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Nash equilibrium: A concept from Game Theory which establishes that a set of strategies followed by economic agents within a game is in equilibrium if, holding the strategies of all other economic agents constant, no economic agent can obtain a higher payoff by choosing a different strategy. For example, when firms operate within an oligopoly, once a Nash equilibrium has been reached, none of them will want to change their strategy because by doing it they cannot obtain a higher profit.

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from *SIAM News*, Volume 35, Number 10, December 2002

The Problem with Blondes

By Sara Robinson

One of the main complaints I hear from mathematicians about *A Beautiful Mind*, the movie based on the life of John Nash, is that there's lots of material about his mental illness but very little about his mathematical achievements. The only reference to any of his theorems is a bizarre bar scene in which Nash and several of his Princeton buddies are ogling a beautiful blonde woman who has just walked in, surrounded by a group of less attractive friends.

As the blonde poses and preens, the fictional Nash ponders the game theoretic problem before him. He reasons that if all the men went for the blonde, at most one would be successful and the rest would be forced to turn to her friends. Since the friends would be miffed at being second choice, those men would end up alone. Nash concludes that they would all do better by ignoring the blonde and going directly for her friends. That way, he reasons, no one would end up alone.

Crowing about his "discovery," the movie Nash skips past the bewildered blonde, inspired to work out the concept now known as Nash equilibrium, the basis of his Nobel Prize in Economics in 1994.

I didn't know what a Nash equilibrium was, but after seeing that scene I had to look it up. I found that a Nash equilibrium is a set of strategies (one for each player) expressed as probabilities that each of a number of choices will be selected, such that even if a player learns everyone else's strategy, he has no incentive to change his own.

In the well-known two-player game "Rock, Paper, Scissors," for example, a Nash equilibrium occurs when each player picks one of the three uniformly at random. It is outside the realm of two-person zero-sum games, however, that Nash's contribution becomes most interesting.

When this definition of a Nash equilibrium is applied to *A Beautiful Mind*, it becomes clear that director Ron Howard erred. The solution to the problem of the blonde, as depicted in the movie, is not a Nash equilibrium: If Nash (or any of his buddies) knew that all the others planned to go for the blonde's friends, he would do better by approaching the blonde. If Nash were to go for the blonde himself, however, while his friends went for her friends, this could be a Nash equilibrium, depending on the payoffs. But are there more Nash equilibria? And how should I, as a former mathematician, advise my friends to behave in bars?

To answer these questions and provide material for a sequel, I formally defined "The Problem with Blondes" as follows:

Suppose that each of n players is given a choice of either going for the blonde or doing nothing. Suppose also that doing nothing (the equivalent of going successfully for the friends) has a payoff of 2, and that going for the blonde successfully has a payoff of 3. Going for the blonde and losing out to some other bozo has a payoff of 0. Each player's goal, as in any social situation, is to maximize his expected payoff.

As for the blonde, suppose that she chooses her man by looking at all the men approaching her and picking one at random, possibly a reasonable approximation to the real-life behavior of blonde women. (OK, I confess: I'm a brunette.)

Question: What are all the Nash equilibria for this game?

I offer this puzzle to the *SIAM News* readership, along with a nice solution provided by my friend Leonard Schulman, a professor of computer science at Caltech, in the hope that it might be useful in social situations; Leonard's solution appears below.

Sara Robinson is a freelance writer based in Berkeley, California.

Solution: Describe a sequence of strategies for the players in the form of probabilities $p_1, \ldots, p_n$ that they will go for the blonde.

If player i bids for the blonde, the probability that he will win her is:

$$W_i = W(p_1,\ldots,p_{i-1},p_{i+1}\ldots p_n) = \sum_{k=1}^{n} 1/k\ P\ \left(k-1 \text{ of the players other than } i \text{ bid for the blonde}\right).$$

Lemma 1: W_i is a symmetric and strictly decreasing function of each of its arguments (i.e., for each $j \neq i$, as p_j increases from 0 to 1, W_i strictly decreases).

Notice that the expected payoff to player i is

$$(1 - p_i)\,2 + 3\,p_i\,W_i = 2 + p_i\,(3W_i - 2).$$

From this we get:

Lemma 2: In a Nash equilibrium, for every player i, either (a) $W_i > 2/3$ and $p_i = 1$, or (b) $W_i < 2/3$ and $p_i = 0$, or (c) $W_i = 2/3$.

Theorem: There are $2^n - 1$ Nash equilibria, each described by a nonempty subset S of the players. There are probabilities $1 = q_1 > q_2 > \ldots > q_n$ such that the equilibrium point described by S, $|S| = k$, has

$$p_i = q_k : i \in S$$
$$p_i = 0 : i \notin S.$$

Proof: Consider any equilibrium point. Notice that if for one player $p_i = 1$, then for all other players j, $W_j \leq 1/2$ and hence $p_j = 0$.

Otherwise, suppose that all $p_i < 1$. Then there must be at least two nonzero p_i: If p_i were uniquely greater than 0, then $W_i = 1$ and, by Lemma 2, $p_i = 1$.

All the nonzero p_i must in fact be equal, which can be shown by supposing to the contrary that $p_1 > p_2 > 0$. Then, by Lemma 1, $W(p_2, \ldots, p_n) > W(p_1, p_3, \ldots, p_n)$, so they cannot both be equal to 2/3, contradicting Lemma 2.

All that remains is to note that for each nonempty subset of S, there is indeed a Nash equilibrium of the type described in the theorem, since $W(0, \ldots, 0) = 1$, $W(1, \ldots, 1) = 1/k < 2/3$, and since W is continuous. Q.E.D.

For the sake of completeness, let's see what q_k is.

For $k \geq 2$, q_k is the unique solution for $0 < q < 1$ of the equation

$$\frac{2kq}{3} = 1 - (1-q)^k.$$

Reason: For $k \geq 2$, consider a player who is in the set S. He, and every one of the other $k - 1$ players in S, bids for the blonde with probability q_k. Since $0 < q_k < 1$, he must fall into case (c) of Lemma 2. So $2/3 = W(q_k, \ldots, q_k)$ where there are $k - 1$ arguments. Using the formula for W,

$$2/3 = \sum_{i=1}^{k} \frac{1}{i}\binom{k-1}{i-1} q^{i-1}(1-q)^{k-i}.$$

Make the substitution $r = \dfrac{q}{1-q}$:

$$2/3 = \frac{(1-q)^k}{q} \sum_{i=1}^{k} \frac{1}{i}\binom{k-1}{i-1} r^i = \frac{(1-q)^k}{q} \sum_{j=0}^{k-1} \binom{k-1}{j} \int_0^r s^j\,ds = \frac{(1-q)^k}{q} \int_0^r (1+s)^{k-1}\,ds = \frac{1-(1-q)^k}{qk}.$$

For a given $k \geq 2$, this has a unique solution strictly between 0 and 1, since W is strictly decreasing in its arguments.

The first few q_k numerically are: $q_1 = 1$, $q_2 = 2/3$, $q_3 = (3 - 5^{1/2})/2 = 0.381966$, $q_4 = 0.266376$, $q_5 = 0.204324$, $q_6 = 0.165677$, $q_7 = 0.13931$, $q_8 = 0.120177$, $q_9 = 0.105662$, $q_{10} = 0.0942734$. Asymptotically, q_k is proportional to $1/k$.

You should decide for yourselves, but I plan to advise my friends to ditch the blonde and all of her friends and opt for a cold beer instead (payoff = 10). Many thanks to Leonard Schulman, though.

From: "Hughes, Owen C" <owen_c_hughes@groton.pfizer.com>
To: "'njl@browdyneimark.com'" <njl@browdyneimark.com>
Date: 4/2/04 4:46PM
Subject: Tulane LR Article

Norm: Our phone chat inspired me to go back to this article but even a short reading is dangerous to my blood pressure. Its opening assertion about Bayh-Dole (page 646 in original text) is breathtaking in its audacious dishonesty: "At the same time, the policy [behind Bayh-Dole] ensured that there could be no abuse of the title incentive by enacting a strict price-control mechanism as part of the so-called march-in rights maintained by the government to oversee its investments." (footnote 88, citing Section 203 of the Act). Call me stupid, where do the words "price control" appear in the Act? The Regulations? The contract forms and policies of NIH? These guys assume the result they want to prove, and then bulldoze the reader with their "evidence." As to which --the caselaw at FN's 115-122-- this is pretty thin stuff. It appears to be taken from cases about your basic contract fight or perhaps utility rate-setting cases, i.e. cases where people are only before the court to fight about money. So exactly how relevant is this to the question of how to read a statute that isn't about money, but about encouraging the creative spark and the dissemination of new and useful knowledge? We'll see; I will go read the cases. But right off the top it looks as if the authors are bending things to suit their purpose. Example: "In Commercial Solvents Corp. v. Mellon, the United Statees Court of Appeals for the D.C. Circuit addressed prices under a statute that demanded 'reasonable terms as to quality, price and delivery'; this language shows that the word 'terms' includes, as a matter of common sense, the element of price." I can't help noticing that this is up-to-the-minute case law, decided in 1922 (see my comment above about these guys rounding up every speck and scrap of what might ostensibly help their cause). But as to the substance of what this language shows about the "common sense" meaning of "terms". Excuse me, I don't see that it necessarily connotes anything about price. What this language shows me is a statute that asks people to give and take "reasonable terms" on parameters that the statute has expressly identified as relevant: namely price, quality and delivery. If the authors were correct, then we should also read into Bayh-Dole a requirement that inventions possess certain "quality" and "delivery" attributes as well. It's nonsense. Whether it is evidence of folly, or knavery, or both, I can't yet decide. More to follow. Regards, Owen.

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To: "Maureen Adams" <adamsm@browdyneimark.com>
Date: Monday, April 05, 2004 9:57AM
Subject: Re: Fwd: First Draft - Rebuttal of James Love's March-In Requests

NT:S
703-605-6429

Norm:

Here's my first draft, which incorporated your suggestions. Let me know what you think. Please give me what bio stuff you want in the footnote. Needless-to-say, I did not mention Jamie's motives nor his Ralph Nader connection.

703-605-6000

John

(See attached file: march-in article with Latker.d01.wpd)

****

John H. Raubitschek
Patent Counsel
U.S. Department of Commerce
Room 4835
14th and Constitution Avenue, N.W.
Washington, D.C. 20230
voice (202) 482-8010; fax (202) 482-0253

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"Maureen Adams" <adamsm@browdyneimark.com> 04/01/2004 11:15 AM

To <jraubits@doc.gov>
cc
Subject Fwd: First Draft - Rebuttal of James Love's March-In Requests

John:

As discussed.

Norm

----- Message from "Maureen Adams" <adamsm@browdyneimark.com> on Mon, 29 Mar 2004 17:56:00 -0500 -----

To: <sheldon#032#steinbach@ace.nche.edu>,<latkerc@bellatlantic.net>, "Norman Latker" <NJL@browdyneimark.com>, <Rhardy@cogr.edu>, <Michael#032#remington@dbr.com>, <ahammer@mit.edu>, <jallen@nttc.edu>, <jon.soderstrom@yale.edu>

Subjec First Draft - Rebuttal of James Love's March-In Requests
t:

I'm attaching a requested first draft of a rebuttal of James Love's march-in requests to DHHS which in most part is also a rebuttal of the Tulane Law Review article which serves as the basis for the requests. Any suggested changes would be welcome either orally or by e-mail.

Norm Latker

[attachment "NJL-29 Mar 04.doc" deleted by John Raubitschek/HCHB/Osnet]

DRAFT

REASONABLE PRICING - A NEW TWIST FOR MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT

John H. Raubitschek[1]
Patent Counsel
Department of Commerce[2]

Norman J. Latker[3]

In 1980, the Bayh-Dole Act gave universities and small businesses the right to own their inventions made with federal funding. Prior to this time, the only existing statutes required certain agencies to own inventions arising from funded research. This law was developed with bipartisan support and the principal sponsors were Senators Robert Dole, a Republican from Kansas and Birch Bayh, a Democrat from Indiana. By memorandum in 1983, President Reagan applied this law to large business contractors.

Universities have been very successful in commercializing their inventions. Bayh-Dole is generally credited for contributing to the dramatic increase over the last 20 years in

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[1] A.B. Princeton University, J.D. Georgetown Law Center. Member of the Bars of the District of Columbia and Virginia.

[2] The views expressed herein are those of the author and not necessarily of the Department of Commerce or the U.S. Government.

[3] XXXXX.

the number of university inventions, patents, licenses and royalties. According to figures published by the Association of University Technology Managers (AUTM), the total license revenue for all universities has been over $1 billion for the fiscal years 2000-2.

Under Bayh-Dole, the Government has certain rights including a paid-up license[4] and march-in rights.[5] Although the Government has never exercised march-in rights under this law, there have been several petitions to the Health and Human Services (HHS) and the Department of Energy (DOE).

On March 3, 1997, HHS was asked by CellPro, Inc. to march-in against Johns Hopkins University and its licensees of three stem cell patents. The matter was referred to NIH, which funded the research. NIH concluded that march-in proceedings were not warranted and denied the petition on August 8, 1997.[6]

Another request for march-in was filed on June 22, 1999 by Ventana Medical Systems, Inc. at the Department of Energy against

[4] 35 USC 202(c)(4).

[5] 35 USC 203.

[6] For a description and analysis of the CellPro case by two NIH attorneys, see McGarey and Levey, "Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition," 14 Berkeley Technology Law Journal 1095 (1999).

the University of California on two inventions for using DNA probes, claimed in U.S. Patent 5,447,841. The university, which operates the Lawrence Livermore National Laboratory, had obtained title through the waiver process prior to the effective date of the amendment to Bayh-Dole in 1984 extending the coverage to university-run laboratories. The waivers were each subject to the terms of the DOE assignment and confirmatory license (ACL) under which DOE could require the licensing of a third party or terminate the waiver if the contractor has failed to demonstrate that it has taken effective steps, or within a reasonable time will take such steps to accomplish substantial utilization of the invention or that the waiver has tended substantially to lessen competition or result in undue market competition. The ACL provided for a hearing at the discretion of the Secretary if the petition provides sufficient justification.

