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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,

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

Indeed, ~~one of the authors~~ ~~maintains~~ that

being banned from the marketplace by ~~the~~ ~~existing~~ monopoly ~~in~~ ~~the~~ industry it destroys.

Indeed, one of the authors maintains that ~~the~~ ~~information~~ ~~industry~~

(consider)

~~needs~~ ~~no~~ ~~patent~~ ~~protection~~ ~~in~~ ~~order~~ ~~to~~ ~~encourage~~ ~~utilization~~ ~~and~~ ~~dissemination~~ of new inventive methods and apparatus.

We believe that "Google" ~~is~~ ~~the~~ "Google" patent

otherwise. Absent ~~such~~ ~~protection~~ ^{is, patent,}

Q Competition such as Microsoft could either stifle ~~the~~ Google's entry into the ~~same~~ marketplace or utilize the new technology ~~if it sees fit with its~~ compensation with ~~comp~~

compensating the inventor in the market ~~provided~~ by the patent system.

The author does not conclude that clearly does not conclude whether inventions are subject to being treated unfairly based on her recommendations that ~~patents be~~ they be denied patent protection in government identified technologies or that an invention made with funds to enhance that ~~technology~~ technology is a separate finding unrelated to ~~the identified~~ ^{the identified} technology either never reaching the marketplace.

to achieve the same result through the ~~specifications~~ ^{specifications} of the Act rejected by the world. Indeed it was China, Brazil, Malaysia and South Africa ^{and} ~~the~~ ^{the} ~~administrators~~ ^{administrators} ~~before~~ ^{before} ~~the~~ ^{the} ~~legislation~~ ^{legislation} ~~was~~ ^{was} ~~enacted~~ ^{enacted} ~~in~~ ⁱⁿ ~~the~~ ^{the} ~~past~~ ^{past} ~~years~~ ^{years} ~~that~~ ^{that} ~~determined~~ ^{determined} ~~the~~ ^{the} ~~need~~ ^{need} ~~to~~ ^{to} ~~pass~~ ^{pass} ~~legislation~~ ^{legislation} ~~modeled~~ ^{modeled} ~~after~~ ^{after} ~~the~~ ^{the} ~~Act~~ ^{Act}.

~~the~~ ~~act~~ ~~and~~ ~~India~~ ~~on~~ ~~their~~ ~~own~~ ~~initiative~~ ~~that~~ ~~determined~~ ~~the~~ ~~need~~ ~~to~~ ~~pass~~ ~~legislation~~ ~~modeled~~ ~~after~~ ~~the~~ ~~Act~~.

an

~~It is not~~ ~~clear~~ ~~that~~ ~~the~~ ~~author's~~ ~~proposed~~ ~~amendments~~ ~~are~~ ~~necessary~~ ~~by~~ ~~the~~ ~~so-called~~ ~~"experts"~~ ~~in~~ ~~the~~ ~~field~~ ~~of~~ ~~legislation~~ ~~and~~ ~~policy~~ ~~making~~ ~~in~~ ~~developing~~ ~~countries~~ ~~such~~ ~~as~~ ~~China~~ ~~and~~ ~~India~~ ~~and~~ ~~other~~ ~~developing~~ ~~countries~~ ~~that~~ ~~are~~ ~~not~~ ~~yet~~ ~~able~~ ~~to~~ ~~pass~~ ~~legislation~~ ~~modeled~~ ~~after~~ ~~the~~ ~~Act~~.

As the initial architects, advocates and practitioners of the Act, we believe it is the intention of the

we ~~it~~ ~~appears~~ ~~clear~~ ~~to~~ ~~us~~ ~~that~~ ~~the~~ ~~author~~ ~~of~~ ~~this~~ ~~article~~ ~~will~~ ~~monitor~~ ~~to~~ ~~persuade~~ ~~the~~ ~~authorities~~ ~~of~~ ~~the~~ ~~developing~~ ~~countries~~ ~~not~~ ~~to~~ ~~pass~~ ~~legislation~~ ~~modeled~~ ~~after~~ ~~the~~ ~~Act~~ ~~in~~ ~~this~~ ~~country~~. As the initial architects, advocates and practitioners of the ~~Act~~ ~~in~~ ~~this~~ ~~country~~.

In one of the more recent
"Nay-sayers" articles, the authors
assume the role of "experts"
in ~~advising~~ ^{warning} developing countries
of not adopting Bayb-Dote
without a number of ~~amendments~~
proposed amendments. ~~Most of these~~
~~amendments.~~ The authors' ~~support~~
~~maintain~~ ^{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 ^{supporting} 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 strengthening the
economy through introduction of
innovation which created new jobs,
increased the GNP and enhanced
the well being of lives throughout

YU

at best

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 ~~the~~ BD's contributions ^{and} ~~and~~ ^{what} ~~the~~ ^{over} years have

1

Act's ~~its~~ 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 Constitution (5) or not. The Act is entirely neutral as to whether universities exercise ^{3.4} that option and if they do, ~~how they go about licensing~~ ^{whether they license ~~exclusively~~ or nonexclusively.}

(7)

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 ~~protected~~ ^{or} not. Accordingly, there is no basis whatever for any assumption that the benefits of publication have ~~already~~ ^{not} been ~~lost~~ before BD have in any ~~way~~ ^{way} substantial manner changed ⁵ after BD as implied by the authors.

