014-028

- o U.S. spends about 2.7% of GNP or R&D -- compares with about 2.5-2.6% for both Japan and Germany

- o Government funds or performs about half this work for tow major reasons -- military and civilian/economy needs.

- o Economy surged after two World Wars, in part because of wartime technology, e.g. jet engines, synthetic rubber, transport aircraft, radar, electronic miniturization, aluminium production, and penicillin (discussed later).

- o In a cold war, the U.S. economy is handicapped if it can not benefit from the unclassified technology as it is developed, rather than waiting for the war to end. 95% of DOD R&D is not classified, but much is not actively commercialized.

- o N.Y. Times article on competitiveness and Military R&D spending.

- o Commercialization -- bring technology to market in new products or processes.

  -- military needs -- secondary use (oil spill containment films for mosquito control)
  -- joint use (weld quality monitoring)

  -- civilian needs -- primary use (vaccines, seeds)

- o Look at civilian technology

  -- 1968 GAO report on medical products -- none based on NIH research.

  -- 2 types of technology -- Public domain information
  -- Intellectual property

- o Publish or perish, no reward for managing as intellectual property, thus no protection of commercialization investment against foreign or domestic copying.

- o Government technology dissemination programs like NTIS can even destroy commercial value of a technology.

- o NIH institutional patent agreements

- o Tale of penicillin vs. gene splicing.

- Types of performers of Government-funded research

  -- Nonprofit contractors at own site

  -- For-profit contractors at own site

  -- Federal laboratories
     - Government-operated
     - Nonprofit contractor operated
     - For profit operated

- 1980 Bayh-Dole Act, first legislation.

- OMB Circular A-124, first Commerce authority -- Stockman letter asked Secretary to extend principles of contractor ownership to all Government contractors.

- Principles

  -- Decentralize authority to manage technology as near as possible to originating organization that understands it best

  -- Provide incentives for inventors and their managers to identify and promote technology that would have commercial potential if protected and managed as intellectual property

  -- Provide private sector with property rights necessary to protect investment.

- Consistently resisted by patent attorneys of agencies with either Government-ownership statutes (NASA, Energy) or large patent attorney staffs (Navy).

File w/speeches

1. You are all aware that on Oct 3 of last year an important law amending 96-517 passed. The primary purpose of the law (P.L. 98-620) was to enhance your ability to manage, assign or license University inventions resulting from federal funding.

2. I believe passage of P.L. 98-620 was prompted in large measure by Congress's recognition of your success in managing the invention rights left to universities under P.L. 96-517.

3. This is clearly reflected from an Office of Technology Assessment study and a Science magazine summary of the study. The study found the U.S. holds "a commanding lead over its industrial competitors in the development and application of biotechnology". Science explains the lead as ~~being based on~~ "recently established links between University scientists and biotechnology companies that have moved the technology rapidly into the private sector." Science further indicates that "University industry links have not flourished as vigorously in Europe and Japan".

4. Over the last 3 years corporate contributions have been said to have increased to about 6-7% of total academic R&D, or about $400-$500 million annually.

5. Your success is NOT going unnoticed. The European common market research community recently announced its intent to abandon large targeted development programs in favor of more basic research and U.S. style university-industry collaboration in furthering the results of this research to the marketplace.

6. Similarly, prompted by the threat of the end to free access to U.S. technology, the most recent Japanese budget increases basic research funding at universities and calls for closer industry-university cooperation in Japan.

7. If any of you are frustrated by the difficulty of technology management take heart — you are doing what the rest of technological world wishes to duplicate. — Imitation is the sincerest form of flattery.

8. Now to address P.L. 98-620. The Act amends 96-517, as follows:

~~1. Ends the discretionary exclusion~~

2. It ends Agency discretion to exclude University run Government owned laboratories from the general rule of University ownership of federally-funded inventions. This impacts primarily on the D.O.E. laboratories who are conducting about 3 billion dollars of research annually. ~~This~~ Henceforth, the first option

to ownership of inventions resulting from that research will be in the universities/nonprofits managing the labs.

b. As part of the change affecting university/nonprofit contractors of Gov't owned facilities a limit was placed on the amount of royalties that the contractors are entitled to retain.

c. The Act includes the favorable reporting provisions that were developed in OMB Circular A-124. These provisions have been proven to work. Small Bus and Nonprofits are now assured of their continuance beyond Feb. 198 when A-124 is scheduled for sunset expiration.

d. The Act repeals - conditions placed on licensing of inventions by universities/nonprofits.
5 yr. cap — limitations on licensing by pat. management corp.

e. Regulation drafting is consolidated in Commerce — Easier to make necessary changes

f. Definition of invention expanded to cover inventions included in the Plant Variety Act.

g. Prohibits ~~on~~ agency retention of patent rights in any invention made under an educational awards (fellowship, training grant, etc) ← Important permits fellows on privately funded projects

Foreign Competition

Let me try to put that ~~matter~~ question in context.

