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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.

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

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,

a competitor such as Microsoft could either strike a ~~deal~~ Google entry into the ~~same~~ marketplace or utilize the new technology ~~and~~ it sees fit without ~~compensation~~ ~~for~~ compensation. ~~the~~ invention in the market is ~~provided~~ by the patent system.

The author does not care that clearly does not care whether invention are subject to being treated unfairly based on her ~~circumstances~~ that ~~patents~~ be they be devised.

patent protection in government identified technologies on that and invention made with funds to enhance that technology is a generalist's funding unrelated to ~~the~~ identified technology either never nash, the market place.

attempt to achieve the same result through the same means. The world is not a homogeneous entity. It is a mosaic of different cultures, languages, and administrative systems. In the world, indeed it was China, before the world.

Denial, Malaysia and South Africa. The author's initiative and administrative system. The author's initiative and administrative system. The author's initiative and administrative system.

AN It is also clear the author's initiative and administrative system. The author's initiative and administrative system. The author's initiative and administrative system.

It is also clear the author's initiative and administrative system. The author's initiative and administrative system. The author's initiative and administrative system.

of the we do believe it is better. The author's initiative and administrative system. The author's initiative and administrative system. The author's initiative and administrative system.

that the author of this article will not hesitate to pursue the amendments. The author's initiative and administrative system. The author's initiative and administrative system. The author's initiative and administrative system.

In one of the more recent
"Naysayers" articles, the authors
assume the role of "experts"
in ~~substantiating~~ developing countries
of act on adopting Bayh-Dole
without a number of ~~assessments~~
prepared assessments. ~~These~~
~~assessments~~ ~~are~~ ~~the~~ ~~author's~~ ~~support~~
position to ~~support~~ their

AM

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 is
at best is derived not from any new data
but primarily from a number
of footnoted "experts" who over
the years have also questioned
BO's contributions while ignoring
the cumulative data of the Act's
contribution to the U.S. economy
economy through introduction of
innovation 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.

and ignoring the evidence of success.

without providing supporting data, for their conclusions

assume the role of experts directed at advising developing countries on adoption of Bayh-Dole.

In one of the more recent

"Nay-sayers" articles, the author's maintain that ~~Bayh-Dole~~ the Act's "contributions to growth in US innovations" is "overstated" ^{word misleading} without identifying how ~~BD~~ might benefit ~~the developing countries~~ ^{the article} ~~addressing~~ ^{position}. Their advice is derived primarily from a number of footnoted "experts" who also questioned ~~BD's~~ contributions (and ~~advising~~ ^{what} ~~the~~ ^{over} years have

1

Act's contribution to strengthening the economy through introduction of innovation to the marketplace which ~~creates~~ ~~new jobs~~ while creating new jobs, increasing the GNP and enhancing 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 representation of the Act itself.

The author's 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 conclusions.

Not so! The Act is limited to providing a first option to title to such ^{organization} 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 that option and if they do, ^{whether they license ~~it~~ ~~exclusively~~ or nonexclusively.} ~~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 ^{an} ~~the~~ inventing organization ~~proposes~~ ~~proposes~~ patent protection or not. Accordingly, there is no bar, whatever for any assumption that the benefits of publication ~~are~~ ~~will~~ be to the BD have in any ~~new~~ substantial manner changed after BD as implied by the author.

The author do not directly challenge the ~~right of an inventor~~ ~~organization~~ granting of exclusive licenses by a government funded inventing organization. No doubt the author's recognize that a direct challenge supported increasing would ~~not~~ be ~~reflected~~ on the basis of ~~the~~ ~~in~~ ~~the~~ ~~inventor's~~ ~~acceptance~~ ~~of~~ ~~its~~ ~~necessity~~ ~~as~~ ~~the~~ ~~inventor's~~ ~~such~~ ~~as~~ ~~in~~ ~~the~~ ~~following~~ ~~of~~ ~~the~~ ~~author's~~ ~~like~~ ~~the~~ ~~following~~ ~~of~~ ~~the~~ ~~author's~~.

(7)

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. 116

(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 ~~is~~ later enacted as law by B.D. 4.

~~It is compared to no~~
This is compared to the Postwar "expenditures" failure to identify any such a therapeutic prior to the 1968 policy change notwithstanding claims ~~that~~ of their existence.

It should be noted that such ~~patent~~ exclusivity is ~~is~~ permitted not only under BP but is provided under the "Orphan Drug Act" to encourage the development of therapeutics, ~~that~~ whether initially ~~started~~ government funded or not.

in the public domain

Reportable

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

earlier the cited support before addressing some of this work, we need to address the authors' representation of how this ~~new field~~ ^{above article and most of the "very serious" earlier work} ~~new field~~ ^{is} ~~represented~~ ^{is} ~~of~~ ^{is} ~~the~~ ^{is} ~~new~~ ^{is} ~~field~~ ^{is}

the Act itself.

