLES OF

Practical technologies-

Mounting fixture for a rotary sander ensures a uniform finish - NASA

Ball bearing assembly device developed permitting dry assembly - Navy

Computer program aids axial compressor design by yielding blade configurations and aerodynamic flow - NASA

Laminate layers are cataloged for fluidic devices - Army

Monitor using tunable atomic line molecular spectroscopy improved to detect toxic organic compounds - EPA

Long term corrosion data to zircaloy - 4 in water established - Energy



UNITED STATES DEPARTMENT OF COMMERCE National Technical Information Service 5285 Port Royal Road Springfield, Virginia 22161

DEVELOPMENT PLAN TO PRODUCE A GUIDE TO COMMERCIALIZING FEDERAL TECHNOLOGY

The Center for the Utilization of Federal Technology proposes to develop and publish a guide to assist U.S. businesses in the commercialization of Federal technology. The guide would be an overview of the steps required to identify potential technologies; to their development and to carry out their production and marketing.

It has been established through discussions with various Federal agencies that there is a need to assure that small companies and individuals developing Federal technologies are cognizant of the necessary business requirements to commercialize these technologies.

Agencies will be solicited to contribute to the production of the publication. The estimated cost is \$60,000.

AUDIENCE:

- o Small businesses or ventures engaging in new technology development
- o Individuals who are technology-oriented, not businessoriented

BOOK FORMAT AND STYLE:

- o Audience has a technical education, but may not have business experience
- o Between 100 to 150 pages
- o Written as a guide
- o Overviews innovation and business steps
- o Provides a thorough reference to other published material or contacts, e.g., associations

TABLE OF CONTENTS

Introduction - Innovation Process Sources of Technology

Government-owned Inventions

How to find inventions

Getting more detail about inventions

How to obtain a license

Technology in the Public Domain

How to find the technology Getting more detail about the technology

Newness
Fit with existing facilities and skills
Proprietary position
Servicing requirements
Technical feasibility
Legal considerations
Organizational support

Product Development

Engineering and Prototype Development

Scale up Testing Refining Production

Refining Production engineering

Market Analysis

Market size and expected growth trends
Market positioning
Effect on existing product line
Competitive status
Distribution characteristics

Legal Considerations

Restrictions by statute Product standards Performance Safety Material and construction Trademark and copyright

Strategies for Production and Marketing Business Plans

Return on investment (ROI)
Overall profit contribution
Total investment requirement
Profit/risk ratios
Effect on cash flow
Accessory income possibilities

Marketing

Market position
Barriers
Pricing
Competition
Cost data
Distribution method
Alternative product applications

Financing Development

Assessing ventures worth
Funding sources
Funding proposals
Assessing cost of funding

Annotated Bibliography