After DOE decided that further consideration of the petition was merited, it established, with the agreement of Ventana, a procedure modeled on 37 CFR 401.6 and formed a panel of the Deputy General Counsel for Technology Transfer and Procurement, a senior program official and a senior policy official. After considering all the arguments and submitted evidence, the panel concluded on __ that there was "insufficient support for the

allegations made by Ventana, and it would not be appropriate to initiate a formal march-in proceeding under 37 CFR 401.6(c) et seq. in this case."

An article by Peter S. Arno and Michael H. Davis[7] submits that march-in rights should be used to combat the high price of drugs invented by universities with federal funding. On January 29, 2004, Jamie Love filed two petitions to HHS on behalf of Essential Inventions, Inc. relying on this theory. These petitions are still pending. But before examining this claim, we should first consider the history of march-in rights.

HISTORY

March-in rights existed prior to Bayh-Dole and were described in the Presidential Memorandum and Statement of Government Patent Policy by Kennedy (1963)[8] and Nixon (1971)[9]. These were implemented in the Federal Procurement Regulations[10]

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[7] Arno and Davis, "Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research," 75 Tulane Law Review 631 (2001).

[8] 28 Fed. Reg. 10,943 (October 12, 1963)

[9] 36 Fed. Reg. 16,887 (August 26, 1971).

[10] Section 1-9.107-5(a) of the Federal Procurement Regulations, 38 Fed. Reg. 23782 (September 4, 1973).

and various agency procurement regulations. In addition, they were mentioned in the Attorney General's Report in 1947.[11] The Report recommended that "[t]he contractor (or his assignee) shall be required to offer nonexclusive licenses at a reasonable royalty to all applicants" if the contractor or assignee does not place the invention in adequate commercial use within a designated period.[12]

According to section 1(f) of the Kennedy statement, the Government shall have the right to require the granting of a nonexclusive royalty-free license to an applicant if (1) the contractor or grantee who has been permitted to own[13] the invention, its licensee or assignee has not taken effective steps within three years after the patent issues to bring the invention to the point of practical application[14] or (2) has made the

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[11] Report and Recommendations of the Attorney General to the President, "Investigation of Government Patent Practices and Policies" (1947)

[12] Recommendation 2(d), Volume 1 of the Attorney General Report, Chapter Four, page 76.

[13] The Statement refers to principal or exclusive rights and not ownership because of the required Government irrevocable royalty-free license for Government purposes throughout the world.

[14] As defined in section 4(g), "to the point of practical application" means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine and under such conditions as to establish that the invention is being worked and that its benefits are reasonably available to the public."

invention available for licensing royalty free or on terms that are reasonable in the circumstances or (3) can show why it should be able to retain ownership for a further period of time. There was also a march-in right in section 1(g) if the invention is required for public use by Government regulations or as may be necessary to fulfill health needs or other public purposes stipulated in the contract or grant. However, the required licensing could be royalty-free or on terms that are reasonable in the circumstances. As stated in the fourth paragraph of the Presidential Memorandum, the reason for march-in rights was to "guard against failure to practice the invention."

The march-in rights in section 1(f) of the Nixon Statement are very similar to those in the Kennedy Statement except that the utilization requirement was expanded to assignees and licensees and the Government could also require the granting of an exclusive license to a responsible applicant on terms that are reasonable under the circumstances. The latter change probably arose because of the new emphasis on exclusive licensing by the Government. The health march-in right in section 1(g) was expanded to refer to safety.

Pursuant to a recommendation in the Report of the Commission on Government Procurement,[15] a task force was established to study the need for further action with respect to march-in rights in the Presidential Patent Policy Statement and to consider ways in which the administration of march-in rights could be improved and strengthened. The task force recommended that an invention utilization report be used to obtain data from which an agency can determine if it should take any action. The task force considered a comprehensive questionnaire which had been drafted by the Data Collection and Analysis Subcommittee of the Committee on Government Patent Policy of the Federal Council and Science and Technology and developed an abbreviated one which focused more on march-in. The questionnaire should be submitted to the contractor or grantee not less than 5 years after it files a patent application on the invention. The task force also recommended that the National Technical Information Service of the Department of Commerce publish a notice on those inventions which have not been brought to the point of practical application or made available for licensing that they are available for licensing.

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[15] Proposed Executive Branch position for Recommendation 3 of Part I of the Report of the Commission on Government Procurement, dated October 31, 1973.

BAYH-DOLE

March-in rights under Bayh-Dole are provided for university and small business inventions made with federal funding in 35 USC 203 and for inventions by large businesses in 35 USC 210(c). These rights are different in a number of respects from those described in the Presidential Statements of 1963 and 1971.

The funding agency may take action if the contractor or grantee or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application in a field of use.[16] "Practical application" is defined in 35 USC 201(f) to mean "to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms." This definition differs from

[16] There are three other bases for exercising march-in rights. 35 USC 203(b)-(d). Two relate to health, safety or public use and so are similar to the Nixon Statement except that they come into play only if the contractor, grantee, assignee or licensee cannot reasonably alleviate or satisfy such needs. The third basis relates to a breach of the "domestic manufacturing" requirement in 35 USC 204.

the Nixon Memorandum, which says merely "that its benefits are reasonably accessible[17] to the public." Section 203 not only authorizes the funding agency to require the contractor or grantee, its assignee or exclusive licensee to grant a license to a responsible applicant but itself can grant a license if the ordered party refuses to grant a license.[18] However, § 203 does not consider utilization activities by the contractor's licensee as did the Nixon Memorandum.

Any decision to exercise march-in is appealable to the Court of Federal Claims within 60 days. The agency's decision is held in abeyance until all appeals are exhausted. A decision not to exercise rights is not reviewable.[19] The Bayh-Dole regulation in 37 CFR 401.6 sets forth a detailed multi-step process although the agency can terminate the proceedings at any time.

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[17] Kennedy Statement says "available."

[18] The granting of any license by the Government would be unusual since it is not the patent owner. If there were royalties, it is assumed that they would belong to the patentee or exclusive licensee.

[19] See S. Rep. 96-480, at 34 ("'Marchin' is intended as a remedy to be invoked by the Government and a private cause of action is not created in competitors or outside parties, although it is expected that in most cases complaints from third parties will be the basis for the initiation of agency action.").

According to the legislative history[20] of Bayh-Dole, "[t]he Government may 'march-in' if reasonable efforts are not being made to achieve practical application, for alleviation of health and safety needs, and in situations when use of the invention is required by Federal regulations." "'March-in' is intended as a remedy to be invoked by the Government and a private cause of action is not created in competitors or other outside parties, although it is expected that in most cases complaints from third-parties will be the basis for the initiation of agency action."

At the present time, no agency is systematically collecting utilization information from its contractors or grantees on their patented inventions.[21] However, some universities do submit a short utilization report to their funding agencies. Thus, it is not surprising that an agency has yet to initiate a march-in rights investigation without a complaint from a private party.[22]

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[20] S.Rep. 96-480, 96th Cong, 1st sess., pg 33.

[21] See GAO Report "Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision" (GAO/RCED-99-242), pages 15-16. GAO noted that most agencies do not require utilization reports and so they do not know if their inventions are being commercialized.

[22] One author has questioned whether the Government will ever exercise march-in rights. See McCabe, "Implications of the CellPro Determination on Inventions Made with Federal Assistance: Will the Government Ever Exercise Its March-in Rights?" 27 Public Contract Law Journal 645 (1998).

Reasonable Pricing

The argument of Arno and Davis is that the reasonable pricing requirement arises from an interpretation of "practical application" which is referred to 35 USC 203(a)(1) and defined in 35 USC 201(f). "Practical Application" means that an invention is being practiced "under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms." Although the authors admit there is no clear legislative history on the meaning of "available to the public on reasonable terms,"[23] they conclude that "there was never any doubt that this meant the control of profits, prices and competitive positions."[24] They further suggest that under Bayh-Dole, the contractor may have the burden to show that it charged a reasonable price.[25] This could be made part of its development or marketing plan.[26]

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[23] Id. at 649.

[24] Arno and Davis, n.6, 75 Tulane Law Review at 662.

[25] Id. at 653.

[26] There is no requirement in Bayh-Dole for contractors to have such a plan although Federal laboratories do in 35 USC 209.

The thrust of their argument is that using the principle of plain meaning as announced by Justice Scalia in his dissenting opinion in Chisom v. Roemer, 501 U.S. 380, 404 (1991) that "reasonable terms" means price, supplementing the very limited legislative history of Bayh-Dole with testimony, many cases and laws, most of which have nothing directly to do with Bayh-Dole. Then, the authors criticize Bayh-Dole and the implementing regulation in 37 CFR 401 for leaving the enforcement of reasonable prices up to the agencies.[27] Of course, this really is not a deficiency since there is no evidence that Congress intended there to be a reasonable pricing requirement.

Prior to Bayh-Dole, the focus of march-in rights was on non-use. This is clear from the practices by the agencies under the Kennedy and Nixon Memoranda. If Congress meant to add a reasonable pricing requirement, it would have set forth one explicitly in the law or at least described it in the accompanying reports. That a new policy could arise out of silence would truly be remarkable. In addition, one of the stated objectives of Bayh-Dole is to "protect the public against nonuse or unreasonable use." 35 USC 200. It does not say "unreasonable prices." Thus, the interpretation taken by Arno

[27] Id. at 648-49.

and Davis is inconsistent with the intent of the Bayh-Dole and so the Scalia rule of "plain meaning" is inapplicable. On the other hand, Bayh-Dole was intended to minimize the costs of administration,[28] which would not be the case if agencies were responsible for ensuring reasonable prices for any patented invention, not just a drug, arising out of federal funding.

We recognize that the Presidential Memoranda and 35 USC 203 mention "available on reasonable terms." Although such terms could involve price, this does not necessary mean that the patented invention must be available for a reasonable price. For example, march-in might be appropriate if a contractor was charging such a high price that only a few could afford to buy it. On the other hand, the fact that a licensee is charging customers in the United States a higher price than in other countries may not be a violation of Bayh-Dole, requiring an agency funding the research which resulted in the drug to exercise march-in rights.

Considering the terms of 35 USC 203(a)(1), this becomes evident. March-in is appropriate if the agency determines that such action is necessary because the contractor or assignee has not taken, or not expected to take within a reasonable time,

[28] 35 USC 200.

effective steps to achieve practical application of the invention. Since universities generally are not permitted to assign their invention,[29] this requirement would apply only to them and not their licensees. Further, this requirement relates to making the benefits of the invention available to the public on reasonable terms. Thus, a university which licenses its invention to a drug company which sells a patented product to any member of the public is fulfilling its responsibility under Bayh-Dole of making the benefits of the invention available to the public on reasonable terms. In other words, the price charged by a licensee would usually not be relevant unless it directly affected the availability of the invention to the public. On the other hand, the high cost of a drug may be the basis to march-in for health and safety reasons under 35 USC 203(a)(2).[30]

Although we disagree with the interpretation of 35 USC 203 by Arno and Davis, Congress could decide to amend Bayh-Dole to impose a reasonable pricing requirement. However, we would not recommend such a change because of the difficulty in determining what is "reasonable." Furthermore, that would make any[31] patent

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[29] 35 USC 202(c)(7)(A).

[30] McCabe at 645.

[31] Although 35 USC 203 applies only to nonprofit organizations and small business firms, it was expanded to large businesses by 35 USC 210(c).

license granted by a Government contractor or grantee subject to attack, which would discourage or inhibit the commercialization of Government-funded technology. [32] At one time, NIH had a reasonable pricing requirement in its CRADAs by withdrew it in 1995 after participation in CRADAs by industry had dropped substantially.

[32] This could be especially damaging for biotech inventions. See McCabe at 645.

From: "Richard Latker" <pristine@netvigator.com>
To: "Maureen Adams" <adamsm@browdyneimark.com>
Date: Wednesday, April 07, 2004 4:08PM
Subject: first two sections for Norman Latker

Dad:

This is the intro and the section that follows "The spirit of Bayh-Dole".

There are three more sections to come: "Bayh-Dole is not healthcare legislation" (which includes the Scalia test), "The allegations are unsubstantiated" (which points out several flaws in the author's argument about comparative pricing, etc) and "conclusion".

Should be ready soon. Let me know what you think so far.

R---

4 to

++++
I would like to comment on recent petitions filed by Mr James Love and Mr. Sean Flynn of Essential Inventions, Inc, requesting the National Institutes of Health to invoke the march-in provisions of the Bayh-Dole Act to invalidate exclusive drug patents held by Abbot Laboratories and Pfizer Corporation.

While the authors of the petition might be commended for embarking on such an innovative approach to controlling drug prices, it must be clearly understood that Bayh-Dole defines critically important aspects of intellectual property law, and is decidedly ill-suited for any other purpose. Any attempt to use it as a weapon in the political debate over drug prices is doomed for certain failure, as the enabling language required for such uses is wholly - and intentionally -absent from the legislation.

In the unlikely event that NIH were to grant the request of the petition's authors, the decision would no chance of surviving judicial review.

The spirit of Bayh-Dole

I hope I can can provide some perspective on the Bayh-Dole Act, large portions of which I helped to draft back in the 1970s, when I served as Patent Counsel for the Department of Health, Education and Welfare (HEW). I was also an architect of the Act's implementing regulations, to which the authors of the petitions heavily refer.

The authors have woefully misrepresented the spirit and purpose of the

legislation, which was intended to enlist the marketplace to develop and distribute government-supported innovations. Judging by the footnoting in the petition, they appear to have been informed primarily by a recent article in the Tulane Law Review, penned by Peter S. Arno & Michael H. Davis, which unfortunately paints a highly distorted picture both of the Act itself and the legislative process leading to its passage.

