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October 19, 1999 letter from NIH Director, Dr. Harold Varmus to Ralph Nader, James Love and Robert Weissman responding to their request calling on the NIH to provide the World Health Organization, WHO, access to US government funded medical inventions.

(Ralph Nader, James Love and Robert Weissman each received separate letters.)

Dr. Harold E. Varmus
Building 1, 126
National Institutes of Health
Bethesda, Maryland 20892

James Love
Consumer Project on Technology
P.O. Box 19367, Washington, DC 20036

Dear Mr. Love:

Thank you for your recommendations on how the National Institutes of Health (NIH) could interact with the World Health Organization (WHO) to provide it with commercial development rights to NIH-owned and -funded health care patents. As we are both aware, the licensing of Government inventions has received much attention in recent months from Members of Congress, patient advocacy groups, representatives of industry and the press. The public debate has been galvanized by concerns about the AIDS crisis in developing countries and the role of anti-AIDS therapeutic drugs in addressing that crisis.

This proposal, if implemented, would have powerful repercussions on the current framework for drug development arising from federally supported basic research. I am concerned that your proposal that the NIH employ its "Government use" license authorities to grant WHO standing authority to contract for the production of Government-supported inventions so as to make anti-AIDS drugs available for less cost than offered by pharmaceutical manufacturers would put the current system at risk without necessarily resulting in greater accessibility to these drugs. I am also troubled by the implications of the NIH intervening on behalf of sovereign foreign governments in a situation in which many of those governments have the authority to achieve the same result and in which U.S. intervention on this matter has not been requested.

Moreover, the AIDS crisis in developing countries is a public health problem involving much broader issues than access to anti-viral drugs. The question of the supply of drug products must be considered in the context of the equally important issues of medical

infrastructure, public health programs, treatment monitoring and compliance, and emergence of drug-resistant HIV strains. Unilateral action by NIH with regard to NIH-supported patent rights would consequently be ill-advised and unlikely to succeed.

My specific thoughts on the intellectual property aspects of this matter follow.

Programmatic Background

In the early 1980s, Congress enacted the Bayh-Dole Act and the Stevenson-Wydler Technology Innovation Act (with later amendments, including the Federal Technology Transfer Act of 1986) to encourage the transfer of basic research findings to the marketplace. The primary purpose of these laws is economic development: specifically, to provide appropriate and necessary incentives to the private sector to invest in federally funded discoveries and to enhance U.S. global competitiveness. To implement these mandates, the Department of Health and Human Services (DHHS) has designated NIH as lead agency for technology transfer for the Public Health Service (PHS).

While NIH respects and is sensitive to the economic development intent of the authorizing legislation, it carries out this mandate in accordance with its public health mission. For inventions developed within PHS laboratories, NIH (and PHS) Patent and Licensing policies consider public health needs as well as financial and market forces. For example, the PHS Patent Policy states that patent protection should be sought where further research and development is necessary to realize a technology's primary use and future therapeutic, diagnostic, or preventive uses [illegible] drugs reported as AIDS/HIV-related [illegible]

rights in selected countries to technologies that have contributed to the development of its grantees have sought and obtained patent protection. Presently, NIH holds patent

NIH can only license or otherwise grant rights to patents in countries where the agency or of NIH in these sovereign matters is, appropriately, extremely limited.

In principle, the U.S. Government can license patent rights to the WHO. Even if the doubts regarding WHO's authority to practice inventions under the Government use license could be overcome, I do not believe that the lack of such a license from the NIH is inhibiting developing countries from addressing their needs. As you stated, many of these countries can issue compulsory licenses, and those that have not enacted that authority to date can do so if they choose. The economies of scale you mention could be achieved by cooperation among these countries or direct interaction with WHO. The role

Granting Rights to WHO

the Government use license has never been employed as you propose, as a blanket measure to facilitate direct competition with a commercial licensee.

On balance, I am not convinced of the benefit of the standardized transfer of manufacturing and distribution rights to the WHO or any other nonprofit organization. Critical to successful technology transfer is the assurance that the Government will exercise its intellectual property rights in a responsible, prudent, and consistent manner. Undermining licensed intellectual property rights would, I believe, unnecessarily jeopardize the development of important therapeutic drugs.

NIH and WHO Interaction

Not all technologies that would be of use to developing countries are currently licensed. In the past, the NIH and WHO have worked together on licensing joint inventions and in negotiating with third parties. In one notable instance, NIH approached WHO with the possibility of manufacturing certain vaccines important of developing countries. Unfortunately, limitations of resources did not permit WHO to take advantage of such an offer. NIH welcomes, and is pursuing, further discussions with WHO on what can be done to assist developing countries with health care needs. I have directed my technology transfer staff to engage WHO on the intellectual property aspects of this matter. Discussions between my staff and WHO representatives are currently being facilitated by Dr. Stuart Nightingale of the Food and Drug Administration.