When a federally-funded creating organization does not establish a proprietary position in its ideas, the organization is really putting those ideas into the public domain. In the public domain they are freely available not only to American but to foreign industry.

The Japanese especially understand this past policy and continue to exploit it beyond any reasonable expectations. They scour the public domain for our basic research results — bring it back to Japan — add some value to it thus creating their own proprietary position — and then export the products covered worldwide.

Insert: Using this technique the Japanese can predict that they will take the lead in all technologies by the end of the decade.

Our change in policy has had a very visible effect on Japanese R+D policy — recognizing we are moving to close down ~~NO~~ easy access to our publicly funded research ideas and facilities by giving ownership of technology to our creating organizations they have increased funding their own university basic research facilities and are actively ~~are~~ trying to buy access into ours.

But our federal laboratories our still dealing on a public domain culture and the Japanese are clearly taking advantage of that in places like N.I.H.

There are 1000 foreign ~~investigators~~ ~~at N.I.H.~~ and 700 U.S investigators at N.I.H. Of 1000 foreign investigators 400 are from foreign industry. 100 of these are from Japan and so from Germany. Only 10-15 of the U.S. investigators are from the U.S. industry. ONLY 3 U.S. industry investigators are in Japanese labs.

These dramatic statistics are not going unnoticed at N.I.H.

Dr Wyngaarden the N.I.H director began advising U.S. industry last fall that the P.L. 99-502 creates a whole new environment for U.S. industry investigators at N.I.H.

1st the Act permits N.I.H. to accept U.S. investigators with industry funds to pay for them.

2nd given a delegation to manage technology - N.I.H. can now agree in advance to ~~[illegible]~~ license industry sponsors under ideas developed jointly at N.I.H. with U.S. industry investigators.

3rd With the prospect of royalty return to N.I.H, industry can be better assured that inventions will be identified & patented.

Dr. Wyngaarden's initiatives under the Act clearly intended to correct the imbalance between foreign & U.S investigators at N.I.H. I would further note that Dr Wyngaarden has the authority under P.L. 99-502 to deny entry into N.I.H. of foreign investigators whose countries do not provide reciprocal treatment to U.S. investigators. Further, the Act leads to the need to require foreign investigators to report inventions made while at N.I.H. for equitable disposition — This is not now done under any stated policy.

we hope other fed. Labs will follow N.I.H's example.

What drives this entrepreneurial revolution? ~~Part the answer starts with John Locke~~ Let me theorize at least to ~~the~~ high-technology entrepreneurship.

John Locke, ~~the~~ was a British philosopher and one of the earliest known supporters of constitutional government. He asserted that constitutional government could only be effective if it ~~guaranteed~~ recognized the natural rights of man including the right to life liberty and property. The recognition of these rights ~~appeared~~ was considered to be the best way to assure prosperity and thus stable government.

~~Locke said that a man has a right in himself and thus in his own labor; in turn he has a right to what "he hath mixed his labor with" or a right to property.~~

Locke's proposition is widely held to be the ~~precursor of the~~ underpinning of the U.S. constitution. While it is unclear whether Locke intended to include intellectual property as part of man's natural right to property, the U.S. constitution gives the Congress the discretion or power to secure for limited times to inventors the exclusive rights to their discoveries. ~~The Congress's action in enacting the patent laws~~ ~~The enactment~~

Congress's enactment of the patent laws evidences their belief that the right to own intellectual property is a natural right of man, and ~~a pre~~ thereby a necessary element for successful constitutional government ~~and [illegible]~~, ~~[illegible]~~ and the prosperity envisioned by such governments. Similarily state law protects trade secrets.

3-8 years to be good. Competes w/ other investments

1. Morrill Act } agricultural tech. transfer
2. Hatch Act }

Three trade-offs
1. To far from market
2. No organization participation
3. No entrepreneurship

Many new means of T.T. of Univ. Research. They do not conflict University's present structure

Management focus for T.T. is being enhanced at universities to include the new means of T.T.

In order for Univ.-Ind R+D collaboration to be success.
1. Recognition of unique roles of each partner be known.
2. Advance understanding of partners responsibilities.
3. How are rights to the results to be protected.
4. (Right of Univ. investigator to publish is unchallengeable)
4. Royalties.
5. Peer review of project on periodic basis.