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 authors recognize that a direct challenge of such licensing would ^{not} ~~not~~ be ^{supported} ~~rejected~~ on the basis of ~~its~~ ^{the universal acceptance} ~~of its necessity as its support from persons such as of the following of the position!~~ ~~idea of following of~~ ~~of the way~~.

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. '66

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 "excesses" practice to identify any such a therapeutic prior to the 1968 policy change notwithstanding claims ~~that~~ ~~that~~ of their existence.

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

in the public domain

Reportable

4

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

either the cited support before addressing some of this work, we need to address the authors' representation of how this ~~new piece~~ ^{above article and most of their career work} cited author's

the Act itself.

~~of the cited article~~
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

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 ~~inventing~~ ^{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}

by the ~~author~~ ^{author's} ~~article~~ ^{findings} ~~interfered~~ ^{with} ~~the~~ ^{the} ~~author's~~ ^{findings.} (3)

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
pursuing patent protection
on their own behalf. ~~(EN)~~ *from documented cases, i.e. Autodesk*

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 apparent acceptance of exclusive licensing under limited circumstances, they recommended it be conditioned on:

- 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 parties . . . when ~~public~~ (unspecified) public interest objectives are not . . . attained"
- 3) "government . . . right to use any invention ~~to~~ (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

*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".

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However, ~~it is clear that~~ the authors would not be satisfied even if the

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positions

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~~

IN

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~~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 place~~ 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 *s* buyer should have no expectation/whatever of a free ride on the

services
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.~~ *with a non-negligible part.*

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

~~as follows:~~ *by indicating that:*

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

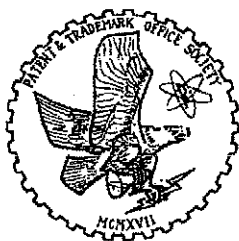
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Re-Discovering Article 1, Section 8 - The Formula for First-to-Invent

Edwin A. Suominen¹

INTRODUCTION

In 1791, the earliest predecessor to the U.S. Patent Office considered adopting a first-to-file system to settle disputes between interfering patent applicants and chose not to do so.² In 1966, a President's Commission on the Patent System recommended adoption of a first-to-file system, and Congress rejected it after a negative reception by industry and bar associations.³ In 1990, the World Intellectual Property Organization (WIPO) published a "basic proposal" draft treaty that would have imposed a first-to-file system on all signatories, including the United States.⁴ This proposed "fundamental change" in U.S. patent law was met with active opposition, and no interested associations took a position in favor of it.⁵

Now, in 2001, the question arises yet again, as the U.S. continues to consider becoming a signatory to the latest edition of WIPO's harmonization treaty.⁶ The U.S. Patent Office has requested comments on whether the U.S. should adopt a first-to-file system, which the treaty in its present form would require all signatories to do.

This article analyzes the command of Article 1, Section 8 of the U.S. Constitution that Congress may grant exclusive rights to "inventors" for their "discoveries." The conclusion of this analysis is

¹ Mr. Suominen is a registered patent agent and an independent inventor with several patents and pending applications. The author is indebted to Louis J. Hoffman, Esq. for editorial assistance and support.

² P. J. Federico, *Operation of the Patent Act of 1790*, 18 J. Pat. Off. Soc'y 237, 248 (1936).

³ Note, *First-To-File: Is American Adoption of the International Standard in Patent Law Worth the Price?*, 1988 Colum. Bus. L. Rev. 543, 544.

⁴ Edward G. Fiorito, *The "Basic Proposal" for Harmonization of U.S. and Worldwide Patent Laws Submitted by WIPO*, 73 IPTOS 83, 88 (1991).

⁵ *Id.* at 89.

⁶ Draft Substantive Patent Law Treaty, WIPO Doc. SCP/5/2 Prov. (Feb. 2001), available on the Internet at www.wipo.int/scp/en.

easily overlooked in the "horse trading" atmosphere of international treaty negotiations, but it is of critical importance. The U.S. should not, and must not, abandon the uniquely American, and uniquely successful, first-to-invent system of patent protection prescribed by Article 1, Section 8 and maintained for over two centuries.

Several commentators have written many practical arguments against switching to a first-to-file system,⁷ and others will no doubt provide many more in response to the Office's Request for Comments. Although those arguments are certainly supportive of the Constitution's wisdom in establishing a clear mandate for a first-to-invent patent system, it is the constitutional mandate on which we focus here.