Before the enactment of Bayh-Dole, an enormous amount of government-sponsored research and innovation went to waste, as there were no clear mechanisms in existence to transfer the resultant inventions to the marketplace.

Although there was spirited opposition to the bill, a powerful bipartisan consensus was built around the basic notion that the market forces would do a far better of disseminating such inventions to society than bureaucracies ever could.

Put simply, the drafters of the acted wanted to ensure that adequate incentives were in place to facilitate inventions, and to attract corporate investment into their development and distribution. We understood that that inventions resulting from government research are conceptual in nature, and require significant investment by the private sector to bring them into practical application.

Our answer to the problem was that intellectual property rights should be accorded in full to the innovators, rather than the government bureaucracy that financed their research, and that innovators should be free to leverage their property rights to their own advantage in the market place. The only conditions to be attached to this freedom were envisioned as follows:

A) Inventions should be developed for practical application; and

B) Inventions should be readily available to society

C) Inventions should not be used in such a way that might threaten public health; and

D) If an invention were subject to a federal order of some kind, the rights-holder must comply with that order; and

E) Inventions should be developed within the United States.

These conditions were translated into the legal language found in section 203a of the Act, which is reproduced in the subject petitions. The march-in clauses were conceived as extraordinary measures to be used only when there

was overwhelming evidence to show that the public resources invested into an innovation were being wasted or abused.

This is clearly not the case with either Retonavir or Latanoprost, both of which have been successfully developed and are readily available to the public at large.

Unedited, coming

From: "Richard Latker" <pristine@netvigator.com>
To: "Norman Latker" <NJL@browdyneimark.com>
Date: 4/7/04 3:54PM
Subject: First two sections

Dad:

This is the intro and the section that follows "The spirit of Bayh-Dole".

There are three more sections to come: "Bayh-Dole is not healthcare legislation" (which includes the Scalia test), "The allegations are unsubstantiated" (which points out several flaws in the author's argument about comparative pricing, etc) and "conclusion".

Should be ready soon. Let me know what you think so far.

R---

++++
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Unedited, coming

NJL

From: "Richard Latker" <pristine@netvigator.com>
To: "Maureen Adams" <adamsm@browdyneimark.com>
Date: Saturday, March 20, 2004 5:13AM
Subject: attn Norm Latker

Dad:

I've made one pass through the presentation & strengthened some of the language.

But I need to know a few things before I can finish:

* Where is it to be published? — Newsletter?
* Should it be sourced (footnoted)?
* Any idea about ideal length?

I worry that there may be some content omissions in the historical chronology you provide for the evolution of Bayh-Dole. Those passages feel a bit choppy. Fleshed-out portraits of the key players would make a more interesting read, and also help bolster your assertion at the the end about profit being a secondary motive.

I have few style questions...eg:

* Does the "Department" always refer to HEW?
* Can we refer to "investigators" as "innovators", "inventors" and/or just "scientists"?

These questions and others you'll need to answer by phone. There are few references to people without full names ... that's a no-no.

Talk to you soon.

R--

----- Original Message -----
From: "Maureen Adams" <adamsm@browdyneimark.com>
To: <pristine@netvigator.com>
Sent: Saturday, March 20, 2004 6:24 AM
Subject: Presentation

Dear Richard:

Attached is the presentation I mentioned. Could you please edit it when you have a chance.

Regards,
DAD

From: Ann Hammersla <ahammer@MIT.EDU>
To: "Norman Latker" <NJL@browdyneimark.com>, <astevens@bu.edu>, <rhardy@cogr.edu>, <jallen@nttc.edu>, <RAdler@venterscience.org>, <jon.soderstrom@yale.edu>
Date: 4/1/04 4:18PM
Subject: Re: Straw man letter to NIH

Jon:

Good letter Jon. I have a couple of edits that will be coming later tonight or tomorrow morning. One thought I wanted to throw out to see if anyone has considered including the following scenario:

Even if NIH decides that the legislative history was wrong and the thirty years of interpretation and practice of BD were wrong, EI would not obtain all the necessary rights for either it or anyone else to produce a competing product. The Government does not have rights in all of the technologies that are necessary to develop a competing product. The result could be as the result of the exercise of march-in rights; higher prices on the drugs available now because of the increased competitive risks for the 2 companies; no immediate alternative drug is available to drive prices down because EI or someone else needs to either do research or license IP and know-how not owned by the Government. Therefore these drugs would not be available to the public under the generic product line for several years. No company would invest any $'s into developing a drug unless it had all the rights to do so.

Comments.

Ann

At 03:31 PM 4/1/2004 -0500, Norman Latker wrote:
>Jon
> Good work! I hope everyone can clear off on this with minimal change.
> Minor typo in the 4th paragraph. I think the word "initiative" or such,
> goes after "failed".
> I 'm in the process of drafting a letter to N.I.H. over my signature
> focusing on the specific positions in the Tulane article if no one has a
> problem with that. I spoke to John Raubitchek in Commerce today. We both
> believe that we need to undo the Tulane article and have agreed to
> collaborate in drafting a rebuttal for submission to a law review with
> high visibility. Your welcome to join too. Good to see things coming
> together but there's a lot left to be done.
> Regards
> Norm
>
> >>> Jon Soderstrom <jon.soderstrom@yale.edu> 04/01/04 01:57PM >>>
>Folks -
>
>I attach a draft letter that I would like to propose AUTM submit to NIH. I
>have focused primarily on the procedural issues of march-in and the chilling
>effect it will have on commercialization efforts. Thanks to
>Norm/Joe/Ashley for many of the ideas that I've borrowed from them. Your
>contributions are well appreciated. I hope you don't have too much pride of

>authorship. I welcome your thoughts/issues/comments/concerns on this *straw
>man*.
>
>Best,
>
>Jon

From: "Richard Latker" <pristine@netvigator.com>
To: "Norman Latker" <NJL@browdyneimark.com>
Date: 4/5/04 12:57PM
Subject: Fw:proposed changes

----- Original Message -----
From: "Richard Latker" <pristine@netvigator.com>
To: "Carole and Norman Latker" <Latkerc@bellatlantic.net>
Sent: Monday, April 05, 2004 5:42 AM
Subject: Re: (no subject)

> Hi:
>
> I wasn't able to start this until a few hours ago. I should have it off to
> you by mid-day today.
>
> It isn't proving difficult, though. I've led off with a brief introduction
> of who you are and why your perspective is worth reading. I've
incorporated
> most of your prose, but I am also working in these ideas:
>
> You are now writing about the spirit of the law, which emphasises the
> cooperative three-way partnership between government, the research
community
> and industry to facilitate innovations and their practical development.
You
> underscore the importance of leveraging market forces, and mention how
> profoundly successful this formula has proven to be. You also discuss how
it
> was never envisaged that the law would be used to compel private entities
to
> divulge internal accounts or pricing information. Bahy-Dole contains no
> criteria that would be required to assess whether or not a price was
> "reasonable," precisely because controlling patent rights on the basis of
> price was antithetical to what the drafters had in mind.
>
> If the authors of the march-in request were to make a compelling case that
> Abbot et al were charging prices so high that the drug were unavailable to
a
> significant portion of society, then their proper course of action is to
> approach the legislature in search of health-care market reforms.
Bahy-Dole
> was never intended to be an administrative mechanism to determine
> health-care delivery policies, but instead forms the basis of modern
> American intellectual property law. Even in developed European countries,
> where many governments mandate drug-price caps, it is the health and
social
> authorities, specifically empowered by their respective legislatures, that
> determine matters of price. To use intellectual property law to administer
> drug-price policy is unheard of, and in fact many of the key provisions of
> Bahy-Dole are steadily being adopted in countries with fully socialised
> health-care regimes.

>
> The march-in clauses were conceived extraordinary measures to be used only
> when there was overwhelming evidence to show that an innovation in
question
> was not being developed and distributed, or if access to a critical
> innovation were somehow being obstructed.
>
> You aren't privy to internal information from Abbot or the other affected
> companies, but the criteria for a march-in order under Bahy-Dole are quite
> obviously not being met. The drugs in question have been successfully
> developed and are now readily available to society at large. Even if Abbot
> were not distributing large quantities of the drug for free, it must be
> permitted to charge whatever price the law allows and the market will
bear.
> This is particularly true as drug companies must function in a global
> economy and negotiate a huge variety regulatory regimes around the world.
To
> use Bahy-Dole as a political weapon to bat drug down prices would be
> counterproductive and dangerous.
>
> Moreover, if the government were to exercise march-in rights solely on the
> basis of price, with no detailed parameters to guide it, the result would
be
> to inject an enormous measure of uncertainty into the research community.
> The effect on the partnership you describe would be chilling, as the very
> market incentives that sustain it would be undermined. The ultimate
results
> would be a reduction of industry resources channelled into R&D , an
erosion
> of competitiveness, and fewer worthwhile innovations appearing in the
> marketplace..
>
> etc.
>
> R---
>
>
>
> ----- Original Message -----
> From: "Carole and Norman Latker" <Latkerc@bellatlantic.net>
> To: "Richard Latker" <pristine@netvigator.com>
> Sent: Sunday, April 04, 2004 2:08 AM
> Subject: (no subject)
>
>
> > Richard
> > I hope you are proceeding with editing my draft. I'm being pressed to
> > move on.
> > Since this is an important business issue here this might be
> > something you could report in your paper. This really is a wrong-headed
> > part of the effort to lower drug prices in the U.S. The real problem
> > appears to stem in part from foreign governments capping prices below
> > what the drug's developer considers necessary to cover costs and their
> > profit projections and world-wide political pressure to give drugs to

> > the poor considerably below their cost. The result is higher prices in
> > the U.S. with the U.S. purchaser subsidizing foreign purchases and the
> > poor. In the press all you see is advocates for lower prices with little
> > intellectual discussion of the ramifications of the government setting
> > such prices.This problem cannot be solved by undermining Bayh-Dole which
> > could at best make a few drugs available to the generic drug industry
> > but would assure fewer new drugs emerging from government sponsored
> > research. The successful collaboration between industry and the
> > universities fostered by Bayh-Dole would certainly screech to a halt.
> >
> >
>

these venues. We have also experienced extensive changes in our own patent laws and practices which have further expanded the opportunities to engage in technology transfer. We have had the benefit of a knowledgeable court in the Court of Appeals for the Federal Circuit which has slain many of the mythical dragons attached to intellectual property law to provide uniformity of interpretation of those laws and before which we can expect equitable treatment. We have obtained the attention of Congress and, particularly, the attention in that body to the university sector's perspective on intellectual property law issues. We have seen the introduction and passage of legislation favorable to the universities and their technology transfer efforts. We have also seen developed, not only in the university sector, but in university-industry relationships and university-industry-government relationship, a greater awareness of technology transfer and a growing recognition of the possibilities which can be made available through creative technology transfer efforts and a much greater sophistication in handling

those possibilities. Today we operate in a climate that recognizes the value of intellectual property and the technology transfer function. We would like to *think* that much of this has come about because the universities, as a source of fundamental discoveries and inventions, have been the source of enlightenment for a recognition of the value of innovation.

A word of caution, however! We work in a very uncertain business where, on the average, it takes in excess of 10 years and hundreds of thousands, even millions, of dollars to bring an invention to the marketplace. We must also remember that, as a licensor, we have very little actual control over the process by which an invention is brought to the market or how, ultimately, it is marketed. We are always vulnerable to the attacks of special interest groups, whether inside or outside of government, which are based not on fact but on emotion or which may be waged for psychological reasons. As long as envy and jealously are part of the human condition such attacks are inevitable, only the intensity will rise and fall.

The emphasis today, as well as the "buzzword" in Washington is "competitiveness." That the university sector has made a tangible contribution to the competitiveness of the United States in a global market through the technology transfer function cannot be denied. The seminal piece of legislation which made that contribution possible was the Bayh-Dole Act. Without doubt, the objectives of the Act have been realized. Through operation under that Act:

- Small business, which is frequently the test bed for embryonic university technologies, has benefited to a very large extent;
- the government is comforted in knowing that taxpayer dollars, which support the bulk of basic research in the university sector, have lead to the development of products and the use of processes that have advanced the quality of life for its citizens.
- industry can rely on a source of technology, data and information and a pipeline of manpower which fulfills its needs and feeds the production processes.

In sum, all sections of society enjoy both the protection and benefits afforded under the Bayh-Dole Act and its progeny.

In recent years we have been experiencing an increasing incidence of efforts to restrict or curtail the

technology transfer capabilities of the University sector under the Bayh-Dole Act through government agency actions, agency programs and legislative activities and through agency-industry consortiums. For example, pending legislation would disenfranchise the universities, as well as other non-manufacturing entities utilizing the patent system, from exercising the constitutional-based right vested in the patentee to exclude others from practicing the invention patented.

We must understand that no matter how much money we spend on research and development the findings are not going to benefit the public unless there are suitable incentives to invest in commercialization. And because no one knows which venture will succeed, we must strive for a society and an environment ruled by the faith that the guarantee of reasonable profits from risk-taking will call forth the endless stream of inventions, enterprise and art necessary to resolve society's problems. The words of the poet Edna St. Vincent Millay seem most apropos to this situation.

We have already passed through an era where science was being made subservient to politics. In today's technologically intense atmosphere, where the maximum protection for intellectual property is more than ever necessary to provide protection for the heavy investment necessary to technology development, we must remain alert.

Even in the current favorable climate for university technology transfer as the heritage of the Bayh-Dole Act, views on the issues in the control of intellectual property, whether by government or special interests, can lend themselves to emotional molding. Outspoken claims to the guardianship of the public interest or welfare is a rich field for cultivating political power. We must never forget that freedom demands a constant price and that vigilance is essential. To quote Pogo, "We have met the enemy and he is us."