Creating capital formation for T.T.
1. 60-40 split of revenue source
"Teaming Agreement"

Leveraged buyout

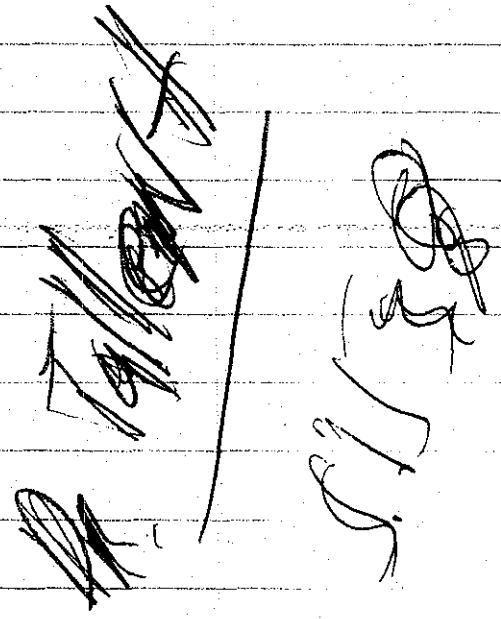
NON-TRADITIONAL T.T. —
Venture Capital
RDLP
Start-Up Joint venture
Add cost-sharing for govt.
Rubic Offering

Two guys in ballon lost
Ask guy on ground where they are?
Up in a ballon
Obviously lawyer — why? told us exactly what we wanted to know but we're no better off than before.

RDLP —
1974 — U.S v. Snow
1979-80 People started to use.

Abandoning white rats in medical testing
Railway to Attorneys
a) Multiple faster
b) Don't get as attached to them.

Dr. Tallent



How important patents? defensive or offensive use.
If used offensively very important.

1. Ideas are product of NIH
2. These ideas are not finished products
3. We either develop them or industry does. NORM
4. These ideas will not sell themselves — must be sold — they are fragile and if not coddled will die — The thought that publishing is going get invention made is incorrect.
5. PMA report — everything touched by our funds belongs to Gov't. — Drug inventions
6. $250,000 to get NDA — industry needs protection.
7. Res. Triangle case. — controls in contract.
8. Dennis Case — Grantee development depends on University — maybe we should be providing services that Research Corp. does? — NASA does — our inventions much more important.
9. M. Kolobow Case — Employee
10. M. Speedsman case — Employee needs NDA — Can we give rights?
11. 8.2(b) + 8.2(d) — dead? :(
12. How do we face issue?
13. AVCO + AMF

(10)

~~Of course~~ The Tulane article's conclusion that the legislative history of the Act supports ~~the~~ its "reasonable price" theory is clearly refuted by the above comments.

In addition, ~~it should also be noted how~~ one needs to take into consideration how the public statements ~~of~~ referenced in the article are used to support the authors' conclusions.

My Sept. 27, 1976 statement on government patent policy referenced in footnote 15-7 is used as the source of the following comment on pg. ___

"There was also some testimony indicating that the pharmaceutical industry acted as a bloc to extract a favorable government patent policy and boycotting government patents in order to gain greater rights."

as the precursor to ~~of Bayh-Dole~~ the Act

My actual comment makes no reference whatever to industry extortion to gain greater rights.

More disconcerting is the fact that the entire statement which I have attached, is directed to the ~~progress~~ Administration's progress in extending the administrative policy referenced by Sen. Bayh to all of the federal R+D ~~policies~~ agencies. This statement provided an ~~far better~~ extensive justification for the need for Bayh-Dole type legislation ~~from anything~~ beyond those the author's choice to quote.

11

~~Indeed this kind of~~ judgment is evidenced in the ~~review of what the authors define as~~ "The Legislative History of The Bayh-Dole Act" ~~starting from page 656 of the article through to page 667 clearly~~ on pages 656-667 further indicates that ~~this~~ it is not a legislative history ~~as commonly understood to be~~ limited to the hearings and report on a specific piece of legislation introduced and passed by the Congress. In the case of the Bayh-Dole Act, ~~such legislative~~ that history is ~~understood to be limited to~~ the ~~1970 hearings and Senate Report No. 96-400~~ May 16 and June 6, on S.414 which resulted in the Act.

In comparison, the legislative history ~~put forth~~ set out by

(12)

This kind of selectivity is evidenced in the purported "Legislative History of the Bayh-Dole Act on pages 656-667 of the article. ~~which is not limited to t~~

The legislative history includes the law itself, the committee report on the bill and the floor debate on that particular bill.

The legislative history does not include debates on other bills that were not enacted.

The legislative history set out on pages 656-667 of the article.