CONSTITUTIONAL TERMS OF RESTRICTION: "INVENTORS" AND "DISCOVERIES"

"At the outset it must be remembered," began the Supreme Court in its seminal patent case of *Graham v. John Deere Co.*,⁸ "that the federal patent power stems from a specific constitutional provision which authorizes the Congress 'To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.'" In deciding the fate of three patents before it that day, the Court held that Article 1, Section 8, the Constitution's patent clause, "is both a grant of power and a limitation."⁹ Thus the Court observed that the patent clause is not merely an open-ended invitation for Congress to grant whatever patents it wishes to whomever it wishes.¹⁰

The Constitution thus authorizes Congress to secure exclusive rights for limited times only to "inventors," and only for their "discoveries."¹¹ This restricted authorization was recognized by the judiciary 24 years after ratification of the Constitution. In one of the "Steamboat Cases," the New York Court of Chancery observed that "the power given to Congress to promote the progress of science and useful Arts is restricted to the rights of authors and inventors."¹² Subsequent

⁷ See Gabriel P. Katona, *First-to-File - Not in the United States*, 73 JPTOS 399 (1991); Coe A. Bloomberg, *In Defense of the First-to-Invent Rule*, 21 AIPLA Q.J. 255 (1993); *supra* note 3, 8 383 U.S. 1 (1966).

⁸ *Id.* at 5.

⁹ See Edward C. Walterscheid, *Disparity Between the Patent Term and the Copyright Term*, 83 JPTOS 233, 249 (2001).

¹⁰ See WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* 69-70 (1890) ("The subject of the exclusive right must be a writing or discovery of the person to whom the right is granted . . . as to all other matters, Congress is supreme").

¹¹ *Livingston v. Van Ingen*, 9 Johns. 505, 564 (1812).

decisions by the U.S. Supreme Court¹³ and other federal courts¹⁴ in the early nineteenth century affirmed this view.

Who then are the "inventors" contemplated by the constitutional language as being the only recipients of exclusivity? As Samuel Johnson defined the term in the framers' era with his authoritative dictionary, and as the term is still understood today, an inventor is "one who produces something new; a deviser of something not known before."¹⁵ Similarly, Johnson defined "To discover" as "to find things or places not known before."¹⁶

The plain language of the terms would thus seem to settle the issue, clearly prohibiting any first-to-file system as unconstitutionally denying actual inventors the exclusive right to their discoveries. That is not the conclusion Edward C. Walterscheid has drawn.¹⁷ Walterscheid asserts that the constitutional language "does not preclude the granting of patent rights to one who is not the literal first inventor."¹⁸ He bases this conclusion largely on (1) contemporaneous interpretation of the words, (2) the founders' omission of the terms "true and first" from contemporaneous English law, and (3) spotty implementation of first-to-invent statutes in the early nineteenth century.

These views cannot withstand careful examination of Supreme Court precedent and ordinary methods of constitutional interpretation.

SUPREME COURT PRECEDENT ON "INVENTORS" AND "DISCOVERIES"

In 1870 the Court discussed how the term "inventors" in the patent clause should be interpreted. The Court sustained validity of several patents by emphasizing the role of patents as "public franchises,"

¹³ *Shaw v. Cooper*, 32 U.S. 292, 318-19 (1833) ("This [constitutional] power was exercised by congress . . . and from an examination of their various provisions, it clearly appears, that it was the intention of the legislature, by compliance with the requisites of the [constitutional] law, to vest the exclusive right in the inventor only").

¹⁴ *Blanchard v. Sprague*, 3 Fed. Cas. 648, 650 (D. Mass. 1839) (Story, J.); *In re Kemper*, 14 Fed. Cas. 286, 287 (D.D.C. 1841) (citing Article 1, Section 8: "There it is evident that the 'discoveries,' the use of which is to be secured, are the discoveries of inventors only").

¹⁵ SAMUEL JOHNSON, *A DICTIONARY OF THE ENGLISH LANGUAGE* (1787) as quoted by A. H. Seidel, *The Constitution and a Standard of Patentability*, 48 J. Pat. Off. Soc'y 1, 13 (1966). Seidel commented, "The present day meaning . . . can be considered the same, that is to bring into being something new as a product of one's own contrivance" (emphasis in original).

¹⁶ *Id.* An alternate definition provided by Johnson (there are several) is "to make known; not to disguise; to reveal." It could be argued, albeit somewhat implausibly, that the framers understood this archaic definition of the term to cover the act of disclosure associated with filing an application. However, see Seidel *supra*: "[I]t is firmly established in the patent law that 'discoveries' has a more restricted meaning, as being the activity of an inventor."

¹⁷ Edward C. Walterscheid, *Priority of Invention: How the United States Came to Have a "First-To-Invent" Patent System*, 23 AIPLA Q.J. 263, 281 (1995).

¹⁸ *Id.* at 283.

as a matter of compensation to the inventors for their labor, toil, and expense in making the inventions, and *reducing the same to practice* for the public benefit, as contemplated by the Constitution and sanctioned by the laws of Congress.¹⁹

It seems unlikely that the Court would have used language so tilted toward the activities of actual reduction to practice if it had considered the Constitution to contemplate "inventors" as including first filers who reduced to practice after late-filing first inventors had already undergone the "labor, toil, and expense in making the inventions."

In an 1884 copyright case, the Supreme Court offered the following dicta interpreting the patent clause in *Burrow-Giles Lithographic Co. v. Sarony*:²⁰

In regard, however, to the kindred subject of patents for invention, they cannot, by law, be issued to the inventor until the novelty, the utility, and the actual discovery or invention by the claimant have been established.