In the struggle to obtain the passage of the Bayh-Dole Act as well as on other pieces of proposed legislation which impinged on the university sector, the universities, collectively, spoke with a loud and single voice. We must continue to do so in all circumstances which threaten the rights and opportunities which we have earned over many years by dint of perseverance, patience and hard work. This will require a unified, active and continuing participation by all members of the university sector.

"The heritage of the past is the seed that brings forth the harvest of the future."

Endnotes

1 Vannevar Bush held the following positions in government: Chairman, National Defense Research Committee 1940; Director-Office of Scientific Research and Development 1941; Chairman-Joint Research and Development Board 1946-47; Member-Research and Development Board of National Military Establishment 1944-48.

2 Harbridge House, Inc., Government Patent Policy Study for the FCST Committee on Government Patent Policy, May 15, 1968 Vol. II, Parts II and III.

3 See Resume of U.S. Technology Policies—Dr. **Betsy Ancker-Johnson**-Les Nouvelles (Journal of the Licensing Executives Society) Dec. 1976, Vol. XI No. 4, P. 186; Statement before the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Dec. 11, 1976. (This latter document also contrasts the experience of universities in licensing patents owned by them, some or most of

From: "Hughes, Owen C" <owen_c_hughes@groton.pfizer.com>
To: "'Norman Latker'" <NJL@browdyneimark.com>
Date: 4/12/04 5:23PM
Subject: RE: Draft Letter To N.I.H.

Norman: Thank you for including me in the circulation list. I hope my (very minor) comments are timely and useful. Here they are: (1) Page 1, paragraph 1: "Pfizer Corporation" should be "Pfizer Inc" (no comma, no period: don't ask!). (2) Page 3, paragraph 1 (beginning "Put simply, the drafters...") I think there is an extra "that" in the sentence "We understood that..." (3) I am not sure if the spelling if "Ritonavir" or "Retonavir" but I guess that's Abbott's call. Maybe Google would help? (Two occurrences of this, one on page 3 and the other on page 7). (4) Page 5, second paragraph (beginning "They also assert...") I think the opening quote is missing on "practical application"? And I found the sense of the paragraph a bit hard to follow (even though I know exactly what you're driving at). Might I offer this alternative? 'This assertion, that funding agencies are vested with the jurisdiction to approve pricing, is said to rest on the Act's definition of "practical application" which includes a requirement that the invention be made available to the public on "reasonable terms." This latter term, argue the petitioners, is to be interpreted "in an ordinary context" as including a "reasonable price;" and thus the funding agency can (and must) assess what that "reasonable" market price might be.' (5) Page 6, end of quotation of Scalia rule: do you want or need to give the citation (apparently, per the Tulane L. Review, it's to his dissent in Chisom v. Roemer, 501 U.S. 380, 404 (1991); but I confess I haven't cite-checked it!). (6) Page 6, first full paragraph (beginning "Scalia's instruction to refer...") In the sentence "The march-in requests and the entire body of the Bayh-Dole Act...." do you intend "march-in requests" or (my guess) "march-in regulations"? (7) On pages 7-8, discussing the price of things here and in Portugal, Poland etc., you might point out that many things are cheaper overseas: I bet a Big Mac costs a good deal less in Warsaw than it does in New York. Does that mean that McDonald's is ripping off the U.S. consumer, or giving the Polish one a discount? Nope. It's a question of local purchasing power parity. It's also a function of exchange rates, which (by definition) change all the time. Part of why drugs look (or looked) so cheap outside the U.S., is the strong dollar relative to say the Canadian one. (By the way, when did the petitioners conduct their pricing comparisons? The dollar has declined a lot recently, particularly against the Euro: at current cross-rates I bet the "overpricing" is less egregious than it was presented in the petition). But this is all econo-speak and may just dilute the force of your excellent points. I can't tell you how glad I am that you are giving voice to your concerns. All best wishes, Owen.

-----Original Message-----
From: Norman Latker [mailto:NJL@browdyneimark.com]
Sent: Friday, April 09, 2004 4:43 PM
To: sheldon_steinbach@ace.nche.edu; astevens@bu.edu; kphillips@cogr.edu; rhardy@cogr.edu; niels@comcast.com; Michael.Remington@dbr.com; P_harsche@fccc.edu; Owen_C_Hughes@groton.pfizer.com; ahammer@mit.edu; jallen@nttc.edu; Hwbremer@warf.org; jon.soderstrom@yale.edu
Subject: Draft Letter To N.I.H.

602
647
0216

POLICY FORUM CONTINUED FROM PAGE 64

matics infrastructure that will link current and emerging clinical research information systems so that data and resources can be shared within and across clinical research networks, across studies and across institutions, reducing duplication and avoiding unnecessary overlap between trials. We expect NECTAR to help streamline clinical research and to accelerate the pace of discovery and application of clinical findings.

We intend to issue RFAs for technologies that improve assessment of clinical outcomes and for regional translational research centers. We will expand efforts to provide advanced training in clinical research, through the Institutional Career Development Award Program and the NIH Clinical Center Clinical Research Training Program. NIH Clinical Research Associates (trained and certified health-care providers) will enroll and follow patients in clinical trials, ensuring that principles of integration will become routine in the clinical research culture.

Roadmap initiatives will also be unique in the manner in which they are funded. All institutes and centers decided to create a new funding mechanism through a common pool of resources agreed upon and contributed to by all of them on the basis of the multiyear roadmap plan. The plan will be administered centrally, but executed by lead institutes or centers as appropriate on behalf of the whole of NIH. This ensures that a steady multiyear and flexible stream of funding is available and also institutionalizes a corporate process for decision-making about trans-NIH priorities. It reflects, in our opinion, a maturation of the NIH toward a more adaptive management of the NIH portfolio—an approach that will enable rapid responses to emerging opportunities that do not fit clearly within the mission of a single or small group of institutes.

The extraordinary participation of hundreds of NIH staff, extramural scientists, and the lay public in developing these initiatives is a reflection of the profound commitment of NIH and its stakeholders to do whatever is necessary to rapidly exploit the revolutionary advances of the past few years for the benefit of our people.

For more information, visit http://nihroadmap.nih.gov

However, we will begin to implement all 28 initiatives in 2004, with a clear focus on making viable, enduring changes that will lead to improvements in health. Let me outline the themes and initiatives in more detail.

New Pathways to Discovery. This theme addresses the need to understand complex biological systems. Future progress in medicine will require quantitative knowledge about the many interconnected networks of molecules that comprise cells and tissues, along with improved insights into how these networks are regulated and interact with each other.

New Pathways to Discovery also sets out to build a better "toolbox" for today's biomedical researchers. To fully capitalize on the recent sequencing of the human genome and many new discoveries in molecular and cell biology, the research community needs wide access to technologies, databases, and other scientific resources that are more sensitive, more robust, and more easily adaptable to researchers' individual needs.

Roadmap initiatives within this theme address technologies and approaches necessary to meet contemporary research challenges, including building blocks and pathways, molecular imaging, the development of small-molecule libraries, bioinformatics and computational biology, nanomedicine, and structural biology. We will issue new Requests for Applications (RFAs) in FY 2004 for National Technology Centers for Networks and Pathways, National Centers for Biomedical Computing, Centers for Innovation in Membrane Protein Production, as well as investigator-initiated grants for related research in structural biology, metabolomics technology development, and proteomics. In addition, we will support development of new screening centers for bioactive small molecules, a publicly accessible cheminformatics reference database to be housed at NIH's National Center for Biotechnology Information, and a database and core facility dedicated to synthesizing and distributing molecular imaging probes. The agency will also begin planning a series of nanomedicine centers that will be launched in 2005. These centers will focus on quantitative measurement of biological processes at the nanoscale and the engineering of new tools to intervene at the nanoscale or molecular level. This research will help scientists construct synthetic biological devices, such as miniature, implantable pumps for drug delivery or tiny sensors to scan for the presence of infectious agents or metabolic imbalances.

Research Teams of the Future. The scale and complexity of today's biomedical research problems increasingly demand that scientists move beyond the confines of their own discipline and explore new organizational models for team science. NIH wants to stimulate new ways of combining skills and disciplines in the physical and biological sciences. The Director's Innovator Awards will encourage investigators to take on creative, unexplored avenues of research that carry a relatively high potential for failure, but also possess a greater chance for ground-breaking discoveries. In addition, novel partnerships, such as those between public and private sectors, will be encouraged to accelerate movement of scientific discoveries from bench to bedside.

Solving the puzzle of complex diseases, from obesity to cancer, will require a holistic understanding of the interplay between factors such as genetics, diet, infectious agents, environment, behavior, and social structures. To devise and use the state-of-the-art technologies developed from the roadmap effort, we will need the expertise of nontraditional teams of biological scientists, engineers, mathematicians, physical scientists, computer scientists, and others. The private sector will play an essential role in this new paradigm, and federal agencies will be required to do more collaborating with industry and each other. We recognize that the research teams of the future will look and feel vastly different from their predecessors.

Effecting these changes will require cultural and scientific adjustments and experimentation with new approaches. The implementation group responsible for the Research Teams of the Future devised a plan to meet these challenges with a series of initiatives that provide mechanisms for high-risk strategies, interdisciplinary research, and public-private partnerships. For example, it has been suggested that investigators do not submit their most innovative applications to the NIH because they think the NIH is risk-averse. We have heard that peer review typically values likelihood of success more than potential impact and that some funding decisions are too conservative. To encourage high-risk research, NIH will solicit nominations for the Director's Innovator Awards, which will provide support to a highly select group of individuals who have the potential to make extraordinary contributions. They will be evaluated in terms of their exceptional creative abilities, potential for ground-breaking discovery, evidence of focused and skillful habits of mind that predict perseverance and thorough exploration of his/her ideas, and, most important, prospects for making seminal biomedical research advances.

To build the research workforce of the future, the agency will issue RFAs to promote collaborative efforts, including Exploratory Centers for Interdisciplinary Research and Training for a New Interdisciplinary Research Workforce. These programs will be augmented by conferences and symposia on timely issues, such as methodological innovations and peer review. To expedite the formation of productive public-private partnerships, the NIH will establish a central point of contact to support and encourage NIH activities involving these partnerships.

Reengineering the Clinical Research Enterprise. Although biomedical research has succeeded in converting many lethal diseases into chronic, treatable conditions, continued success requires that the United States recast its entire system of clinical research. Over the years, clinical research has become more difficult to conduct. However, exciting basic science discoveries demand that clinical research continue and even expand, while striving to improve efficiency and better inform basic science. This is undoubtedly the most difficult but most important challenge identified by the NIH Roadmap process.

Clinical research needs to develop new partnerships among organized patient communities, community-based physicians, and academic researchers. In the past, all research for a clinical trial could be conducted in one academic center; that is unlikely to be true in the future. In these initiatives, NIH will promote creation of better integrated networks of academic centers that work jointly on clinical trials and include community-based physicians who care for large groups of well-characterized patients. Implementing this vision will require new ways to organize how clinical research information is recorded, new standards for clinical research protocols, modern information technology, new models of cooperation between NIH and patient advocacy alliances, and new strategies to reenergize the clinical research workforce.

Critics of the nation's current clinical research system have cited several factors that promote inefficiency, including poor integration of existing clinical research networks, inadequate training mechanisms for clinical investigators, inconsistent data standards and database requirements, and lack of information. In addition, successful clinical research relies on public trust, and any proposal that addresses the nation's investment in this area must be sensitive to the needs of the most important NIH constituency, the American people.

The NIH annually funds and conducts billions of dollars of clinical research—$8.4 billion in FY 2003—addressing the full panoply of public health problems that confront the nation. As such, we have a vested interest in catalyzing the transformation of policies throughout the federal government, while maintaining an emphasis on the integrity and effectiveness of federal and institutional systems of oversight. In the upcoming year, the NIH will design pilot programs for a revolutionary National Electronic Clinical Trials and Research (NECTAR) network. These pilot programs will begin to develop an infor-

CONTINUED ON PAGE 72

Subject: correction
From: "Richard Latker" <pristine2@hotmail.com>
Date: Wed, 14 Apr 2004 10:52:07 +0800
To: Latkerc@bellatlantic.net

"Doomed" and "certain" are redundant. Use "doomed to failure" or "will certainly fail."

2) Intro: "this marvellous engine of innovation could stall."

Take out "of innovation", as you have the same reference in the preceding para.

3) "Bayh-Dole is not an instrument to control drug prices."

Remove this. It was originally a subhead, and you repeat the same thing in the next sentence.

4) "Accordingly, I feel strongly that the petitioners' request for a march-in action based on a misinterpretation of the controlling intellectual property laws motivated entirely by a desire to control drug prices, must be denied."

Pretty terrible. Rewrite: "Accordingly, I feel strongly that the petitioners' request for a march-in action, motivated entirely by a desire to control drug prices and based on a misinterpretation of the law, must be denied."

R---

Get 10Mb extra storage for MSN Hotmail. Subscribe Now!
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Subject: Re: test
From: Carole and Norman Latker <Latkerc@bellatlantic.net>
Date: Thu, 08 Apr 2004 07:35:51 -0400
To: Richard Latker <pristine2@hotmail.com>

Maureen
Some
Minor
Changes —
Pl. G for Pick-up at 12.00

NORMAN J. LATKER
5112 Edgemoor Lane
Bethesda, MD 20814

April 13, 2004

Dr. Mark Rohrbaugh
Dir. of the Office of Tech. Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852

Dear Dr. Rohrbaugh:

I would like to comment on recent petitions filed by Mr. James Love and Mr. Sean Flynn of Essential Inventions, Inc, requesting the National Institutes of Health to invoke the march-in provisions of the Bayh-Dole Act to invalidate exclusive drug patents held by Abbott Laboratories and Pfizer Inc.