I appreciate the opportunity to explain our position on this issue.

Sincerely,

Harold Varmus, M.D.
Director

September 3, 1999, Ralph Nader, James Love, Robert Weissman letter to Dr. Harold Varmus, Director of NIH, asking for NIH to give the World Health Organization, WHO, access to US government funded medical inventions.

In conjunction with the patent strategy, the PHS licensing strategy gives preference to nonexclusive licenses so that market competition and broad distribution are fostered. Exclusive licenses are granted when such rights are believed to be necessary to ensure product development. As to inventions developed with NIH funding, the Bayh-Dole Act gives NIH grantees and contractors authority to retain title patents and to license inventions that arise from the NIH funding.

As you have pointed out, the Government has a royalty-free license to practice and have practiced an invention it owns or has funded on behalf of the United States and on behalf of a foreign government or international organization pursuant to a treaty or other agreement with the United States. This royalty-free license provides the Government with no-cost use of a technology it invented or funded. It does not provide rights or access to a licensee's final product. The Government use contemplated by this provision has been interpreted generally to include research use, although its full scope has not been determined. Providing the owner of the technology (licensor) freedom to do further research is a common and reasonable provision of exclusive licenses. To our knowledge,

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The author's do not seem to understand that the patent system lies at the core of Schumpeter's description of capitalism ~~as~~ being "creative self-destruction" in that it ~~is~~ maybe a single inventor's patent that protects a new industry from ~~destruct destruction by~~ the ~~monopo~~ monopoly ~~that it destroys~~

~~Indeed, one of the author's maintains that~~

being banned from the market place by ~~the~~ the older monopoly ~~industry~~ industry it destroys.

Indeed, one of the author's maintains that ~~the~~ the information industry (consumers) ~~needs no~~ ~~unintended~~ unnecessary patent protection ~~in when~~ to encourage ~~pursuing~~ utilization of new inventive methods and apparatus. We believe that ~~"Google" believes~~ ~~otherwise~~ the "Google" patent portfolio ~~that~~ indicates otherwise. Absent ~~such~~ its patent protection

a competitor such as Microsoft could either stifle ~~its entrance~~ Google's entry into the ~~place~~ marketplace or utilize the new technology ~~in any manner~~ as it sees fit without ~~compensation com pe~~ compensating the inventor in the manner intended ~~provided~~ by the patent system.

The author ~~does not care~~ and their assignees ~~that~~ clearly does not care whether inventors are subject to being treated unfairly based on her suggestion ~~recommendation~~ that ~~patents be~~ they be denied patent protection in government identified technologies on that an invention made with funds to enhance that ~~technology~~ technology is a serendipitious finding unrelated to to ~~the identified~~ the funded technology either never reach the marketplace.

attempt to achieve the same result through ~~the~~ innovations ~~of the~~ not reflected in the world. Indeed it was China, Brazil, Malaysia and South Africa ~~the~~ that determined the need to pursue legislation modeled after the Act.

Initiative and in addition to the measures before listed ~~in~~ ~~the~~ ~~Act~~ ~~to~~ ~~the~~ ~~Act~~ ~~to~~ ~~the~~ ~~Act~~ ~~to

In one of the more recent "Nay-sayers" articles, the authors assume the role of "experts" in ~~advising~~ warning developing countries ~~of act~~ on adopting Bayh-Dole without a number of ~~amendments~~ proposed amendments. ~~Most these amendments. The author's support maintain~~ To ~~support~~ bolster their position the author's first maintain that the Act's "contributions to growth in U.S. innovation" is "overstated and misleading" without providing any supporting data for their position. Their position at best is derived not from any new supporting data but primarily from a number of footnoted "experts" who over the years have also questioned BD's contributions while ignoring the cumulative data of the Act's contribution to strengthening the economy through introduction of innovation ~~to~~ which created new jobs, increased the GNP and enhanced the well being of lives throughout

In a recent speech,

~~The opening remarks of~~ Sen. Birch Bayh, co-sponsor of the Bayh-Dole

~~ent speech~~ said:

> After a quarter century of what by most objective standards has been an exceptional success, the Bayh-Dole law is under increasing attack today.
>
> Most of the attacks have come from individuals who have little experience with the comprehensive nature of how the law is implemented. They do not know what Bayh-Dole does and does not do, and why certain features were incorporated in the law. Equally important, these nay-sayers have no appreciation for the factors that motivated our efforts to develop this legislation in the first place. Most unfortunate of all, these modern-day experts in technology transfers apparently do not understand the basic factors on which our nation's free enterprise system is based.

assume the role of "experts" ~~directed at~~ in advising developing countries ~~on adoption of Bayh-Dole~~

and ignoring the evidence of success above.