The Supreme Court recognized in that case that early statutes, passed by the constitutional framers, established "almost conclusive" interpretation entitled to at least "very great weight."²¹ Thus, what the first patent act of 1790 and its immediate successor of 1793 say about "inventors" and "discoveries" is critical to the analysis.

The Act of 1790 could not be more clear in its grant of exclusive protection to the first inventor. The Act begins as follows:

Be it enacted . . . that upon the petition of any person or persons . . . setting forth, that he, she, or they, *have or have invented or discovered any useful art, manufacture, engine, machine, or device, or any improvements therein not before known or used* . . . it shall be lawful to . . . cause letters patent to be made out . . .²²

It continues with language authorizing repeal of patents not granted in accordance with the requirements of the petition:

[I]f it shall appear that the patentee was not the first and true inventor or discoverer, judgment shall be rendered by such Court for the repeal of such patent or patents . . .²³

¹⁹ *Seymour v. Osborne*, 78 U.S. 516, 533 (1870) (emphasis added).

²⁰ 111 U.S. 53.

²¹ *Id.* at 57.

²² Patent Act of 1790, § 1, 1 Stat. 109, 109-110 (emphasis added).

²³ *Id.* at § 5, 111 (emphasis added).

Finally, the Act contains language that deems issued patents or specifications as

prima facie evidence, that the said patentee or patentees was or were the *first and true inventor or inventors, discover or discovers* of the thing so specified. . . .²⁴

The Act of 1793 begins with language similar to that in the introduction of the 1790 Act:

Be it enacted . . . that when any person or persons . . . shall allege that he or they have invented any *new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter, not known or used before the application*, and shall present a petition . . . it shall and may be lawful . . . to cause letters patent to be made out . . .²⁵

It also added a requirement that

every inventor, before he can receive a patent, shall swear or affirm, that he does verily believe, *that he is the true inventor or discoverer of the art, machine or, or improvement*, for which he solicits a patent . . .²⁶

The 1793 Act contained an updated version of the 1790 Act's repeal provisions, authorizing repeal "if it shall appear, that the patentee was not the true inventor or discoverer."²⁷ In addition, it permitted a defendant to plead for a declaration of invalidity if, *inter alia*,

the thing, thus secured by patent, *was not originally discovered by the patentee*, but had been in use, or had been described in some public work *anterior to the supposed discovery of the patentee* . . .²⁸

Finally, the 1793 Act added the first interference provision in U.S. patent law.²⁹

What language could better convey the desire of the First Congress to jealously guard the exclusive right for first inventors than its repeated use of the phrase "first and true inventor"? How could the Second Congress have better affirmed that same desire than by instituting an

²⁴ *Id.* at § 6, 111 (emphasis added).

²⁵ Patent Act of 1793, § 1, 1 Stat. 318, 318-19 (emphasis added).

²⁶ *Id.* at § 3, 321 (emphasis added).

²⁷ *Id.* at § 10, 323.

²⁸ *Id.* at § 6, 322 (emphasis added).

²⁹ *Id.* at § 9, 322-23 (emphasis added).

interference system³⁰ and protecting the patent rights of the "original discoverer" against use or public work that occurred *after* his own discovery, regardless of his filing date?³¹ Can there thus be any doubt about the "construction placed upon the constitution" by the "men who were contemporary with its formation" in the Patent Acts of 1790 and 1793? Under the interpretation directed by the Supreme Court's holding in *Burrow-Giles* and its required reference to the Patent Acts of 1790 and 1793, the Constitution authorizes granting of exclusive rights only to first and true inventors.

THE ORIGINALIST VIEW OF "INVENTORS" AND "DISCOVERIES"

With the literal text and binding precedent so firmly on the side of first-to-invent, it is difficult to sustain an argument for the constitutionality of first-to-file under any theory of interpretation. The founders' "original intent" provides no consistent basis for an argument either way.

In the originalist view, the Constitution should be interpreted according to understandings made public at the time of its drafting and ratification.³² Walterscheid's analysis appears to use this technique. An originalist analysis, however, does not provide a clear answer to the question of who are "inventors" of "discoveries," because there was no debate in the Constitutional Convention with reference to the patent clause, and no committee minutes reference it.³³ Walterscheid himself acknowledges that "no delegate left any record as to what the Convention intended 'inventors' and 'discoveries' to mean."³⁴

Much of Walterscheid's analysis of the framers' understandings thus cannot help but be highly speculative. For example, he states that the constitutional language "seemed to suggest" that the exclusive right

³⁰ Walterscheid states that was nothing in the language of Section 9 that obligated the arbitrators to award the patent to the first inventor. See *supra* note 19 at 306. But later he seems to contract this statement. See *Id.* at 318 ("Priority seems to have been generally viewed as requiring a determination as to who had invented first"). In any event, it is implausible that this omission was intended to give the arbitrators *carte blanche*. Section 9 did not recite any standards for the arbitrators, instead relying on the requirements set forth in the other portions of the Act for their guidance. One could just as well conclude that the arbitrators were free to award patents for inoperative or well-known devices, and such award would "be final, as far as respects the granting of the patent." 1 Stat. 318, 323. This was surely not Congress' intent, and the failure of the arbitrators to abide by it, which Walterscheid describes at length, does not lessen the precedential value of that intent under *Burrow-Giles*.