While the authors of the petition might be commended for embarking on such an innovative approach to controlling drug prices, it must be clearly understood that Bayh-Dole defines critically important aspects of intellectual property law, and is decidedly ill suited for any other purpose. Any attempt to use it as a weapon in the political debate over drug prices is doomed for ~~certain~~ failure, as the enabling language required for such uses is wholly - and intentionally -absent from the legislation.

In the unlikely event that NIH were to grant the request of the petition's authors, the decision would have virtually no chance of surviving judicial review.

Nonetheless, I feel compelled to speak out in defense of Bayh-Dole, which has fostered the development of a potent four-way partnership between researchers, their institutions, government and industry. This partnership has become a powerful engine of innovation, generating more practical advances than the rest of the world combined. Nowhere is this more true than in the fields of medical technology and pharmaceuticals.

Should the petitioners succeed in subverting one of the key precepts of Bayh-Dole - that of according broad marketplace prerogatives to the developers of government-funded inventions - this marvelous engine ~~of innovation~~ could stall.

The Spirit Of Bayh-Dole

I hope I can provide some perspective on the Bayh-Dole Act, large portions of which I helped to draft back in the 1970s, when I served as Patent Counsel for the Department of Health, Education and Welfare (HEW). I was also an architect of the Act's implementing regulations, to which the authors of the petitions heavily refer.

The authors have woefully misrepresented the spirit and purpose of the legislation, which was intended to enlist the marketplace to develop and distribute government-supported innovations. Judging from the petition, they appear to have been informed primarily by a recent article in the Tulane Law Review, penned by Peter S. Arno & Michael H. Davis, which unfortunately paints a highly distorted picture both of the Act itself and the legislative process leading to its passage.

Before the enactment of Bayh-Dole, an enormous amount of government-sponsored research and innovation went to waste, as there were no clear mechanisms in existence to transfer the resultant inventions to the marketplace.

Although there was spirited opposition to the bill, a powerful bipartisan consensus was built around the basic notion that market forces would do a far better job of disseminating such inventions to society than government bureaucracies ever could.

Put simply, the drafters of the act wanted to ensure that adequate incentives were in place to facilitate invention and to attract corporate investment into their development and distribution. We understood that inventions resulting from government research are conceptual in nature, and require significant investment by the private sector to bring them into practical application. This is especially the case with regard to life science inventions, the subject of the march-in requests.

Our answer to the problem was that intellectual property rights should be accorded in full to the innovators, rather than to the government agency that financed their research, and that innovators should be free to leverage their property rights to their advantage in the market place as intended by the patent system. The only conditions to be attached to this freedom were envisioned as follows:

a) Reasonable efforts were required to develop the inventions to practical application;

b) The inventions should be readily available to society;

c) The inventions should not be used in such a way that might threaten public health;

d) If an invention were subject to a federal order of some kind, the developer must comply with that order; and

e) The inventions should be manufactured within the United States.

These conditions were translated into the legal language found in section 203a of the Act, which is reproduced in the subject petitions. The march-in clauses were conceived, as extraordinary measures to be used only when there was overwhelming evidence to show that the public resources invested into an innovation were being wasted or abused. This is clearly not the case with either Retonavir or Latanoprost, both of which have been successfully developed and are readily available to the public at large.

Control Of Drug Prices

~~Bayh-Dole is not an instrument to control drug prices~~. What I find most disturbing about the subject petitions is the attempt to transform a fundamental piece of intellectual property law into an administrative mechanism to control drug prices, with no regard for the consequences.

The drafters of Bayh-Dole never envisioned that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information, which is why the Act lacks any functional criteria specifying how this could be done.

Nonetheless, the petition's authors hold that the government should issue multiple licenses for the drugs because the companies are charging too much for them, and quite falsely assert that the Act invests funding agencies with the authority to approve the pricing of inventions after they have been developed and distributed in the marketplace by private sector initiatives.

The assertion that funding agencies are vested with the jurisdiction to approve pricing is said to rest on the Act's definition of "practical application" which includes a requirement that the invention be made available to the public on "reasonable terms". The petitioners argue that the latter term is to be interpreted, in an ordinary context, as including a "reasonable price", and that the funding agency is therefore authorized to assess what a "reasonable" market price might be.

The Scalia Rule

That "reasonable terms" must include the notion of price, they maintain, is evidenced by a number of court decisions supporting that definition. They also cite the Scalia rule:

> [First], find the ordinary meaning of the language in its textual context; and second, using established canons of construction, ask whether there is any clear indication that some permissible meaning other than the ordinary applies. If not - and especially if a good reason for the ordinary meaning appears plain - we apply the ordinary meaning.

Scalia's instruction to refer to the "textual context" of the language is indeed helpful-but not to the argument put forth by the authors of the petition. The march-in conditions and the entire body of the Bayh-Dole Act stress the overriding importance of delivering intellectual property rights to innovators and developers. Property rights are inherently invested with the ability to set prices. The Act also emphasizes the broad dissemination of the benefits of the invention to society.

In context, therefore, "reasonable terms" cannot be interpreted to mean a limitation on the developer's ability to set prices in the marketplace.

In fact the opposite is true: if the rights-holder were not given the freedom to set prices, it would not be willing to commit resources required to ensure an invention's delivery into the marketplace, thereby obviating the requirement that it be widely available. No commercial concern would invest in the commercial development of any invention knowing that their sales price could be challenged by the government after marketing.

Again, if the drafters had intended such an interpretation, we would have inserted specific criteria into the law to enable the funding agency to assess exactly what a reasonable price might be. No such criteria are found, precisely because controlling patent rights on the basis of price was antithetical to what the drafters had in mind.

The Price Of Drugs

Of course it could be argued that extremely high prices might prevent an invention from achieving widespread application, and the petition authors attempt to show that this is the case with Retonavir or Latanoprost.

However, while the authors might show that the drugs are expensive, they fail utterly to substantiate the notion that high prices have curtailed their availability, or their continued improvement by the developer. For example, the authors fail to show that the 600-800 people nationwide who do not have access to Retanovir would necessarily be granted access if the price of the drug were reduced. They also fail to mention the tens of thousands of people who do have access to the drug, and that many of these individuals receive it for free.

Price comparisons with other countries are also of dubious value. The authors argue that since the developers companies offer the same drug at lower prices in other countries, that this somehow violates the notion of reasonable terms. Not only do they fail to substantiate this logically, they also fail to point out that the average prices paid for drugs overseas are often reduced by means of direct government subsidies and/or price controls, neither of which are effected through intellectual property law.

The authors also imply that since the drug was developed in the United States, it is unfair that Europeans are getting it cheaper:

> "Prices in the U.S. are generally 2-5 times the price in most European countries, despite American taxpayers funding its early development."

Even if one accepts the prices the authors provide for Latanoprost in various countries at face value - although one must wonder about the methodology used, and how representative or timely the data really are - they provide no insight into how or why drug prices come to be lower in other countries.

Note that prices are lower not only in the low income countries like Nicaragua where weak spending power could compel lower prices - but also in countries like Germany and Sweden, where per capita spending power is roughly equivalent to that in the U.S. The primary reason is that the vast majority of drug purchases in such countries are financed by governments, which use their monopoly power to keep the price of medications low.

Healthcare Policy

That is not to say that the needs of the minority who do not have access should be ignored. But it must be plainly understood that medical access problems in the United States stem from the way healthcare entitlements are ascribed and healthcare resources are distributed.

Healthcare reform has been under consideration in the Congress recently and the possibility of the policies of state-mandated price controls or broad entitlements to healthcare as they exist in European countries have been discussed. But the appropriate means to effect such policies must be through public debate, legislation and/or referenda.

Obviously any healthcare reform effort could face resistance from vested interests, and it is tempting for some to look for shortcuts. But twisting intellectual property law into a political weapon of expediency is not the answer.

In the absence of government price controls, drug companies will seek to maximize their profits by balancing

prices with the need for market penetration - and that is exactly what the drafters of Bayh-Dole expected. Pricing freedom is one reason often cited by the pharmaceutical industry for concentrating their research and development activities in the U.S. It is why the U.S. remains the world leader in medical research, and why so many drugs are made available here first.

If a political consensus were to emerge that drug prices need to be controlled by the government, the only legal and appropriate means of instituting such controls would be through a full-fledged legislative process, tested by the courts and administered through empowered organs of government.

Accordingly, I feel strongly that the petitioners' request for a march-in action based on a misinterpretation of the ~~controlling intellectual property laws~~ motivated entirely by a desire to control drug prices, must be denied.

Sincerely,

Norman J. Latker

NJL:ma
G:\BN\MISC\Final Rohrbaugh Ltr 13April04.doc

Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852

Dear Dr. Rohrbaugh:

We are writing on behalf of the Association of University Technology Managers (AUTM®), to comment on the petition to use the authority under the Bayh-Dole act to promote access to: (a) Ritonavir, supported by National Institute of Allergy and Infectious Diseases Contract no. A127220; and (b) Latanoprost, supported by U.S. Public Health Service Research Grant Numbers EY 00333 and EY 00402 from the National Eye Institute, filed by Essential Inventions, Inc. with Secretary Thompson on January 29, 2004. AUTM® is a nonprofit association with membership of more than 3,200 technology managers and business executives who manage intellectual property at over 300 universities, research institutions, teaching hospitals and a similar number of companies and government organizations.

While the subject of delivering affordable health care is certainly a serious issue for the United States, we believe it must be addressed through other means. There are no expressed authorities in the Act or implementing regulations that would support the petitioner's position for Governmental actions such as those requested. As noted in 35 U.S.C. 200, the general description of the authorities reserved to the government are limited, "...to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non-use or unreasonable use of the invention..." (underlining added).

The general reservation of rights in the Government is specifically implemented in the march-in provision of 35 U.S.C. §203, which should not be read to be any broader than intended in the general reservation of 35 U.S.C. §200, which would be necessary to grant the requested march-in request. Indeed, such actions as proposed by the petitioner were never contemplated by the Congress and are not reflected in a proper understanding of the legislative history of the law. On the contrary, it is clear that such authorities would actually frustrate the stated policy and objectives of the Act to create incentives for commercial development by assuring, when necessary, an exclusive patent position (see 35 U.S.C. 200).

We believe that an NIH interpretation of the Bayh-Dole Act as advocated by Essential Inventions would disable the Act. The primary basis for the Act lies in the belief of individual action as opposed to government action and the power of the market. Most inventions resulting from government research are conceptual in nature and require significant investment by the private sector to bring them into practical application. This is particularly true of life science inventions requiring licensure by the Food and Drug

Administration. Commercial concerns are unlikely to invest substantial financial resources in the commercial development of any invention, funded in part by the government, knowing that the government could challenge their competitive position after the product was introduced onto the market. As was the experience in the years before the passage of the Bayh-Dole Act, when government policy was to grant only non-exclusive licenses, no drugs for which the government held title were developed and made available to the public.

Currently, exclusive licenses of federally funded inventions are believed to be dependable. This dependability can be maintained only if all those involved in the process retain full confidence that the march-in remedy will be exercised only in those extraordinary circumstances clearly anticipated by the Act. In 1997, Harold Varmus, then Director of the NIH, recognized this potential when he rejected the march-in petition of CellPro after it lost a patent infringement suit brought by Johns-Hopkins University, Becton Dickinson and Baxter. In issuing his determination, he stated:

> *"The patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the dissemination and development for new and useful technologies. It has proven an effective means for the development of healthcare technologies."*

On May 13, 2003, after a detailed study of technology transfer mechanisms, the President's Council of Advisors on Science and Technology concluded:

> *"Existing technology transfer legislation works and should not be altered."*

Interpreting agency authority to exercise march-in rights as advocated by the petitioner would be a major alteration to the existing technology transfer legislation. Granting a march-in in this instance would, we believe, serve only a narrow interest and be contrary to the broader public interest the Act is intended to serve. While we do not wish to diminish the seriousness of the issue of delivering affordable health care we believe it must be addressed through other means and urge the NIH to reject Essential Inventions's petition.

Sincerely,

AUTM

Call for Topics

2005 AUTM Annual Meeting℠
Feb. 3-5, 2005
JW Marriott Desert Ridge Resort & Spa
Phoenix

AUTM is the world's leading nonprofit organization dedicated to promoting, supporting and enhancing the global academic technology transfer profession. AUTM strives to provide educational forums that help technology transfer professionals get new products to market, build research efforts and improve our quality of life. Each year, more than 2,000 individuals from around the globe attend AUTM meetings and courses.

AUTM Annual Meeting
The 2005 AUTM Annual Meeting will be held Feb. 3-5, 2005 in Phoenix at the JW Marriott Desert Ridge Resort & Spa. The meeting is a three-day educational conference that draws from the global community of technology transfer professionals, researchers and other intellectual property experts. The Annual Meeting features 10 tracks and 40 interactive workshops developed for individuals with years of experience in academic technology transfer as well as newcomers to the field.

Review Procedure & Timeline
The Annual Meeting Program Committee will meet in mid-April 2003 to plan sessions for the 2005 meeting. Any session ideas received prior to **April 15, 2004** will be considered by the Program Committee; ideas received after that date may be held for consideration for the 2006 Annual Meeting. For sessions selected for the 2005 meeting, moderators will be asked to identify an abstract and speakers by July 30, 2004; final session information will be due to AUTM September 30, 2004.

Session Specifics
I would be interested in ☒ attending or ☐ organizing sessions on the following topic(s) at the 2005 AUTM Annual Meeting.