without providing any supporting data for their conclusion

1

In one of the more recent "Nay-sayers" articles, the author's maintain that ~~Bayh-Dole's~~ the Act's "contributions to growth in US innovations" is "overstated and misleading" ~~without their identifying how BD might benefit the developing countries they are addressing.~~ Their ~~advice~~ position is derived primarily from a number of footnoted "experts" who also questioned ~~BD's~~ BD's contributions ~~and equally~~ have ~~also~~ ignored ~~the~~ over years have

Act's
~~Bair~~ contribution to strengthening the economy through introduction ~~to~~ of innovation to the marketplace ~~which creates new jobs~~
while creating new jobs, increasing the GNP and enhancing the the well-being of lives throughout the world.

(2) But before addressing ~~the~~ some of the footnoted articles, we need to ~~address the report~~ further address the author's misrepresentation of the Act itself.

The authors maintain that:

> "Bayh-Dole encouraged American universities to acquire patents on inventions resulting from government-funded research and to issue exclusive licenses to private firms [5,6]... ." (emphasis added)

There is no basis whatever in the Act for the author's conclusion.

~~Not so~~! The Act is limited to providing a first option to title to such organizations which permits a government funded inventing a inventions (4) ~~so as to be able~~ to elect to function under Article I, Section 8, of the

3,4

Constitution (5) or not. The Act is entirely neutral as to whether universities exercise whether they license exclusively or nonexclusively that option and if they do, ~~how they go about licensing~~.

Further, it is important to note that the Act does not address an inventor's right to publish his/her findings whether ~~the~~ an inventing organization ~~[illegible]~~ pursues patent protection or not. Accordingly, there is no documented basis whatever for any assumption that the benefits ~~[illegible]~~ of publication ~~have~~ ~~[illegible]~~ before BD have in any ~~[illegible]~~ substantial manner changed after BD as implied by the authors.[5]

(7)

The authors do not directly challenge the ~~right of an inventing organization~~ granting of exclusive licenses by a government funded inventing organization. No doubt the author's recognize that a direct challenge of such licensing would not ~~[illegible]~~ be supported ~~rejected~~ on the basis ~~of [illegible] the universal acceptance of by of its necessity as its support from persons such as of the following of the positions like the following of of the many~~

the Director of NIH,

Such as that of Dr. Harold E. Varmus

OPINIONS

"... It is well documented that technologies with potential as therapeutics are rarely developed into products without some form of exclusivity, given the large development costs associated with bringing the product to the market. No benefit accrues to the public if the technology is left to languish and no product reaches the marketplace. "6

(4)

Of course, the above is supported by the many therapeutics reaching the marketplace after NIH's administrative change in policy in 1968 to permit such exclusivity ~~as~~ later enacted as law by BD. ~~as compared to no~~

This is compared to the footnoted "experts" failure to identify any such a therapeutic prior to the 1968 policy change notwithstanding claims ~~that~~ ~~this~~ of these existence.

It should be noted that such ~~exclusivity~~ exclusivity is ~~pr~~ permitted not only under BD but is provided under the "Orphan Drug Act" to ~~encourage~~ encourage the development of therapeutics in the public domain ~~that~~ whether initially ~~funded~~ government funded or not.

unpatentable

Notwithstanding, the author's apparent acceptance of exclusive licensing under limited circumstances, they recommend that it be conditioned on an open-ended ability to challenge it after

before addressing some of this work, we need to address the authors' representation of the Act itself.

The authors begin by indicating that:

> "Bayh-Dole encouraged American universities to acquire patents on inventions resulting from government-funded research and to issue exclusive licenses to private firms [5,6]... ." (emphasis added)

Not so! The Act is limited to providing a first option to title to such inventions (4) so as to be able to elect to function under Article I, Section 8, of the Constitution (5) or not. The Act is entirely neutral as to whether universities exercise that option and if they do, how they go about licensing.

Much of the author's article is directed to non-exclusive licensing under Bayh-Dole. The record clearly shows that a large portion of executed licenses are non-exclusive rather than exclusive. In this context, the authors discuss the non-exclusive licensing of the Cohen-Bayer and Axel patents. In these situations, the involved universities had the good sense to recognize that the patents involved important processes that were useful in the possible creation of many life science

inventions which are now the basis for the numerous start-ups that make up the bio tech industry. That the university is aware of the importance of pursuing non-exclusive licensing of patented process or biological material invention useful in the making of life science products is evidenced by the authors reference to "Nine Points to Consider in Licensing University Technology".

However, the authors make clear that they would not be satisfied even if the university community successfully identified all the process and biological material inventions that should appropriately be licensed on a non-exclusive basis as they indicate such licensing is unnecessary, primarily because a cost to the licensee is attached.