³¹ See *Thompson v. Haight* *infra* note 48.

³² KEITH E. WHITTINGTON, CONSTITUTIONAL INTERPRETATION 35 (1999).

³³ Karl Fenning, *The Origin of the Patent and Copyright Clause of the Constitution*, 17 Geo. L. J. 109, 112 (1929).

³⁴ Walterscheid *supra* note 17 at 281.

could be granted to other than the literal true and first inventor because there "is no reason to believe that the framers were not conversant with the English common law interpretation 'true and first inventor' to include a first importer."³⁵ But an equally plausible explanation, in view of Samuel Johnson's clear dictionary definition of the word "inventor,"³⁶ is that the framers simply chose to avoid redundancy.

As another example, Walterscheid attributes the Patent Board's decision to reject a first-to-file interference system alternately to discomfort with deciding the actual filing date of petitions that were originally filed with Congress and to political pressure from the steamboat rivals Rumsey and Fitch.³⁷ However, Walterscheid admits that "that the board may have interpreted 'inventor' to mean the true and first, i.e. original, inventor in a literal sense."³⁸

Speculation could easily support an originalist view opposite Walterscheid's. For example, Thomas Jefferson was one of the members of the original Patent Board,³⁹ and his part in its decision to reject first-to-file could well reflect his "original intent" as one of the framers.

Another one of the framers, Madison, apparently proposed constitutional language securing "to inventors of useful machines and implements, the benefits therefore, for a limited time."⁴⁰ The thoughtful originalist might thus discern, in that framer's mind at least, an emphasis on actual reductions to practice rather than mere application filings. If Madison's proposed language had been incorporated into the ratified Constitution, the result under an originalist interpretation may well have been the restriction of patent protection only to tangible "machines and implements" that had been shown to be useful, i.e., actually reduced to practice. Clearly, only a first-to-invent system would be realistic where an application filing, without more, would be insufficient to obtain a patent.

THE MODERNIST VIEW OF "INVENTORS" AND "DISCOVERIES"

Some who would argue against a textualist or "original intent" interpretation of the constitutional term "Discoveries," may advocate instead that the Constitution is a "living document adaptable to new

³⁵ *Id.*

³⁶ JOHNSON *supra* note 15.

³⁷ *Supra* note 17 at 291-92.

³⁸ *Id.* at 293.

³⁹ Federico *supra* note 2 at 238.

⁴⁰ Fenning *supra* note 33 at 114. In attributing this language to Madison, Fenning cites a five volume *Documentary History of the Constitution of the United States of America* published by the U.S. State Department between 1894 and 1900, and FERRAND, RECORDS OF THE CONSTITUTIONAL CONVENTION (1911).

In a recent speech, Sen. Birch Bayh, co-sponsor of the Bayh-Dole Act

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.

THE BASIS OF THE ACT

To the extent that the Act is "an exceptional success" should be attributed to the drafter's understanding of the evolution, purpose and the intended rewards of the U.S. patent system starting with John Locke's belief that:

A man has the right to what he hath mixed his labor with" and "whatsoever then he removes out of the state that nature has provided and left it in, he has with, and joined to it something that is his own, and thereby makes it his property"²

² Locke, J. The Second Treatise on Civil Government, 1690.

A hundred years later, the drafters of our constitution implemented these principles and intended rewards by granting to Congress the power to secure "for limited times to authors and inventors the exclusive right to their respective writings and discoveries" an incentive "to promote the progress of science and useful arts"³.

James Madison, the primary draftsman of the Constitution, stated his unequivocal support for this provision in the Federalist:

"The utility of this power will scarcely be questioned. The copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides to both cases with the claims of individuals."⁴
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Abraham Lincoln fully embraced our patent system in his second lecture on *Discoveries and Inventions*:

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³ Article I, Sec. 8 of the United States Constitution.

⁴ Federalist, January 23, 1788.

Next came the Patent laws. These began in England in 1624; and, in this Country, with the adoption of our Constitution. Before then, any man might instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor, for a limited time, the exclusive use of his invention; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things." (emphasis added)

It is exactly this fire of interest that was eliminated in the previous patent policy system. Based upon a misguided, and arrogant, belief that extinguishing the fire of interest would better serve the public, federal agencies took inventions from their creators and gave them away freely through public dedication of non-exclusive licenses. Predictably, this system failed miserably to produce commercial products; although it had probably helped our economic competitors to easily search through our best science looking for good ideas.

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That Senator Bayh's claim that his Act is "an exceptional success" is clearly supported by at least the following:

- (1) **As of 200?**, American universities have witnessed a ten-fold increase in their patents, based on an even larger increase of invention reports, creates more than 2,200 licensed companies to exploit their technology which has produced 260,000 new jobs and have contributed \$40 billion annually to the American economy⁸.
- (2) China, Brazil, Malaysia, South Africa and India,, on their own initiative and evaluation, have determined to pursue legislation modeled after the Bayh-Dole Act⁹.
- (3) **Page 9 of Soderstrom ? Google other important inventions made under Bayh-Dole.**

⁸ Economist

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(4) Permitted ^{the} ~~to~~ patenting of all inventions made un the SBIR Act of 1982 which serve as ~~an~~ ^{investment} ~~an~~ ^{to} attract VC input for further development ^{enabled} ~~the~~ ^{the} ~~inventing~~ ^{small business} ~~development~~ ^{beyond government funding.}

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(6) Public statement from Governors' Strickland of Ohio and Doyle of Wisconsin F.N.