Suggested Title or Topic*: THE EVOLUTION OF THE BAYH-DOLE BODY OF LAW

Suggested Abstract*: _____

Possible Moderator: Howard Bremer, Ashley Stevens

Position: _____

Organization: W.A.R.F. BOSTON UNIVERSITY

Address: _____

Phone: _____ E-mail: _____

** For review purposes only. Presenters will later be asked to submit a final title, session description and list of participants for inclusion in conference materials.*

Intended Audience/Interest Group (check all that apply):

- [x] Technology Managers
- [ ] Directors
- [ ] Company (Affiliate members)
- [ ] Operations
- [x] International

The **experience level** I would like this session directed toward is (check one):

- [x] Beginner (1-2 years experience in this area)
- [x] Advanced (3+ years experience in this field)

I see this session fitting into the following **type of programming**:

- [ ] Workshop
- [x] Educational Track
- [ ] Plenary session (AUTM Board makes these decisions)
- [ ] Special Interest Group (SIG)
- [ ] Add-on (before/after conference)

I see the session fitting into this **track** (check one):

- [ ] Professional Development
- [ ] Office Operations
- [x] Policy Framework
- [x] IP Law & Application
- [ ] Pre-Disclosure Management
- [ ] Marketing
- [ ] Licensing process
- [ ] Post License Management
- [ ] Technology Specific
- [ ] Outreach

I am interested in **assisting with this session** by

- [ ] moderating
- [x] speaking
- [ ] finding speakers

Your contact information:

Name: Norman J. Latker	Address: 624 9th Street N.W.
Position/Title: Managing Attorney	
Institution: BROWDY AND NEIMARK PLLC	City: Washinton
Phone: (202) 628-5197	State/Province: D.C.
E-mail: NJL@BROWDYNEIMARK.COM	Country: USA

Thank you for your input!

Please return this form to the AUTM registration desk or send it to AUTM headquarters by fax at 847/480-9282 or via e-mail at autm@autm.net.

Confirmation Report – Memory Send

Time : Apr-06-2004 15:43
Tel line : 2027373528
Name : BROWDY NEIMARK

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AUTM
Association of University Technology Managers

Call for Topics

2005 AUTM Annual Meeting℠
Feb. 3-5, 2005
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Phoenix

AUTM is the world's leading nonprofit organization dedicated to promoting, supporting and enhancing the global academic technology transfer profession. AUTM strives to provide educational forums that help technology transfer professionals get new products to market, build research efforts and improve our quality of life. Each year, more than 2,000 individuals from around the globe attend AUTM meetings and courses.

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Suggested Abstract*: _____

Possible Moderator: Howard Bremer, Ashley Stevens

Position: _____

Organization: W.A.R.F. BOSTON UNIVERSITY

Address: _____

Phone: _____ E-mail: _____

** For review purposes only. Presenters will later be asked to submit a final title, session description and list of participants for inclusion in conference materials.*

From: <jallen@nttc.edu>
To: <NJL@browdyneimark.com>
Date: 4/22/04 2:35PM
Subject: Fw: [Publicpolicy] What next?

Looks like this bounced back from your home e-mail address
----- Forwarded by Joe Allen/NTTC on 04/22/2004 02:34 PM -----

Joe Allen/NTTC
04/22/2004 11:13 AM

To
Norm Latker, Howard Bremer, Patricia Harsche
cc

Subject
Fw: [Publicpolicy] What next?

Not sure if you are on the AUTM public policy committee or not, so sending this along.

----- Forwarded by Joe Allen/NTTC on 04/22/2004 11:11 AM -----

Joe Allen/NTTC
04/22/2004 11:09 AM

To
Janna Tom <janna.tom@ucop.edu>
cc
Publicpolicy@autmlists.net
Subject
RE: [Publicpolicy] What next?

Thanks, as we discussed at the AUTM meeting, to me that most important thing we can do is to re-awaken the Senate Judiciary Committee that Bayh-Dole is their baby-- and a pretty one at that!

One of the problems is that with the staff turn overs, no one on the Committee remembers that this law comes under their wing. If you look where the debate's taking place now, these are Committees with no oversight of Bayh-Dole, but they are having individual members getting energized by the other side to move into the breach.

Luckily, many of the original Senate Judiciary Committee sponsors of Bayh-Dole (Hatch, Kennedy, Leahy, Biden) are still there and running things. While they fight about judicial nominations, they could be

brought together on how important their state universities are to growing their economies if they are approached the right way.

This is what Birch Bayh suggested in Texas, and as usual, I agree with my old boss.

Janna Tom <janna.tom@ucop.edu>
04/22/2004 10:59 AM

To
jallen@nttc.edu
cc
Publicpolicy@autmlists.net
Subject
RE: [Publicpolicy] What next?

Joe:

I agree that our message needs to get out to policy makers more than it has. If we're going to have any effect, we need a coordinated and concerted effort. So, let's strategize for a moment.

Educating our Federal Relations folks is important, so they'll know what Bayh-Dole is and how it's important. Encouraging them to talk it up whenever possible as they are visiting your state's delegation. Should our Public Policy Committee develop Talking Points on Bayh-Dole (to which each institution can add their own examples) that would encourage tech tx offices to approach their Fed Relations folks? Then leave Talking Points with Fed Relations folks so they can talk fluidly about it with the state's delegation?

I have given presentations to both my Fed and State offices on tech tx at our university, Bayh-Dole and government issues, but don't know how many other tech tx offices have that opportunity. Would it be worthwhile trying to have the AUTM Public Policy Committee put together a breakfast presentation in D.C. and have every institution encourage their Fed Rels folks to attend (early breakfast, because you know how hard it is to get them to be in one place for a long time)?

The AAU Tech Transfer Working Group seems to also be talking along these same lines. I'm not a regular member of that group, but someone on this listserv is bound to be. Maybe having a presentation at one of the AAU meetings so that this remains on the radar of our Presidents and other top university reps, plus presentation for Fed Rels folks (have AAU Presidents encourage their attendance), maybe even presentation for staffers if we can herd them into one room for awhile.

I know this is sounding earnest, but to be effective, we need a plan or we'll just continue drifting. I'm open to other ideas and constructive criticism. Jon, are you a member of the AAU TT Working Group - can we plan something with them? Maybe approach them and select a few people from each group plus from COGR in order to come up with a plan of attack?

Janna

At 10:15 AM 4/22/2004 -0400, jallen@nttc.edu wrote:

I agree with you. The reason the other side is making such an impact is that they have had the field all to themselves. Look at the progression they've successfully made: from the Tulane law review, to the Wash. Post Op-Ed piece, to putting the Director of NIH on the defensive. They are determining the debate by picking the battlefield.

I believe what's really needed is to get policy makers to see the bigger picture of how Bayh-Dole is an important part of our economic development. Frankly, I can't defend particular decisions of drug companies, but am very comfortable talking about what would happen to our economic future if we un-coupled universities from industry. What state is not including their research universities in their economic development plans? I know that West Virginia certainly is and our leaders see our research universities as one of the major ways to work our way out of the hole our economy is stuck in.

We can win that fight--- if we we're willing to get engaged rather than waiting until we get attacked -- and you can bet that this is not the end of their attacks.

"Wolf, Rich" <Rich.Wolf@caltech.edu>

04/21/2004 11:06 AM
To
"James A. Severson" <jasever@u.washington.edu>, <jallen@nttc.edu>, <Publicpolicy@autmlists.net>
cc
Subject
RE: [Publicpolicy] What next?

Joe,

I could not believe the exchange so much that I had to read it once again. This guy, Arti Rai, and others could create an opinion swell that may turn against universities in a way that none of us want. I do not want to sound like an alarmist, but the more I read these types of messages, the more I think that our cause on the public policy committee is more

critical than ever before. The drug pricing issues are more prevalent than they have ever been, and we are a perfect target (even though we all know that undermining Bayh-Dole could eventually have no imnpact whatsoever on drug prices, but rather would likely slow down the expansion of research at the companies). I sent this on to our government affairs person, and I would encourage everyone else on the list to do the same if you have not already done so. It would be nice to create a united front among universities that extends beyond the public policy committee. We may need all the assistance we can get.

Rich

Richmond Wolf, PhD
Director
Office of Technology Transfer
California Institute of Technology
Mail Code 210-85
Pasadena, CA 91125
(626) 395-2322

-----Original Message-----
From: James A. Severson [mailto:jasever@u.washington.edu]
Sent: Tuesday, April 20, 2004 1:23 PM
To: jallen@nttc.edu; Publicpolicy@autmlists.net
Subject: RE: [Publicpolicy] What next?

This is an incredible series of messages. It does show the fervor of the groups that we are dealing with. Joe, I know that it does not count for much, but we're supporting you. Thanks for being the point man on this one.

==========

James A. Severson, Ph.D.
Vice Provost, Intellectual Property and Technology Transfer
UW TechTransfer
University of Washington
4311 11th Avenue NE, Suite 500
Box 354990
Seattle, WA 98105-4608

Voice: 206.543.0905
Fax: 206.543.0586
Email: jasever@u.washington.edu

[rest deleted]

****

Janna C. Tom
Policy, Analysis and Campus Services
Office of Technology Transfer
University of California, Office of the President
1111 Franklin Street, 5th Floor
Oakland, CA 94607-5200
phone: 510-587-6059
fax: 510-587-6090 (please note new fax number)
http://www.ucop.edu/ott/
****

From: Carole and Norman Latker <Latkerc@bellatlantic.net>
To: <njl@browdyneimark.com>
Date: 4/22/04 9:53AM
Subject: [Fwd: techno-l site]

-------- Original Message --------
Subject: techno-l site
Date: Wed, 21 Apr 2004 16:31:33 -0400
From: jallen@nttc.edu
To: latkerc@bellatlantic.net

Here's what "Jamie" Love posted on the "techno-l" website. I highlighted below where you can reply. Let me know when you post your comments!

Thanks

-----Original Message-----
From: James Love [mailto:james.love@cptech.org]
Sent: Tuesday, April 20, 2004 2:14 AM
To: techno-l@lists.uventures.com
Subject: [techno-l] Joseph P. Allen opposition to Abbott/Norvir March-in Request

Joseph Allen was written the NIH in opposition to the Essential Inventions petition for march-in rights on Abbott's patents on ritionavir, an AIDS drug that Abbott prices 5 to 10 times higher in the USA than in other high income countries. (400 percent higher in the USA when you buy non-Abbott protease inhibitors). Mr. Allen's letter (below) claims that an "unreasonable price" is not prohibited by the federal requirments that inventions be "available to the public on reasonable terms." Jamie

7 CFR § 401.2 Definitions.

(e) The term practical application means to manufacture in the case of a composition of product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

-------- Original Message --------
Subject: [Ip-health] Nat'l Tech Transfer Ctr on March-in

Date: Mon, 19 Apr 2004 12:27:39 -0400
From: Sean Flynn <sean.flynn@cptech.org>
Organization: http://www.cptech.org <http://www.cptech.org/>
To: ip-health@lists.essential.org

March 31, 2004

Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer Office of Intramural
Research National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852

Dear Dr. Rohrbaugh:

I recently became aware of a petition addressed to you by Mr. James Love, President of Essential Inventions, Inc. requesting that the National Institutes of Health exercise the march-in rights provision of the Bayh-Dole Act to lower the price of several drugs developed from NIH extramural research.

While the subject of delivering affordable health care is certainly a serious issue, the provisions of the Bayh-Dole Act do not provide for governmental actions such as those requested by Essential Inventions. Indeed, such actions were never contemplated by the Congress and are not reflected in the legislative history of the law.

The interpretation of the intent of Congress in passing this landmark legislation reflected in Mr. Love's petition is, therefore, entirely fanciful.

While serving former Senator Birch Bayh on the Senate Judiciary Committee, I staffed the hearings and wrote the report of the Senate Judiciary Committee on the bill. I also served for many years as the Director of Technology Commercialization at the U.S. Department of Commerce. There I oversaw the implementation of the regulations for Bayh-Dole and chaired the Interagency Committee on Technology Transfer which developed guidelines for utilizing the Federal Technology Transfer Act, under whose authorities NIH develops many of its intramural partnerships with U.S. industry.

Regrettably, Mr. Love and several others making the same case mix up the legislative history of the Bayh-Dole Act with hearings on rival legislation that was not enacted. The only legislative history with any bearing on the law are the hearings of the U.S. Senate Judiciary Committee in the 96th Congress on S. 414, the University and Small Business Patent Procedures Act (commonly called Bayh-Dole), the report of the Senate Judiciary Committee on the same, and the Senate debates on S. 414.

Fortunately, we do have an unambiguous opinion from Senators Birch Bayh and Robert Dole themselves on the topic at hand. The Washington Post ran an article by Professors Peter Arno and Michael Davis on March 27, 2002,

Paying Twice for the Same Drugs, making the same arguments as Mr. Love. They wrote:

Bayh-Dole is a provision of U.S. patent law that states that practically any new drug invented wholly or in part with federal funds will be made available to the public at a reasonable price. If it is not, then the government can insist that the drug be licensed to more reasonable manufacturers, and, if refused, license it to third parties that will make the drug available at a reasonable cost.

A joint letter by Senators Bayh and Dole on April 11, 2002, to The Washington Post effectively refutes this argument. Here is the complete text of what the authors of the law said was their intent with regard to fair pricing of resulting products:

As co-authors of the Bayh-Dole Act of 1980, we must comment on the March 27 op-ed article by Peter Arno and Michael Davis about this law.

Government alone has never developed the new advances in medicines and technology that become commercial products. For that, our country relies on the private sector. The purpose of our act was to spur the interaction between public and private research so that patients would receive the benefits of innovative science sooner.

For every $1 spent in government research on a project, at least $10 of industry development will be needed to bring a product to market. Moreover, the rare government-funded inventions that become products are typically five to seven years away from being commercial products when private industry gets involved. This is because almost all universities and government labs are conducting early-stage research.

Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.

The article also mischaracterized the rights retained by government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product. (Emphasis added).

The law we passed is about encouraging a partnership that spurs advances to help Americans. We are proud to say it's working.

Birch Bayh/Bob Dole

In their typically succinct manner, the authors of the law effectively rebut the argument now before you.

The Bayh-Dole Act has become a linchpin of our economy. While not perfect, the U.S. record of commercializing new products and services funded by the Government is the envy of the world. The Economist Technology Quarterly said: "Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980." Any legislative or administrative actions undertaken to alter this Act must be done very carefully.