Norman J. Latker
Page 2
March 29, 2004

DRAFT

~~on pages 656-667~~

~~the [illegible]~~ is a compilation of selected comments and quotes with ~~their~~ the author's interpretation ~~by the authors~~. The bulk of the comments and quotes are derived from various oversight or legislative hearings either preceding, concurrent with or after the introduction of S.414 directed to legislative hearings on issues outside of Bayh-Dole. ~~[illegible]~~ These quotes are made in the context of legislative language and issues so different from that of the Act ~~[illegible]~~ that ~~[illegible]~~ objective ~~to~~ interpretate the Act. Research would not use them to

The comments and quotes made outside the legislative history of S.414 are ~~found~~ identified in footnotes 1~~46, 151, 153, 154, 157, 169, 175, 179, 181, 194, 197, 199 and 202-227~~ of the total number of 81 ~~footnotes (146 to 227)~~ on pages 656-667. Indeed, only 12 footnotes, ~~152, 155, 156, 170-174, 180, 196, and 200-201~~ of the total 82 are directed to comments or quotes from the 1979 hearings or Senate Report 96-480 ~~on S:414~~. Not one of these 12 explicitly or by implication addresses the issue of pricing. Indeed, footnotes 174, 180 discussed by Sen. Bayh references a discussion in Senate Report 96-48 limited to the "pay-back" provision of ~~the~~ a deleted S:414 ~~which was deleted before passage of the Act.~~ The author's ~~comment on this~~ which the ~~[illegible]~~ incorrectly maintains ~~that this discussion somehow~~ supports their thesis on pricing.

~~The preponderance of the comments and quotes identified to be outside of what is commonly known as a~~

20 of the 70 footnotes ~~outside~~

12

~~[illegible]~~ skewed to support their reasonable price ~~thesis~~ theory.

(13)

~~Act's legislative history~~, reflect quotes by well-known opponents of contractor ownership of inventions touched by government funding including Adm. H.G. Rickover, Sen. Russell Long, Cong. Jack Brooks, Ralph Nader and others.

There is nothing in these quotes beyond their objection to contractor ownership that suggests that they would accept a contractor ownership policy if it was conditioned by a reservation

in the government to determine a reasonable price after marketing a drug. ~~Further, there is~~ No evidence ~~that proponents of the Act~~ agreed that the march in provisions ~~were intended~~ ~~would be target triggered~~ were to ~~defined~~ be defined as suggested by the Tulane article, so as to mollify critics of the Act ~~wh~~ even though ~~the critics made no such~~ they ~~need~~ made no suggestion to so.

P. 647 At the same time, the policy ensured that there could be no abuse of the title incentive by enacting a strict price control mechanism as part of the so-called manch-in rights maintained by the government to oversee its investments.

P. 648 — ARNO/DAVIS

"It does not expressly establish any mechanism whereby the funding agency can reliably learn whether patentees are honoring their obligation to charge no more than a reasonable price for an invention".

P. 649 — What "available to the public on reasonable terms means is not jurisprudentially troublesome, even absent the clear legislative history of the term"

14^2
8
111111 12
4
25

6, 1, 1
12, 4,
14, 2
25

8 ~~24~~ ~~78~~ 65
65
11
76

~~Nothing in these articles~~ ~~[illegible]~~ ~~[illegible]~~ ~~[illegible]

Pg. 6-10 — March-in

June 6th

1. First do no harm
2. Reality — harm is done
3. Sometimes
3. Ghetto
3. Critics
4. NASH - Equilibrium
5. BATH - DOLE Equilibrium
6. Not conflict if consistent w/ assigned duties
7. Bayh - Dole Success
8. ~~etc.~~ Economist
9. letter NIH

especially delegation to Dept. !!

~~BAO~~ GROUNDRULES

My comments are prompted by Yours Apr. 20 Art: Presume to be factually correct.

Establish the context of discussion

2) Not talking about clinical testing by an NIH investigator of industry owned drug.

1) Not interested in stock ownership of biotechs. problem of

3) Main interest ~~is industry~~ is consulting arrangements ~~but~~ between industry and NIH investigators

If ~~this~~ the relationship is intended to further or ~~an investigator's~~ capitalize on an investigator's findings from his assigned duties ~~that is no~~ there can be no conflict and is clearly authorized by FTTA of 1986 and 1987 Executive Order

~~Reqs~~. If the Reqs. are not a breach of the letter of these laws they are completely inconsistent with the spirit of the laws

This is clear from ~~the~~

If in fact the determination of conflicts in these situations is intended to be made at Dept. level, ~~[illegible]~~ especially if determined by attorneys w/ NO science background — completely inconsistent w/ the delegation to enter into these relationships to the laboratory level.

Bremen's comments are correct — and based on along history which was changed by the FTTA + Executive Order.