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 See page 11 of Soderstrom (not complete)

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In the article in question, its authors might initially be identified as at least "nay-sayers". This is certainly supported by a number of their comments including the author's position that Bayh-Dole's "contributions to growth in U.S. innovations" is overstated (1) and failure to identify in any way how Bayh-Dole might benefit a developing country (2). But more important is the authors near complete reliance on the faulty work of the individuals the Senator alluded to above (3). But 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 in documented failures to report inventions and instances of patent protection on their own behalf. (F.N.)

Further, the complaints listed by the authors regarding the costs attached to non-exclusive licensing are no more than what would 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.

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- (4) Permitted to patenting of all inventions made un the SB/R Act of 1982 which serve as protection to attract VC input for further development.
- (5) Triggered substantial increase in small business start-up around research oriented universities in Palo Alto's "silicon valley" and Boston's "route 128". F.N.
- (6) Public statement from Governors' Strickland of Ohio and Doyle of Wisconsin F.N.

See page 11 of Soderstrom (not complete)

In a recent speech

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

~~Act, in a recent 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

Some Rogates
for every existing monopoly
in this country

the basis of The Act

To the extent that the Act is "an exceptional success" ^{should} ~~can~~ be attributed to the drafter's understanding of the ~~next few hundred years~~ ^{and purpose} ~~the~~ evolution of the U.S. patent system ^{starting with} ~~rewards~~ John Locke's belief that:

"a man has a right to what he hath mixed his labour with" and "Whatsoever then he removes out of the state that nature has provided and left it in, he has with, and joined to it ^{something} his own, and thereby makes it his property" ^{2 emphases added}

~~economic~~
~~benefit~~
~~benefit~~

2 Locke, The Second Treatise on Civil Government, 1690

①

A hundred years later
the drafters of our constitution
implemented ~~the~~ ^{and intended} these
principles by granting to
Congress the power to secure
"for limited times to authors
and inventors the exclusive
right to their respective
writings and discoveries"
an ~~an~~ incentive "to
promote the progress of
science and useful arts".³

(2) James Madison, ~~supp~~
~~port~~ ^{stated} ~~of this provision~~
Noted ~~UN~~ ^{un} ~~available~~
the primary draftsman of the
Constitution, supported this
provision in the Federalist
~~as follows:~~

"The utility of this power
will scarcely be questioned.
The copyright of authors
has been solemnly adjudged,
in Great Britain, to be a
right of common law.

3. Article I, section 8 of the
United States Constitution.

(3) The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincide, to both cases, with the claims of individuals. (emphasis added)

Abraham Lincoln fully understood embraced our patent system in his second lecture ON Discoveries and Inventions:

... In anciently inhabited countries, the dust of ages—a real downright old-foggism—seems to settle upon, and smother the intellects and energies of man. It is in this view that I have mentioned the discovery of America as an event greatly favoring and facilitating useful discoveries and inventions.

Next came the Patent laws. These began in England in 1624; and, in this

Country, with the adoption of our constitution. Before then, any man might instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor, for a limited time, the exclusive use of his invention; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.

(Emphasis added)

4. Federalist, January 23, 1788

Public dedication
OR
commercial
products

was eliminated

It is exactly this fire of interest that was missing in the previous patent policy system. Based upon a misguided, and arrogant, belief that extinguishing the fire of interest would better serve the public, federal agencies took inventions from their creators and gave them away freely through non-exclusive licenses. Predictably, this system failed miserably to produce results; although it probably helped our economic competitors to easily search through our best science looking for good ideas.

(4)

to report

Put simply, the drafters of the act wanted to ~~ensure that adequate~~ restore the 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 research requests.~~

of the patent system

To achieve this, the Act ~~the~~ first option accords the first option to all invention rights to the inventor and their assignees. Rather than the government agency that financed their research so that they are free to leverage their rights to their advantage in the marketplace as intended by the patent system.

The Act provides much in rights to the government as an extraordinary measure

5. ~~AD~~ SEC. 202 BD

6 SEC. 203 BD

5) to be used only when there is overwhelming evidence to show that the public resources invested into an innovation were being wasted on abuses. To the extent the government pursues such ^{property} rights, it must be done under ~~the~~ prescribed due process procedures ~~of~~ ^{as} required by the fifth amendment of the Constitution, FR.

"No person shall be deprived of life, liberty or property without due process of law."

~~Sen. Bayh's quote~~

~~Further Evidence of Success~~

That Sen. Bayh's claim that his Act is "an exceptional success" is clearly supported by at least the following facts:

on an even larger
based on
increase in number of inventions
of reports

As of 2009 -
1) American Universities have witnessed a ten-fold increase in their patents created more than 2,200 ^{licensed} companies to exploit their technology which have produced 260,000 new jobs and have contributed \$40 billion annually to the American economy.