We have already witnessed well-intended Congressional attempts to impose fair pricing clauses on NIH intramural research partnerships. These efforts failed. Technology transfer cannot be a vehicle for trying to control prices. Rather than allowing Government to dictate drug prices, companies simply walked away from partnering with NIH. Wisely recognizing its mistake, Congress rescinded the fair pricing requirement. NIH's subsequent success in building effective partnerships with industry is well documented, and is a great benefit to the public.

President Johnson asked in 1968 how many NIH owned inventions had been commercialized. The answer was none. At that time there were no incentives for industry to undertake the risk and expense inherent in developing such early stage inventions. We should reflect that because of the Bayh-Dole Act, many life saving drugs and therapies are now available for those in need. By altering this delicately balanced law, we may well discover that publicly funded inventions go back to gathering dust on the shelves. Before Bayh-Dole such discoveries were not available at any price.

Sincerely,

Joseph P. Allen
President
National Technology Transfer Center

Ip-health mailing list
Ip-health@lists.essential.org
http://lists.essential.org/mailman/listinfo/ip-health

--

James Love, Director, Consumer Project on Technology
http://www.cptech.org <http://www.cptech.org/>,
mailto:james.love@cptech.org tel. +1.202.387.8030, mobile +1.202.361.3040

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From: "Richard Latker" <pristine@netvigator.com>
To: "Maureen Adams" <adamsm@browdyneimark.com>
Date: Wednesday, March 31, 2004 1:10PM
Subject: Re: First Draft - Rebuttal of James Love's March-In Requests

I'll do my best.

What is a "march-in," exactly?

I can probab ly find the Tulane Law review article, but if you could provide Love's document somehow it would be appreciated.

----- Original Message -----
From: "Maureen Adams" <adamsm@browdyneimark.com>
To: <sheldon#032#steinbach@ace.nche.edu>; <latkerc@bellatlantic.net>; "Norman Latker" <NJL@browdyneimark.com>; <Rhardy@cogr.edu>; <Michael#032#remington@dbr.com>; <ahammer@mit.edu>; <jallen@nttc.edu>; <jon.soderstrom@yale.edu>
Sent: Tuesday, March 30, 2004 6:56 AM
Subject: First Draft - Rebuttal of James Love's March-In Requests

I'm attaching a requested first draft of a rebuttal of James Love's march-in requests to DHHS which in most part is also a rebuttal of the Tulane Law Review article which serves as the basis for the requests. Any suggested changes would be welcome either orally or by e-mail.

Norm Latker

M E M O R A N D U M

To: Patent Attorneys and Allen

From: Sheridan Neimark SN

Date: April 12, 2004

Subj: New Examiner "Interview Summary" Form

The new form imposes obligations on the applicant's representative which the old form did not impose.

The bottom paragraph on the front of the first page states as follows:

> THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (see MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Thus, if a Reply has already been filed, it is necessary to in effect file a second Reply within one month, which second Reply contains "a statement of the substance of the interview".

The back side of the form (or it will be a second page if mailed or faxed) sets forth details of what is required for the "statement of the substance of the interview", and further notes that the examiner "Interview Summary" form itself "will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview."

There then follows a list of seven items including, most important,

2) an identification of all the claims discussed,

3) an identification of the specific prior art discussed,

4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the examiner,

5) a brief identification of the general thrust of the principal arguments presented to the examiner,

6) a general indication of any other pertinent matters discussed, and

7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

PUBLIC MEETING

National Institutes of Health - Building 50
May 25, 2004

9:00	**INTRODUCTION**
9:05	The Honorable Birch Bayh
9:20	Ted Poehler, Ph.D., Vice Provost for Research, Johns Hopkins University, American Association of Universities
9:35	Daniel Ravicher, Executive Director, Public Patent Foundation
9:50	John Erickson, President & Chief Scientific Officer, Sequoia Pharmaceuticals
10:05	Robert Huff, Editor, *Treatment Issues*, Gay Men's Health Crisis, NYC
10:20	**BREAK**
10:30	Norman J. Latker, former Patent Counsel, Department of Health, Education and Welfare
10:45	James Love, President, Essential Inventions, Inc.
11:00	Andrew Neighbour, Board Member and Chair, Intellectual Property Committee, Council on Governmental Relations
11:15	Jerome Reichman, Bunyan S. Womble Professor of Law, Duke University School of Law
11:30	Benjamin Young, M.D., Ph.D., Organization of Healthcare Providers
11:45	Jeff Leiden, M.D., Ph.D., President and Chief Operating Officer, Pharmaceutical Products Group and Chief Scientific Officer, Abbott Laboratories
12:00	**ADJOURN**

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- Models that use game theory to predict the actions of either cooperative or competitive individuals (or firms). In cooperative game theory, the agreements that emerge from colluding individuals are examined. Noncooperative game theory is concerned with the actions of rational, intelligent individuals competing independently. A key element of this theory is the Nast equilibrium, i.e., a set of strategies, one for each individual, such that no individual would then unilaterally like to change the strategy. Typically, the individuals are assumed to adopt strategies in accordance with this equilibrium (assuming that such an equilibrium exists). For an overview of game theory in marketing, see Moorthy (1985).

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The Back Half - The great game

The Back Half
Simon Singh
Monday 25th March 2002

Mathematics - **Simon Singh** on "Nash's equilibrium", the brilliant legacy of an unstable mind

A *Beautiful Mind* is a film about a mathematician, but it is not a film about mathematics. It concentrates on John Nash's battle with schizophrenia, and barely touches on his great mathematical achievements, which are mentioned only in bar-room scenes or hinted at via arcane equations scrawled on window panes.

To try to complete the picture, it is important to understand Nash's passion - game theory - and how his contribution to that subject has had a huge influence on modern economics. In just a few short years, a man barely out of his teens laid the foundations for a discipline that had an enormous impact on economies all over the world.

Game theory, put simply, is the mathematical study of the strategies used to win games. It began with the study of such games as noughts and crosses and chess, which are relatively easy to analyse because they are games of "complete information" - in other words, each player can see the other's position.

Then mathematicians became interested in games such as poker, which is much more interesting because players cannot see each other's cards. Poker is a game of "incomplete information", so more subtle elements such as bluff come into the analysis.

Eventually, mathematicians attempted to analyse more important games, including economics, warfare and divorce settlement. In each case, you have two parties competing over money or territory; each party develops a strategy based on its own strengths and objectives, and on the perceived mindset and skills of their opponent. Game theory is maths plus a dash of psychology.

And the man who did more than anyone else to apply game theory to the real world was John Nash. Between 1950 and 1953, Nash published four papers that revolutionised game theory. Still in his early twenties, he conducted a deep analysis of a special set of games that were said to be non-zero sum.

In most games, including chess, there is a zero sum, which means that if I win, then you lose, or vice versa. But in a non-zero-sum game, both players can win . . . or both can lose. For example, pay negotiation between management and a trade union can be a non-zero-sum game. The result can be a long strike that hurts both sides, or a fair agreement that benefits

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The great game: Simon Singh on "Nash's equilibrium", the brilliant legacy of an unstable mind. (Mathematics).(Review)

New Statesman, March 25, 2002, by Simon Singh

Continued from page 1

In contrast, economists now encourage the auctioning of licences. Using Nash's equations, economists treat the auction like a game and construct the rules to achieve the seller's goals. The game theorist will optimise the rules of the auction, which involves setting the reserve price, deciding whether to request sealed or open bids, deciding if lots should be sold simultaneously or consecutively, and fixing the penalty for a successful bidder who then defaults on payment.

The UK 3G auction was a great success and raised a phenomenal [pounds sterling]22.5bn. Critics have argued that the companies paid too much, but the mathematician who designed the auction argues that the companies paid what they knew they could recoup in future profits. Professor Ken Binmore of University College London argues that "a carefully designed auction achieves this end by creating a competitive environment in which the bidders are forced to put their money where their mouth is".

Binmore's work is a direct consequence of Nash's brilliant mathematics, which enshrined the essence of bargaining, bidding and negotiation within a rigorous framework. But how does the story of his research tie in with the tragedy of his insanity, which is the subject of Ron Howard's film? It cannot be denied that Nash was unable to do research when his schizophrenia took over. However, I still remember the opening page of Sylvia Nasar' s biography A Beautiful Mind, the basis for the film, which recounts how a friend visiting Nash in hospital asked how he could believe that aliens were recruiting him to save the world. Nash simply replied: "Because the ideas I had about supernatural beings came to me the same way that my mathematical ideas did. So I took them seriously."

Theatre of Science, Simon Singh 's show about game theory and risk, is at London's Soho Theatre, W1 (02074780100), in April

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(Strategic) Equilibrium

Profile of plans leading to an outcome of a game that is stable in the sense that given the other players adhere to the equilibrium prescription, no single player wants to deviate from the prescription. Any outcome that is reached by the play of strategies which do *not* form an equilibrium is an implausible way of playing the game, because at least one player could improve by selecting another strategy.

The concept of strategic equilibrium is completely unrelated to (Pareto) efficiency. Correspondigly, infinitely many games have (only) inefficient strategic equilibria; for a striking example, see the Prisoners' Dilemma game. As a strategic equilibrium is a profile of strategies that is unilaterally unimprovable given that all (other) players conform to their equilibrium strategies, the concept is weak and very general, but on the other hand most games possess *several* strategic equilibria. One of the major achievements of game theory accordingly has been the refinement of the concept of strategic equilibrium to allow for sharper predictions.

Two major achievements in refining the concept of equilibrium center around the 'time consistency' of strategically stable plans for sequential games, and on making precise the role of the players' beliefs about other players' plans of actions and information. A more general definition of strategic equilibrium is the following: an equilibrium is a profile of strategies *and* a profile of beliefs such that given the beliefs, the strategies are unilaterally unimprovable given equilibrium behavior, and such that the beliefs are consistent with the actual courses of action prescribed by the equilibrium strategies.

Nash Equilibrium: A profile of strategies such that given the other players conform to the (hypothesized) equilibrium strategies, no player has an incentive to unilaterally deviate from his (hypothesized) equilibrium strategy. The self-reference in this definition can be made more explicit by saying that a Nash equilibrium is a profile of strategies that form 'best responses' to one another, or a profile of strategies which are 'optimal reactions' to 'optimal reactions'. Nash equilibrium is the pure form of the basic concept of strategic equilibrium; as such, it is useful mainly in normal form games with complete information. When allowing for randomized strategies, at least one Nash equilibrium exists in any game(unless the players' payoff functions are irregular); for an example, see the game of matching pennies in the entry on game theory. Typically, a game possess several Nash equilibria, and the number of these is odd.

Refinement: Either a sharpening of the concept of strategic (or, Nash) equilibrium, or another criterion to discard implausible and to select plausible equilibria when a game exhibits multiple equilibria. For example, symmetric or Pareto efficient equilibria may more plausibly be played by the players in favor of asymmetric or inefficient equilibria. Likewise, equilibrium outcomes that are 'focal' in the cultural and psychological context in which the game is played might be more plausible than those which lack such salient features. Preferring symmetric outcomes in many games leads to the selection of an equilibrium in mixed strategies. In the following, we give an idea of the basic modifications of Nash equilibrium in more complex games.

Subgame perfect equilibrium: In extensive-form games with complete information, many strategy profiles that form best responses to one another imply incredible threats or promises that a player actually does not want to carry out anymore once he must face an (unexpected) off-equilibrium move of an opponent. If the profile of strategies is such that no player wants to amend his strategy *whatever* decision node can be reached during the play of the game, an equilibrium profile of strategies is called

subgame perfect. In this sense, a subgame-perfect strategy profile is 'time consistent' in that it remains an equilibrium in whatever truncation of the original game (subgame) the players may find themselves.

Bayes-Nash equilibrium: In normal form games of incomplete information, the players have no possibility to update their prior beliefs about their opponents payoff-relevant characteristics, called their *types*. All that a player knows, except from the game itself (and the priors), is his own type, and the fact that the other players do not know his own type as well. As their best responses, however, depend on the players' actual types, a player must see himself through his opponents' eyes and plan an optimal reaction against the possible strategies of his opponents *for each potential type of his own*. Thus, a strategy in a Bayesian game of incomplete information must map each possible type of each player into a plan of actions. Then, since the other players' types are unknown, each player forms a best response against the *expected* strategy of each opponent, where he averages over the (well-specified) reactions of all possible types of an opponent, using his prior probability measure on the type space. Such a profile of type-dependent strategies which are unilaterally unimprovable in expectations over the competing types' strategies forms a Bayes Nash equilibrium. Basically, a Bayes Nash equilibrium is thus a Nash equilibrium 'at the interim stage' where each player selects a best response against the *average* best responses of the competing players.

Perfect Bayesian Nash equilibrium: Parallel to the extension of Nash equilibrium to subgame perfect equilibrium in games of complete information, the concept of Bayesian Nash equilibrium loses much of its bite in *extensive form* games and is accordingly refined to 'Perfect Bayesian' equilibrium. In a sequential game, it is often the threats about certain reactions '*off the equilibrium path*' that force the players' actions to be best responses to one another *'onto* the equilibrium path'. In sequential games with incomplete information, where the players hold *beliefs* about their opponents' types and optimize given their beliefs, a player then effectively 'threatens by the beliefs' he holds about his opponents' types after moves that deviate from the equilibrium path. Different beliefs about other players' types after deviations typically yield different reactions, some of which force the players back on the (candidate) equilibrium path, some of which lead them even farer away. In the first case, the plans of actions are confirmed by the beliefs about them, and the crucial self-confirming property of equilibrium beliefs and equilibrium strategies is met. The concept of Perfect Bayesian equilibrium makes precise this self-confirming 'interaction' of beliefs about types selecting certain actions and their 'actual' strategies. First, it requires that players forms a complete system of beliefs about the opponents' types at *each* decision node that can be reached. Next, this system of beliefs is updated according to Bayes' rule whenever possible (in particular, 'along the equilibrium path'), and finally, given each player's system of beliefs, the strategies from best responses to one another in the sense of ordinary Bayesian Nash equilibrium. A Bayesian equilibrium thus is a profile of complete strategies *and* a profile of *complete* beliefs such that (i) given the beliefs, the strategies are unilaterally unimprovable at each potential decision node that might be reached, and such that (ii) the beliefs are consistent with the actual evolution of play as prescribed by the equilibrium strategies.

