(1)

After more than 20 years after passage of the Bayh/Dole Act and 15 after the Federal Technology Act of 1986 I am compelled to attempt to document the history of their development and enactment along with their companion implementing directives (in all a body of law forming the primary subject of this history). The need to pursue this history has become compelling due to a number of intersecting factors

1) I remain the single principle contributor common to the creation of each piece of this body of law able to provide first hand observations,

2) A continuous wrong headed populist opposition to exclusive control by industry of patents arising from government funded research (and "patents" in general) on the basis that industry established prices of products i.e drugs sold in the marketplace is certain on that the results of patentable research are not

(2)

shared with other investigations to the extent that unpatented results were prior to enactment of the body of law.

3) A revisionist piecemeal telling of the history without exploring the facts ~~by those having No involvement on incentive to research the history~~

4) A disinterest of the highest level of the science community to properly acknowledge the contribution of the few good people who made this body of law possible. This particularly distressing in light ~~Not in standing~~ the enormity of its success or ~~and impact~~ in establishing for the first time a system for delivering the results of basic research to the marketplace in the form of useful products. Indeed,

The problem of revisionism and inadequate acknowledgement was forceably delivered to me in a recent policy paper,

It is now clear that basic research can no longer be undertaken without considering a public obligation to pursue commercialization of useful results. This of course feeds the populist opposition favoring a [illegible] Tower's government [illegible] by [illegible] policy.

(3)

"The acceptance of Bayh-Dole is also unusual in its absence of strong policy entrepreneurs or advocates. Indeed, its component idea had been debated for more than thirty years, going back to the Bush Report of 1945. Throughout the 1960s and 70s legislative proposals arose from several sources. Many in the private sector had advocated it for some time, and no single individual can really be credited with its origin or advocacy. Even in the Congress, the concept of the legislation was well-formed before Senator Bayh introduced it. The essential process was more one of slow consensus-building than radical policy innovation, and when consensus had matured, it was acted on with little debate." 1.

The authors of this paper identify their information ~~sources~~ as being based on - "Not only ~~on~~ on published sources but also on the personal involvement of the authors in the areas chosen for study." 2 Of these author's, I know by name only one to be a hill staffer who I can attest ~~that~~ by choice made no discernible contribute to this body of law. "effort" to the advancement of

"There was an "absence of strong policy entrepreneurs or advocates." 2 This is incorrect on its face. No act yet alone Bayh/Dole survives multiple sessions of Congress without a strong advocate. Further,

(4)

even a cursory search of the subject would have uncovered a number of concurrent newspaper, magazine articles etc. identifying the advocates and many of the issues involved.[3,4] "No single individual can really be credited with its origin or advocacy." This is refuted by the same items and any number of other items in my files.

The author's are correct that the existence of the "component idea" of industry exclusive control of patents arising from government funded research had been indeed debated for more than thirty years. However, not until Bayh-Dole were acceptable specific conditions and limitations justifying such control in a subset of contractors granted even put before the Congress. Again a modest amount of research would have uncovered major differences between, for example the Thornton bill[5]

(5)

introduced in ~~which~~ covered all contractors but failed to attract the support necessary to achieve enactment. Notwithstanding, the Thornton bill served as an important teaching experience for those of us that went on to ~~craft~~ Bayh/Dole.

The kind of mean spirited attitude displayed by the _____ flies in the face of one of my primary motivations for involvement with ~~the~~ subject body of laws ~~It has always~~ and has convinced me ~~against~~ that I must do my best ~~at~~ even if tardy to make know the noble spirit that underlies this body of law.

I have always belie.—

Dear Dr.

In September 2000, I was invited to speak before NIGMS advisory committee on the evolution of the Bayh-Dole Act (hereinafter, the Act) hopefully on the basis of my involvement in its creation. At that same meeting, Dr. Al Gilman, U. of Texas, S.W. spoke after ~~my presentation~~ me on how he intended to manage disposition of inventions that might be made under a "glue grant" for which he was to be the principle investigator.

After what I considered a visceral and ~~non-substantive~~ baseless attack on the Act, prompted I suspect by my presentation, ~~the~~ Dr. Gilman stated that he was in the process of requiring investigators to be funded under ~~the~~ his grant to sign an ~~agreement~~ as a condition of their participation ~~in which~~ wherein they agreed to report NO inventions made in performance

of the grant as a condition of their participation in the grant. During the question period after his presentation I pointed out that such agreements were not required by the Act and were entirely unnecessary in order to achieve the result he wished as that could be accomplished in a number of ways consistent with the Act. Dr. Gilman made it indicated no interest in pursuing these alternatives, notwithstanding that they would avoid an open breach of the Act.

My emphasis

I must further note to my disappointment that while NIGMS grant officials and an official from the N.I.H. technology transfer office were present, none felt

It necessary to ~~[illegible]~~ comment on Dr. Gilman's public expressed contempt and open breach of the Act.

~~Notwithstanding~~

Sometime later I spoke to a number of my university colleagues and found that Dr. Gilman was indeed requiring investigators to sign his agreement as a condition to participate ~~in his grant~~. Even ~~though~~ though we ~~my colleagues~~ all agreed that this was a serious breach, ~~there was~~ the investigators involved felt that the ~~grant sue~~ prospect of immediate grant funding ~~was more important than the possibility of~~ outweighed the slim possibility of producing a valuable invention in the future. ~~[illegible]~~ Accordingly, my colleagues were placed in the position of accepting the determination of their investigators or protesting without their support.

~~that~~ These signed agreements were later submitted with his grant application.

my colleagues

Given these circumstances ~~at the time, I felt it~~ that ~~inappropriate~~ and the fact I am no longer ~~being~~ a public servant, I felt it inappropriate to pursue the matter further.

I now believe that this ~~decision~~ was a mistake.

Enclosed is a Mar. 24 article summarizing a presentation by professor Arti Rai ~~which supports advocates~~ made at a Health Policy Forum at Duke on Mar. 19. Ms. Rai, who is ~~we~~ a well-known populist opponent of the Act, ~~advocates~~ cites ~~her presentation~~ the NIGMS "glue grants" her presentation as precedent for "open, collaborative research" ~~translates into~~ ~~really means~~ ~~The~~ destroy ~~[illegible]~~ of all ~~resulting~~ intellectual property rights ~~[illegible] exactly what the Act~~

translates in her opinion in the need which that might result from the collaboration

~~Pres~~ There is ~~no basis~~ little ~~whatever to presume that~~ to no evidence supporting

~~The~~ Ms. Rai's, on that ~~the~~ presumption the destruction of intellectual property rights is necessary to conduct "open ~~collab~~ collaborative research". However, there is significant evidence that destruction of these rights can ~~deter the~~ impede the movement of research findings into practical life and that "open collaborative research" can be conducted along with protection of intellectual property rights.

as you know

~~Both~~ If Ms. Rai and Dr. Gilman are really ~~should be~~ concern about the public interest ~~wondering~~ why any investigator ~~worth his~~ ~~s~~ ~~all would interested~~ ~~wishing~~ who yearns to see his findings move into practical life would want to join the kind of grant they envision.

they should ask

IN ~~conclus~~ conclusion,

I believe N.I.H. needs to ~~elm~~ eliminate the agreements required by Dr. Gilman and bring his grant into compliance with the Act. ~~If some concern about there some concern regarding "open collaborative research~~

If Dr. Gilman has some concerns regarding "open collaborative research", I ~~know~~ certain that the collaborating institutions involved ~~would be~~ are able to address those concerns without the destruction of the intellectual property rights that might ~~evolve~~ result from his grant.

~~I bet~~ I would appreciate you