

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 two 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.

- o 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
- o 1980 Bayh-Dole Act, first legislation.
- o OMB Circular A-124, first Commerce authority -- Stockman letter asked Secretary to extend principles of contractor ownership to all Government contractors.
- o 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.
- o ~~Consistently resisted by patent attorneys~~ of agencies with either Government-ownership statutes (NASA, Energy) or large patent attorney staffs (Navy).

R. Kite
W. J. ...
NO

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:
~~It ends the discretionary provision~~
It ends agency discretion to exclude university non-government owned laboratories from the general rule of university ^{non-profit} ownership of federally-funded inventions. This impacts primarily on the D.O.C. laboratories ^{who are conducting} about 3 billion dollars of research annually. ~~Thus,~~ Henceforth, the first option

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

d. 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.

e. 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 pub. management corp.

e. Regulatory 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 ~~any~~ agency retention of patent rights in any invention made under an educational award (fellowship, training grant, etc.) of important permits fellows for directly 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 Americans 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 own 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.

Our change in policy has had a very visible effect on Japanese R & D policy — recognizing we ^{moving to} are closing down ~~open~~ access to ^{publicly funded} our 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 are still dealing in ^{namely a full} 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 50 from Germany. Only 10-15 of the U.S. investigators are from the U.S. industry. Only 3 U.S. industry investigations are ^{at Japanese labs.}

USury
this
tech. are
the Japanese
are
one of
that they
will
take
the
lead
in
all
tech. by
end
of
the
decade

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

Dr Wynsgarden the N.I.H. director began advising U.S. industry last fall that the PL 99-502 creates a whole new environment for U.S. ^{industry} investigations at N.I.H.

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

2ND give a delegation to manage technology - N.I.H. and now agree in advance to ~~patent~~ 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. Wynsgarden's initiative is clearly intended to correct the imbalance between foreign & U.S. investigators at N.I.H. ^{under the Act}

I would further note that Dr. Wynsgarden has the authority under PL 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? ~~But the answer starts~~
~~with John Locke let me recognize at least~~
to the high-technology entrepreneurship.

John Locke ^{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
^{recognized} ~~guaranteed~~ the natural rights of man
including the right to life, liberty and
property. ^{The recognition of these rights} ~~is~~ ^{appears} to be the best way to assure ^{consideration}

~~Locke said that a man has a right to~~
~~himself and thus in his own labor; in fact~~
~~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~~ ^{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 law~~

~~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~~ ^a ~~pre~~ ^{truly}
a necessary element for successful
constitutional government ~~and prosperity~~.
~~and~~ the prosperity envisioned by
such governments. Similarly state
law protects trade secrets.

Prosperity
and thus
stable
government.

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

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

- Three main steps
- 1. To Agr. from market
 - 2. No participation portion
 - 3. No independence

retention

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 one 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

Team
Essential
to
Get
Funding
to
Work

- NON-TRADITIONAL T.T.
- Venture Capital
 - RDLF
 - Start-Up ^{joint venture}
 - Add cost-sharing for govt.
 - Public Offering

Two guys in bullpen - lost

Ask guy on ground where they are?

Up in a bullpen

Obviously lawyer - why? told us exactly what we wanted to know but we're no better off than before.

RPLP -

1974 - U.S. v. Snow

1979-80 people started to use.

Abandoning white coats
in medical testing -
Reasons to Abandon -
a) Multiple tasks
b) Don't get as attached
to them.

~~M. Talbot~~

~~SS~~

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.

NDA/N

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 to get ^{investions made is incorrect.} inventions 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. — contracts 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. Dr. Kolobow Case — Employee

10. Dr. Sjoerdsma Case — Employee needs NDA — Can we give rights?

11. § 2(b) + § 2(d) — dead?

12. How do we force issue?

13. AUCO + AMF

(100)

~~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 comment. 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 author's conclusions.

My Sept. 27, 1976 statement on government patent policy referenced in Footnote 157 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 extort a favorable government patent policy and boycotted 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.

11
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
~~programs~~ agencies. This
statement provided an far
~~extensive~~ justification for
need for Bayh-Dole ~~legislation~~
anyway the author's choice
to quote.

~~included in this kind of~~
~~what 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 ~~indicates that this is not a~~
legislative history as commonly understood 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 history is understood to be limited
to the 1976 hearings and Senate Report No. 96-400, on S.414
which resulted in the Act.

In comparison, the legislative history put forth by

set out

(12) This kind of selectivity is evidenced in the punctuated "Legislative History of the Bayh-Dole Act" on pages 656-667 of the article, ~~which is not limited to~~

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 author~~ is a compilation of selected comments and quotes with their 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.

best viewed to support their reasonable price theory.