Sequential equilibrium: Kind of refinement of Perfect Bayesian Equilibrium that puts sharper requirements on the beliefs which cannot be formed by Bayes' rule, but which are hold after moves off the equilibrium path. These beliefs have to be formed in a 'continuous' way from the information available in the extensive form of the game. Further refinements of Perfect Bayesian equilibrium restrict the players' beliefs about moves off the equilibrium path to the set of those types only for which the observed off-equilibrium move could have been worthwhile at all.

See also: equilibrium (in economics), competitive market equilibrium

Entry by: *Jan Vleugels*

December 1, 1997
Direct questions and comments to: Glossary master



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Nash equilibrium (Definition)

A Nash equilibrium of a game is a set of (possibly mixed) strategies $\sigma = (\sigma_1, \ldots, \sigma_n)$ such that, if each player i believes that that every other player j will play σ_j, then i should play σ_i. That is, when u_i is the utility function for the i-th player:

$$\sigma_i \neq \sigma_i' \rightarrow u_i(\sigma_i, \sigma_{-1}) > u_i(\sigma_i', \sigma_{-1})$$

$$\forall i \leq n \quad \text{and} \quad \forall \sigma_i' \in \Sigma_i$$

Translated, this says that if any player plays any strategy other than the one in the Nash equilibrium then that player would do worse than playing the Nash equilibrium.

"Nash equilibrium" is owned by Henry.
(view preamble)

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Attachments:
example of Nash equilibrium (Example) by Henry

Cross-references: utility function, player, strategies, game
There are 2 references to this object.

This is version 5 of Nash equilibrium, born on 2002-07-24, modified 2002-09-30.
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Classification:
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Pending Errata and Addenda

None.

[View all 2]

Discussion

Style: Threaded Expand: 1 Order: Newest firs reload

No messages.

Interact

rate | post | correct | update request | add derivation | add example | add (any)

May 19, 2004
Page 1

My name is Norman Latker. I am here as a private citizen to speak in the defense of the Bayh-Dole Act as it was intended to be read and as it has been followed, faithfully, for 25 years. The Act has fostered the development of a potent four-way partnership between researchers, their institutions, government and industry. This partnership has become a powerful engine of innovation, generating more practical advances than the rest of the world combined. Nowhere is this more true than in the fields of medical technology and pharmaceuticals.

One of the key precepts of Bayh-Dole is that the developers of government-funded inventions should be accorded broad marketplace prerogatives. If the petitioner succeeds in subverting this key precept, - the equilibrium of the Bayh-Dole partnership will be broken and this marvelous engine of innovation will stall.

I hope I can provide some perspective on the Bayh-Dole Act, large portions of which I helped to draft back in the 1970s, when I served as Patent Counsel for the Department of Health, Education and Welfare (HEW). I was also an architect of the Act's implementing regulations, to which the authors of the petitions heavily refer, and the HEW administrative policy that Senator Bayh referenced.

The petition reaches high but it does so from an extremely narrow intellectual base. In fact, the petition's stated authority consists of exactly one article, that appeared recently in the Tulane Law Review. The petition merely republishes the contention, made in that article, that federal agencies have the authority to end the exclusive right of a developer of a government funded invention, if the invention is being sold at an unreasonable price. In my humble opinion, the Tulane Law Review article sacrifices scholarly rigor and objectivity in the service of its obvious political ambitions. As a result, it paints a picture of the Bayh-Dole Act and the legislative process that led to it passage, that is more than creatively colored; it is flatly inaccurate.

Before the enactment of Bayh-Dole, an enormous amount of government-sponsored health research went to waste, because there was no incentive to invest in establishing the utility and safety of the resulting inventions and thus bring them to the marketplace.

The drafters of the Act understood that inventions

resulting from government research are mostly conceptual in nature, having no established utility or safety. That research might show that it was possible to treat silicon so it could act like a switch for electrical current; but it did nothing to produce the transistors, and the multitude of solid-state devices, we use every day. That work, of bringing the basic invention to practical application, to make something that is safe and useful in the hands of the consuming public, has always required a significant investment by the private sector. The private investment normally exceeds by many multiples the government funding that produced the original invention. This is especially the case with inventions in the life sciences, the subject of the march-in requests. The Act recognized that the contribution by the American public to supporting health research was a public equity that should be, and would be, recognized and rewarded by the Act's success in extending and improving the lives of American taxpayers.

This problem, of how to encourage industry to make the risky investment needed to turn basic research ideas into goods and services for everyone, was addressed by the Act. In drafting the Act, we answered this problem by giving intellectual property rights not to the government agency that funded the invention, but to the inventors themselves. This allowed them to use the patent system as it has always been used: to leverage their property rights to attract risk capital and fund the development of safe and useful things. This freedom was not unlimited: the conditions attached to it are the march-in provisions of the Act, found §203a of the Act. The march-in provisions were conceived as extraordinary measures to be used only when there was overwhelming need to protect the public against non-use or unreasonable use of inventions as called for in §200 of the Act.

Let me emphasize again that in writing the Act as we did, we understood the need to attract private investment so as to further the early work funded by the government, and we understood that, in a typical case, the amount of private investment might well exceed the public funding. By contrast, neither the petition nor the Tulane Law Review article takes this into account. Instead the article attempts to justify its overturning of the entire Bayh-Dole system by an appeal to an aggregate statistic: that the total sum of government funded health research exceeds that of industry. This disparity, they submit, creates "a public equity" beyond that addressed by the Act; and they argue that the "public equity" thus constructed is sufficient to support a march-in based on unreasonable pricing

(see "Thematic Question" posed on page 634).

This argument rests on what is most politely seen as intellectual confusion by the authors of the article. The "public equity" addressed in the legislative history of Bayh-Dole is very different from that devised by the authors of the article. But they equate the two in an effort to interpret the the Act's march-in provisions on page 659 as follows:

> "The march-in provisions became the linchpin of the entire enterprise because Congress wanted to balance the demands of private industry against the "public equity" that resulted from the massive public investment of funds to produce these patented inventions."

Having begun their article with this desired conclusion in mind, the authors proceed to invent for the Act a legislative history that it never had, on pages pages 656-667 of the article. Let me be clear about this: the legislative history of the Bayh-Dole Act, properly understood, consists of only three things: the law itself, the committee report on the bill, and the floor debate on that particular bill. The Act's legislative history does not include debates on other bills that were not enacted.

Notwithstanding this elementary point, the authors lard their article with citations to what is extraneous and, worse, misleading. On pages 665-667 of the article, there are 82 footnotes; of these, all but 12 (that is, almost seven-eighths) referto statements that are clearly outside of the Bayh-Dole legislative history. Among these 70 errant footnotes are the three republished by the petition as support for its assertion that the "legislative history" shows a Congressional intent to include "reasonable pricing" in the "reasonable terms" language of Section 203 of the Act (footnotes 10, 12 and 14 of the petition [Norm: I don't follow this citation of footnotes as 10, 12 and 14: maybe that's how they are numbered in the Norvir petition which I haven't seen. In the Xalatan petition, they appear to be numbered 5, 6 and 7, supporting a statement that begins "The legislative history demonstrates that Congress intended…" and ends "Notably the proposal by the Electronic Industry Association that 'practical application' be rewritten…"]). Thus the petitioners reproduce the authors' error, referring to matters outside the Act's legislative history. All

of them are barking up the wrong tree entirely.

The authors of the article do bark, a little, up the right tree; but their efforts produce only noise. As I said before, of the total 82 footnotes in the article on legislative history real or imagined, only 12 are directed to comments or quotes from the hearings and Senate Report on the Act. And not one of these addresses the question of pricing, either explicitly or by implication. Of the 12, two (footnotes 174 and 180) discussed by Senator Bayh reference a discussion in the senate hearings and report limited to a proposal, never adopted, that patentees whose inventions produced enough commercial return might be asked to "pay-back" the public funding they had received. As would be obvious to anyone who took the trouble to read the legislative discussion on this "reimbursement" notion, it has nothing to do with the price control system advocated by the article.

That price control theory is, however, propped up by the testimony cited by the authors in 20 of the 70 footnotes pertaining not to the Bayh-Dole Act. This testimony is irrelevant but entertaining, coming as it does from well-known opponents of contractor ownership of federal inventions including Admiral H. G. Rickover, General Russell Long, Congressman Jack Brooks, Ralph Nader and others. Their words restate their well-known objections to such contractor ownership, but do not suggest that, if only the contractor's title to an invention were made subject to a right of the government to determine its reasonable price, they would withdraw what was, for them, a categorical opposition to contractor ownership. Thus, even if this testimony had been offered in connection with Bayh-Dole, it would not have supported the price control reading for which the authors argue.

Creative reinterpretation of testimony by the authors also extends to my own words. On September 27, 1976, before a House Committee considering (again) legislation other than Bayh-Dole, I gave a statement on on government patent policy. In that statement, I provided an extensive justification for the patent ownership policy ultimately adopted in Bayh-Dole. My entire statement was directed to showing the Administration's progress to extend to all the Federal R&D agencies the administrative policy referenced by Senator Bayh as the precursor to the Act. Yet for all the obvious intent and considerable length of my statement, the only words deemed useful by the authors of the Tulane article are these, found on page 657:

> "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."

My actual comments makes no reference whatsoever to industry "extortion" to gain greater rights. The only "extortion" that I can see here is the coercive pressure applied by this article to my words. It is typical of the selectivity found throughout pages 656-667 of the article.

Control Of Drug Prices

What is most disturbing about the subject petition is the attempt to transform this fundamental and successful piece of intellectual property law into an administrative mechanism to control drug prices, with no regard for the consequences.

The drafters of Bayh-Dole never envisioned that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information, which is why the Act lacks any functional criteria specifying how this could be done. This lack, which the Tulane article laments (page 648), was deliberate.

Based on the Tulane article, the petition holds that the government should issue multiple licenses for a drug because the industry owner is charging too much, and asserts that the Act invests funding agencies with the authority to approve the pricing of inventions after they have been developed and distributed in the marketplace by private sector initiatives. This assertion is false. There is no such authority vested in funding agencies by the Act.

The authors of the Tulane article attempt to find this authority both in their invented version of the Act's legislative history; and also in an argument from the text of the Act and its regulations. Like the fictional legislative history, this textual argument is creative; and wrong.The authors argue that the Act's definition of "practical application" includes a requirement that the invention be made available to the public on "reasonable terms". However, the authors admit (on page 649 of the article) that there is no clear legislative history on what

is meant by "available to the public on reasonable terms" . And they also admit (on page 651) that "reasonable terms" applies to conditions other than "reasonable prices". The petitioner, echoing the article, then arguesthat "reasonable terms" can be interpreted, in an ordinary context, as including not only those other (non-price) conditions but also a "reasonable price." From this, they proceed to the conclusion that the funding agency is therefore authorized to assess what a "reasonable" market price might be.

The Scalia Rule

That the phrase "reasonable terms" must include the notion of price, they maintain, is evidenced by a number of court decisions supporting that definition. They also cite the Scalia rule:

> [First], find the ordinary meaning of the language in its textual context; and second, using established canons of construction, ask whether there is any clear indication that some permissible meaning other than the ordinary applies. If not - and especially if a good reason for the ordinary meaning appears plain - we apply the ordinary meaning.

It is strange that the petitioners cite Scalia's words in their aid. His instruction, that the reader must refer to the "textual context" of the language, is indeed helpful-but not to their argumentj. On the contrary, applying the Scalia rule to the entire body of the Bayh-Dole Act and its legislative history, one finds emphasized the overriding importance of delivering intellectual property rights to innovators and developers. The plain meaning of a patent is the right to exclude others from the practice of the claimed invention. It follows that the patent owner may choose not to exclude others completely, but allow them to practice the invention on such terms -including price—as the owner freely bargains for with those others. The right to own property is fundamental to our system, and inherent in the right of ownership is the right to part with one's property only consensually and at a price that one judges right. The exercise of these rights, in the marketplace, is what draws investment to invention, and leads to the benefits of invention being disseminated broadly across society. The Act's words and purpose emphasize exactly these meanings.

In context, therefore, "reasonable terms" cannot be interpreted to mean a limitation on the developer's ability to set prices in the marketplace, but can be interpreted to apply to other conditions as noted by the authors on page 651.

If the rights-holder were not given the freedom to set prices, it would not be willing to commit resources required to ensure an invention's delivery into the marketplace, thereby obviating the requirement that it be widely available. No commercial concern would invest in the commercial development of any invention knowing that their contribution in proving utility and safety would be ignored and the government could challenge their sales price after marketing.

Again, if in drafting Bayh_Dole we had intended such an interpretation, we would have inserted specific criteria into the law to enable the funding agency to assess exactly what a reasonable price might be. As the Tulane article agrees, no such criteria are found, precisely because controlling patent rights on the basis of price was antithetical to what the drafters had in mind.

Healthcare Policy

Healthcare reform has been under consideration in the Congress recently and the possibility of the policies of state-mandated price controls or broad entitlements to healthcare as they exist in European countries have been discussed. But the appropriate means to effect such policies must be through public debate, legislation and/or referenda.

Obviously any healthcare reform effort could face resistance from vested interests, and it is tempting for some to look for shortcuts. But twisting intellectual property law into a political weapon of expediency is not the answer.

Accordingly, I feel strongly that the petitioners' request for march-in under §203(a) of the Act, motivated entirely by a desire to control drug prices and based on a contrived interpretation of the law must be denied.