2) Total research and development funding has increased \$6 billion in 1980 to \$33 billion in 2009.

2) China, Brazil, Malaysia and South Africa and India have on their own initiative and evaluation have determined to pursue legislation modeled after the Bayh-Dole Act.

(6)

Permitted
Small Business
INVENTIONS

3) Pg. 9 of Sudeastman
Cooyle + other important
~~relevant~~ inventions
made under B.D.

~~4) Permitted, ~~the~~ inventions
made under the SBIR Act of
1982~~

4) Permitted the patenting
of all inventions made under
the SBIR Act of 1982 ~~to~~
~~to~~ which serve as
protections to attract
VC input for further
development

5. triggered substantial
increase in small business,
start-ups around research
oriented universities in
Palo Alto's "silicon valley" and
Boston's "route 128". F.N.

6. Public statements from
Governors' Strickland of
Ohio and Doyle of Wisconsin
F.N.

see pg. 11 of
Sudeastman.

(Not complete)

Finally, while the ^{deed of} ~~economic~~ ^{successful} success of BO is as well as more than enough to justify the economist's belief that the Act was "possibly the most inspired piece of legislation to be enacted in America over the past half-century" (4) the naysayers fail to recognize the Act's complete success in giving government funded inventors, not only the right to see their invention reach the marketplace through the patent system but to know that their employer used their best efforts to do so but failed as envisaged by Cottrell (5). ~~That~~ Indeed, it is this fact ^{alone that may} explain the extraordinary increase in invention reporting by government funded inventors (6).

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 SBIR 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.

RETAINING FIRST-TO-INVENT:
CONTINUED PROMOTION OF THE PROGRESS OF USEFUL ARTS

The Supreme Court has found a standard expressed in the Constitution, "inherent requisites" of "innovation, advancement, and things which add to the sum of useful knowledge." It is a standard that "may not be ignored."⁵⁶ To conclude our analysis of how the Constitution would prevent adoption of any first-to-file system, it is appropriate to consider which system better promotes "the progress of useful Arts" and fulfills the Court's inherent requisites. The answer is clear, and is consistent with the rest of the Constitution's patent clause. The first inventor, unlike another person who "invents" later but files earlier, is the one who brings an innovation or advancement into being. It is that person who fulfills the constitutional objective and is entitled to its prescribed reward. Thus the Constitution shows its wisdom; it expressly prohibits what would hinder the results it requires.

In consonance with this view, the Supreme Court observed that the patent laws promote the constitutional goal of progress

by offering a right of exclusion for a limited period as an incentive to inventors to risk the *often enormous costs in terms of time, research, and development*. The *productive effort thereby fostered* will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for citizens.⁵⁷

The Court did not speak of incentives to "win a race to the Patent Office." It spoke, instead, in the traditional American terms of invention, of research and development, of productive effort.

The United States is under intense pressure to conform to the rest of the world and adopt a first-to-file system. As we have seen, however, the Constitution of this country simply does not allow for such a change. Yet it is entirely appropriate for the United States, a country that progressed from a small band of colonists to being the single largest source of worldwide patent filings,⁵⁸ to continue standing apart in rewarding "compensation for [the] ingenuity, labor, and expense"⁵⁹ of first inventors in producing their discoveries.

⁵⁶ *Graham*, 383 U.S. 1.

⁵⁷ *Keweenaw Oil Co. v. Bicon Corp.*, 416 U.S. 470 (1974) (emphasis added).

⁵⁸ United States residents originated about 40% of all PCT applications during 1998 and 1999, more than twice the percentage filed by residents of any other single country. WIPO, *The Patent Cooperation Treaty (PCT) in 1999*, available on the Internet at www.wipo.int/pct/en/activity/1999/pctin99.htm#P22_952.

⁵⁹ *Allen v. Hunter supra* note 51.

and
foreign

Government
of Western
Europe

~~Self-
appointed
experts~~

Notwithstanding the
outstanding success of the
Act set out above, the
Act has attracted a
cottage industry of scatter-
brain academics, presenting
themselves as "experts"
within the Federal government
with ~~the~~ amendments to
the exceptional circumstances
and march-in provisions
of the Act and its implementing
regulations. They describe
these amendments as being
supported by ~~an~~ a number of
~~unproven or unverifiable~~ ~~sources~~
that are unproven or ~~sources~~
that have been shown to be
failures in practice
utilized before the
enactment of the
Act and

situations"⁴¹ and thus would not prohibit a first-to-file system. Clearly, however, no interpretation can be so expansive as to entirely vitiate a significant term in a constitutional requirement.⁴² Patents simply cannot be granted to any but "inventors" for anything but "discoveries."⁴³

Even modernists rely on "deeply embedded traditional ways of conducting government" to give meaning to the words of a text or even supply them.⁴⁴ What then, have been the "deeply embedded traditional ways" in which the U.S. government has granted exclusive rights to inventors for their discoveries? Perhaps the most enduring and consistently followed principle of American patent law has been to grant such rights to first and original inventors. The statutes and published decisions found throughout the nearly two centuries of legal history since ratification of the Constitution are an important consideration.⁴⁵ In view of that "gloss which life has written upon" its words, the patent clause overwhelmingly favors a first-to-invent interpretation of its mandate.