12

These quotes are made in the context of legislative language and issues different from that of the Act and ~~to be relevant to the Act.~~

that was objective to interpret the Act. Research would not use them to

The comments and quotes made outside the legislative history of S.414 are found in footnotes 146, 151, 153, 154, 157, 169, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000

footnotes, 152, 155, 156, 170, 174, 180, 196, and 200-201 of the total 82 are directed to comments or quotes from the 1979 hearing or Senate Report 96-480 on S.414. Not one of these 12 explicitly or by implication addresses the issue of pricing. Indeed, footnote 180 references a discussion in Senate Report 96-48 limited to the "pay-back" provision of the S:414 which was deleted before passage of the Act. The author's comment on this maintain that this discussion somehow supports their thesis on pricing.

discussed by Sen. Bayh
174, a deleted

7/2
6/2
1/2

20 of the 70 footnotes outside

identified to be outside of what is commonly known as a

(13)

~~Act's legislative history, reflect~~
ote, 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 majority~~
~~provisions were intended~~
~~and would be suggested~~
~~were to be defined~~
~~as suggested by the Tulane~~
~~article, to mollify critics of~~
~~the Act even though the~~
~~critics made no such~~
~~need made no suggestion to so.~~

P. 647 At the same time the policy ensured that there could be no abuse of the patent by erecting

~~P. 648 - HANO/DAVIS~~
 It does not expressly establish any mechanism whereby the funding agency can reliably ascertain whether patentees are honoring their obligation to charge no more than a reasonable price for an invention.

strict price control mechanism

P. 649 - What "available to the public on reasonable terms" means is not (un)prudentially troublesome, even absent the clear legislative history of the term.

so-called march-in rights

11111
 14
 8
 12
 4
 2

maintained by the government to oversee its investments

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

24 78
 66
 11
 76

~~Nothing in these laws author~~
~~of author~~ ~~in~~ ~~no way~~ ~~have any~~
but ~~in~~ ~~no way~~ ~~have any~~ ~~on~~ ~~technology~~
author ~~Dean~~ ~~Mr.~~ ~~under~~ ~~these~~ ~~transfer~~

I would like to thank you
for your Feb. 2 article. It is
the ~~most~~ most sensible comment
on ~~the~~ ~~subject~~ the subject
I have read in quite awhile.

In the last few years ~~there~~
~~have been a number of~~
~~similar~~ to the
the Los Angeles Times and the
Boston Globe have run a series
of columns ~~about~~ ~~as~~
consulting arrangements that
they view as "conflicts of
interests" ~~and~~ that they

~~maintain~~ ~~in~~ ~~an~~ ~~incorrectly~~ ~~maintain~~
~~strong~~ ~~view~~ ~~of~~ ~~the~~ ~~direct~~ ~~result~~
~~of~~ ~~the~~ ~~Buyh-Dole~~ ~~Act~~ ~~of~~ ~~1984~~
~~or~~ ~~the~~ ~~Technology~~ ~~Transfer~~ ~~Act~~ ~~of~~ ~~1986~~.

Some of these arrangements
could be ~~viewed~~ ~~as~~ ~~being~~
~~viewed~~ ~~as~~ ~~being~~ ~~beyond~~ ~~an~~
acceptable threshold. The

~~article~~ Chicago Tribune article
below is more of the same.

Unfortunately, Dr. NIH
Director Elias Zerhouni under
only professional pressure stimulated

with
NU
Publishing

Py. 670 — March-in

5

JUNE 6TH

1. First do no harm
2. Reality - harm is done
3. ~~Some things~~
~~CHARITIC~~
4. NASH - EQUILIBRIUM
5. BATH - DUE EQUILIBRIUM
6. NOT CONFLICT IF CONSISTENT
w/ assigned duties
7. Hugh - Dale Success
8. ~~at~~ ~~to~~ ~~from~~ ~~is~~ ~~7~~
9. Letter WITH

especially ~~the~~ Ground Rules
delegation of my own efforts are presumed by me
to 11 Dept. Apr. 20 1987: Presumably by me

- 1) Establish the context of discussion
- 2) Not talking about clinical testing by an NIH investigator of industry owned drug.
- 3) Not interested in stock ownership of biotech. problem of
- 3) main interest is industry
is consulting arrangement not between industry and NIH investigators

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

~~steps~~ If the deys. 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, ~~by attorneys~~
especially if determined by
attorneys w/ NO science
background — completely
inconsistent w/ the delegation
to enter into these relationships
to the laboratory level.

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