~~of the cited article~~
cited ~~manuscript~~
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)

~~This clearly does not connect.~~

SINCE THE ACT provides NO funding for technology transfer offices and organizations electing to pursue patent protection do so at their own cost.

to permit the gov't funded inventing organization inventions (4) so as to be able to elect to function under Article I, Section 8, of the ~~United~~ ^{State}

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.~~ ^{whether they license exclusively or non-exclusively}

The Act does not address ~~the inventor's right to publish his/her findings~~ ^{the inventor's right to publish his/her findings}
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

whether they are the invention organization (universities) patent protection or not. ~~Ultimately, there is no basis for~~ ^{Ultimately, there is no basis for} ~~the~~ ^{the} ~~author's~~ ^{author's} ~~conclusion~~ ^{conclusion} ~~that~~ ^{that} ~~the~~ ^{the} ~~Act~~ ^{Act} ~~is~~ ^{is} ~~neutral~~ ^{neutral} ~~as~~ ^{as} ~~to~~ ^{as to} ~~whether~~ ^{whether} ~~universities~~ ^{universities} ~~exercise~~ ^{exercise} ~~that~~ ^{that} ~~option~~ ^{option} ~~and~~ ^{and} ~~if~~ ^{if} ~~they~~ ^{they} ~~do~~ ^{do} ~~how~~ ^{how} ~~they~~ ^{they} ~~go~~ ^{go} ~~about~~ ^{about} ~~licensing.~~ ^{licensing.}

by the ~~author's~~ ^{author's} ~~conclusion~~ ^{conclusion} ~~that~~ ^{that} ~~the~~ ^{the} ~~Act~~ ^{Act} ~~is~~ ^{is} ~~neutral~~ ^{neutral} ~~as~~ ^{as to} ~~whether~~ ^{whether} ~~universities~~ ^{universities} ~~exercise~~ ^{exercise} ~~that~~ ^{that} ~~option~~ ^{option} ~~and~~ ^{and} ~~if~~ ^{if} ~~they~~ ^{they} ~~do~~ ^{do} ~~how~~ ^{how} ~~they~~ ^{they} ~~go~~ ^{go} ~~about~~ ^{about} ~~licensing.~~ ^{licensing.}

inventions which are now the basis for the numerous start-ups that make up the bio

When point —
encouraged the
non-exclusive licensing
of such inventions

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".

Unfortunately

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

would result
~~resulted in documented failures~~ *no possibility of the* to report inventions and instances of patent protection
on their own behalf (ENN) *pursuing patent protection*
from documented cases, i.e. autoacbe

Further, the complaints listed by the authors regarding the costs attached

to non-exclusive licensing are no more than what *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
appearance acceptance of exclusive
licensing under limited circumstances
they recommend of the conditions
of:

- 1) A finding that it ~~is~~ "is"
necessary to promote "...
commercialization"
- 2) "governmental ... power
to override such licenses
and grant licenses to
additional or alternative
countries ... when ~~public~~
conspicuous public interests
objectives are met ... affairs"

3) "given now to ... Right to
use any invention ~~public~~
(~~can~~ publicly or privately funded)
under international law

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

of pursuing non-exclusive licensing of patented process or biological material

*a cost to
to attached
the license
is attached
to
support
the license*

invention useful in the making of life science products is evidenced by the authors

reference to "Nine Points to Consider in Licensing University Technology".

note claim that they

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successfully

university community identified all the process and biological material inventions that

*as they believe such licensing
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positions

This demonstrates the authors failure to understand a primary purpose of

IN

not only Bayh-Dole but the patent system itself, ~~which evolved from the 17th century~~

age

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). *(The footnote supports this)*

~~Clearly the author's suggestion of mandatory government rules~~

~~concerning the affordability of end products is ~~to~~ price fixing which has no~~

record of success and is completely inconsistent with the incentive provided by Bayh-

permits
manipulates the use of NON-EXCLUSIVE license,

Dole as intended by the patent system as an incentive and reward to inventors to

remain involved in the difficult *iterative* process of research and *and the university licensing*

development. The drafters of Bayh-Dole knew, for example, that failure to recognize

instances of

inventor rights resulted in documented failures to report inventions and ~~patent~~

government funded inventions pursuing
patent protection on their own behalf. *(F.M.)*

Regarding the costs,

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 *attached to non-exclusive licensing*

open market. Such *§* buyer should have no expectation/whatever of a free ride on the

seller's effort to provide the *services* ~~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.~~ *with a non-negligible part.*

then
The authors conclude ~~these~~ comments regarding non-exclusive licensing

~~as follows:~~ *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 ^{and} excludes inventors ^{or} their assignees from the benefits bestowed by the patent system ^{notwithstanding that their invention ~~has~~ ^{has} been} if the invention happens to be 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."

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