This position demonstrates the authors failure to understand a primary purpose of not only Bayh-Dole but the patent system itself. In the 17th century age of enlightenment, John Locke pointed out as a natural right that "Man hath a right to what he has mixed his labors with" (6). This served as the underpinning of the British

patent system that in turn served as the foundation for the founding fathers inclusion of Article I, Section 8 of the Constitution (7). (The footnote supports this.)

Bayh-Dole permits the use of non-exclusive licenses as intended by the patent system as an incentive and reward to inventors and the university licensor to remain involved in the difficult iterative process of research and development. The drafters of Bayh-Dole knew, for example, that failure to recognize inventor rights ~~resulted~~ would result in ~~documented~~ failure to report inventions and ~~instances of patent protection~~ the possibility of the pursuing patent protection on their own behalf. ~~(FN)~~ (from documented cases, I.P. Automade

Further, the complaints listed by the authors regarding the costs attached to non-exclusive licensing are no more than what ~~would~~ should be expected from potential "buyers" when bargaining with a "seller" in an open market. Such buyers should have no expectation whatever of a free ride on the seller's effort to provide the services offered along with the expertise on its intended use. The author's description of such services by the seller as a "tax" is both derogatory and completely unjustified, as the cost involved is the seller's estimate of the cost entailed with a reasonable profit.

The authors conclude their comments regarding non-exclusive licensing by indicating that:

> "Where exclusive licenses are not required for commercialization, one may ask whether universities and public sector labs should be patenting research at all."

Clearly they believe that universities and their inventors are deserving of no consideration whatever for the efforts expended in bringing their inventions into public use. We need note here that there is nothing in Article I, Section 8 which excludes inventors and their assignees from the benefits bestowed by the patent system notwithstanding that their invention has been partially funded with federal funds.

The author's position on exclusive licensing of government funded inventions is not explicitly discussed other than their comment that they:

> "... should not be exclusively licensed unless it is clear that doing so is necessary to promote the commercialization of that research."

We would submit that it is now exactly the reason universities chose to grant exclusive licenses rather than a non-exclusive license. However, even if the

above comment is acceptance of the Bayh-Dole policy of permitting university exclusive licensing if they believe that necessary, the authors tie that decision to a government requirement that the invention so licensed be monitored to see that they are "priced fairly". This concept was unsuccessfully tried by NIH from 19_?__ to 19__?__ and abandoned after industry refusal to enter into any licensing agreements with NIH during that period (8) and is not required by Bayh-Dole. To mandate such a requirement would require amendment of both Bayh-Dole and the FTTA and would on the basis of the NIH experience make BD, FTTA and SB1R inoperative for their intended purposes.

We now turn our attention to the author's primary reliance on the work of individuals characterized by Senator Bayh.

Notwithstanding, the author's apparent acceptance of exclusive licensing under limited circumstances, they recommend the conditions on:

1) A finding that it "is necessary to promote . . . commercialization"

2) "governmental . . . power to override such licenses and grant licenses to additional or alternative parties . . . when public (unspecified) public interest objectives are not . . . attained"

3) "government . . Right to use any invention (either publicly or privately funded) under international law

4) "Compulsory licenses . . to avoid abusive licensing practices.

of pursuing non-exclusive licensing of patented process or biological material invention useful in the making of life science products is evidenced by the authors reference to "Nine Points to Consider in Licensing University Technology".

However, it is clear that the authors would not be satisfied even if the university community identified all the process and biological material inventions that should appropriately be licensed on a non-exclusive basis.

This demonstrates the authors failure to understand a primary purpose of not only Bayh-Dole but the patent system itself, which evolved from the 17th century of enlightenment. During that time, John Locke pointed out as a natural right of humankind that "Man hath a right to what he has mixed his labors with" (6). This served as the underpinning of the British patent system that in turn served as the foundation for the founding fathers inclusion of Article I, Section 8 of the Constitution (7).

Clearly the author's suggestion of mandatory government rules concerning the affordability of end products is evidence price fixing which has no

record of success and is completely inconsistent with the incentive provided by Bayh-Dole as intended by the patent system as an incentive and reward to inventors to remain involved in the difficult long haul process of research and development. The drafters of Bayh-Dole knew, for example, that failure to recognize inventor rights resulted in documented failures to report inventions and pursuit of patent protection on their own behalf. (F.N.)

Further, the complaints listed by the authors are no more than what would be expected from a potential "buyer" when bargaining with a "seller" in an open market. Such a buyer should have no expectations whatever of a free ride on the seller's effort to provide the product offered along with the expertise on its intended use. The author's description of such services by the seller as a "tax" is both derogatory and completely unjustified, as the cost involved is the seller's estimate of the cost entailed and the profit.

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