We begin with the decision of the 1791 patent board to reject a first-to-file proposal, which is appropriate for two reasons. First, it was arguably the first administrative decision regarding such a proposal under the Constitution, which had been in effect only three years. Nothing could be considered more "deeply embedded," or the start of a more "traditional way of conducting government" than that early decision.⁴⁶ Second, Jefferson was one of the three board members, and his influence on American patent law is well established.⁴⁷

In 1826, the Circuit Court for the Southern District of New York observed that the whole law relating to patents, which remained essentially under the Act of 1793, could still be regarded as novel in the United States.⁴⁸ That state of affairs did not prevent the court from pointing out that

⁴¹ *Youngstown Sheet & Tube Co. et al. v. Sawyer*, 343 U.S. 579, 682 (1952) (Vinson, C.J., dissenting). Also, see WHITTINGTON *supra* note 32 at 196.

⁴² GREGORY BASSHAM, ORIGINAL INTENT AND THE CONSTITUTION 93 (1992). Bassham, though generally eschewing the originalist view, quotes Thomas Jefferson as expressing concern about elected officials rendering the Constitution "a blank paper by construction."

⁴³ See *supra* notes 11-14.

⁴⁴ *Youngstown supra* note 41.

⁴⁵ Kenneth Burchfiel, *Revising the "Original" Patent Clause: Pseudohistory in Constitutional Construction*, 2 Harv. J. Law & Tech. 155, 209 (1989) ("In the effort to determine the original meaning of a constitutional term, as in any legal history, a *sine qua non* is consideration of the most coherent and persuasive available data, contained in statutes and published decisions").

⁴⁶ Federico considered it "very unlikely that duplicate patents were granted [by the board] to the four steamboat claimants without deciding the question of priority." See *supra* note 2 at 249.

⁴⁷ See *Graham*, 383 U.S. at 7. Also, see text at note 39 *supra*.

⁴⁸ *Thompson v. Haight*, 23 Fed. Cas. 1040, 1041.

[i]t is very true that "the right to a patent belongs to him who was the first inventor, even before the patent is granted." [No citation given.] That is, none but the first inventor can have a patent.⁴⁹

Shortly after the Act of 1839 (and less pertinent Acts of 1842, '46, '48, and '52)⁵⁰, another federal district court observed that

[n]o exclusive right can be granted for anything which the patentee has not invented or discovered. . . . the right of the patentee entirely rests on his invention or discovery of that which is useful, and *which was not known before*. And the law gives him the exclusive use of the thing invented or discovered, for a few years, as a *compensation for 'his ingenuity, labor, and expense in producing it.*"⁵¹

The court, in instructing the jury, addressed the question of whether the plaintiff, who had been issued a patent for his invention, had protection against issuance of a rival patent to the defendant under the early caveat system then still in effect:

[The plaintiff] is protected by the law [against issuance of a rival patent], unless the defendant's invention entitled him to a patent before the plaintiff applied for his patent.⁵²

Interestingly, the jury found for the defendant, evidently heeding the court's instruction that "the one who perfected his invention first" would be entitled to protection if both the plaintiff and defendant could properly be considered rival inventors. This case, then, is an example of a first applicant losing out to a first inventor under legislation enacted some 60 years after ratification of the Constitution.

First-to-invent maintained its steady hand on the course of American patent law through the remainder of the nineteenth century and into the twentieth. In 1920, the D.C. Court of Appeals affirmed an award of priority to an interference party who was first to conceive and first to reduce to practice.⁵³ The court observed that the award was grounded on what had been the rule in the Patent Office since 1872, a rule that had received the approval of the court in earlier cases.⁵⁴ Since then, it has never become the law that one who "invented" later but filed first would receive a patent against a first inventor who had not forfeited rights.⁵⁵

⁴⁹ *Id.* at 1048.

⁵⁰ See ROBINSON *supra* note 11 at 78-79.

⁵¹ *Allen v. Hunter*, 1 Fed. Cas. 476, 477 (D. Ohio 1855) (emphasis added).

⁵² *Id.* at 482.

⁵³ *Erben v. Yardley*, 267 F. 345.

⁵⁴ *Hubbard v. Berg*, 40 App. D.C. 571; *Thompson v. Storrie*, 46 App. D.C. 324.

⁵⁵ The first inventor can forfeit his constitutional rights by his action or inaction, just as the citizen can forfeit his constitutional rights (e.g., to vote) by his actions (e.g., felonious crimes). The statutory and common law has long cautioned the first inventor to act diligently lest he lose his rights. See 35 U.S.C. 102(b),(c),(d)(g); *Howe v. Shumway*, 12 Fed. Cas. 678 (D. Mass. 1854) (First inventor "gave nothing to the public." Court held he had "only an idea, never carried out in a machine [i.e., actually reduced to

while these experts maintain that
~~such arguments are~~
merely