KEI Comment 4: The 2002 Bob Dole and Birch Bayh letter to the editor of the Washington Post makes no sense when you look at the historical legislative proposals, including their own

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The lobby against the use of march-in rights has a standard talking point that former Senators Birch Bayh and Bob Dole both claim the Bayh-Dole Act was never designed to deal with drug prices. The anti-march-in right lobby routinely refers to an April 11, 2002 letter to the Editor of the *Washington Post* by the former Senators,[1] written at the time in response to Professors Peter Arno and Michael Davis, who had presented the opposite view in a March 27, 2002, *Washington Post* Op-Ed, "Paying Twice for the Same Drugs."[2]

It is significant that the Bayh/Dole letter to the editor is often referred to as an op-ed, and the actual op-ed by a professor of law and a professor of health economics is rarely read or quoted, or for that matter, is the scholarly article the op-ed is based on.[3] When the letter was written, Birch Bayh had been out of the Senate for more than two decades and was working as a lobbyist. Bob Dole had also left the Senate and was working as a lobbyist, and even working in television commercials about Viagra for Pfizer.

To this day, the Bayh/Dole letter is cited and used to assert that the Bayh-Dole Act makes no reference to reasonable pricing and that this omission was intentional,[4] and that "[th]e law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialised the invention as a product."[5]

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[1] Birch Bayh and Bob Dole, Our Law Helps Patients Get New Drugs Sooner, *The Washington Post,* April 11, 2002.
https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/
[2] Peter Arno and Michael Davis, Paying Twice for the Same Drugs, *The Washington Post*, March 27, 2002.
https://www.washingtonpost.com/archive/opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931/
[3] Peter Arno and Michael Henry Davis, Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally-Funded Research, 75 Tulane Law Review 631 (2001).
[4] The Editorial Board, "Biden Ambushes Pharma Patents", *Wall Street Journal*, December 10, 2023. https://www.wsj.com/articles/biden-ambushes-pharma-patents-30a71b62; Rohit Khanna, "March-in rights explained", *PMLiVE*, January 25, 2024.
https://www.pmlive.com/blogs/smart_thinking/archive/2024/rohit/march-in_rights_explained; Dan Leonard, Biden Administration Policy Jeopardizes The System That Gave Us Gene Editing", *International Business News*, January 19, 2024.
"https://www.ibtimes.com/biden-administration-policy-jeopardizes-system-that-gave-us-gene-editing-3722509
[5] Birch Bayh and Bob Dole, Our Law Helps Patients Get New Drugs Sooner, *The Washington Post,* April 11, 2002.

The subject of the Arno/Davis article and op-ed and the 2002 Bayh/Dole letter to the editor is a single definition in the Bayh-Dole Act, the definition of "practical application."

The definition of practical application includes an obligation by patent holders to "make the benefits of inventions . . . available to the public on reasonable terms".

Arno and Davis argued, with some power and logic, that "available to the public on reasonable terms" meant that prices to consumers should be reasonable. Both Arno and Davis had been following Congressional and NIH discussions of reasonable pricing of taxpayer funded inventions, and wanted policy makers to focus on this under-enforced part of the Bayh-Dole Act.

The Bayh and Dole 2002 letter to the Washington Post included these passages:

> *"Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.*
>
> *The article also mischaracterized the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product."*

But since Bayh and Dole and the anti-march-in lobby raised the issue, it's worth going back in time to the actual negotiations that led to the 1980 Act.

The Bayh-Dole Act came from debates in two different sessions of Congress. Senators Bayh and Dole were co-sponsors of three different bills in the 95th and one in the 96th Congress, and there were at least nine other competing bills. What is notable is that the first bill that Bayh and Dole introduced is quite different from what they described in their 2002 letter to the Washington Post.

In 1978, the first bill by Bayh and Dole was S. 3496, 95th Congress. Practical application was defined as follows:

> (e) The term 'practical application' means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the

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https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/

> invention is being utilized and that its benefits are to the extent permitted by law or government regulations available to the public on reasonable terms from the subject inventor or licensee or assignee of the subject inventor. [emphasis added]

Several bills by other members of Congress also made a distinction between various obligations regarding working inventions, licensing inventions and making the benefits available to the public.

To turn Bayh and Dole's letter around, one could ask, if the only obligation was to license the inventions to drug companies on reasonable terms, why did they drop the language on licensing in the final version of the bill?

Their argumentation, which relies on the omission of any pricing references, contradicts their simultaneous claim that the provision exclusively pertains to licensing.

In the final version of the Act, the concept of being "available to the public on reasonable terms" was deliberately conceived as a broader umbrella term, encapsulating both licensing and prices to end users.

Here are the definitions of practical application in the 12 different versions of what eventually became the 1980 Bayh-Dole Act.

Table 1: Definitions of practical application in competing bills from 1977 to 1980

H.R. 8596, 95th Thornton, Brown, etc	July 28, 1977	(g) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine or system, and, in each case, under such conditions as to establish that the invention is being worked and that its benefits are available to the public either on reasonable terms or through reasonable licensing arrangements.	invention is being worked and that its benefits are available to the public either on reasonable terms or through reasonable licensing arrangements.
S. 3496, 95th Dole, Bayh, etc	95th Cong., 2d Sess. (Sept. 13 (legislative day, August 16), 1978)	"(e) The term 'practical application' means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or government regulations available to the public on reasonable terms from the subject inventor or licensee or assignee of the subject inventor.	invention is being utilized and that its benefits are to the extent permitted by law or government regulations available to the public on reasonable terms from the subject inventor or licensee or assignee of the subject inventor."

S. 1215 96th Schmitt , Canon, etc	May 22, 1979	(12) “practical application” means to manufacture in the case of a composition or product, to practice in the case of a process or method or to operate in the case of a machine or system, and, in each case, under such conditions as to establish that the invention is being worked and that its benefits are available to the public either on reasonable terms or through reasonable licensing arrangements;	invention is being worked and that its benefits are available to the public either on reasonable terms or through reasonable licensing arrangements;
S.414, 96th Bayh, Dole, etc	February 9 (legislative day, January 15), 1979	"(f) The term 'practical application' means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the in-vention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.	invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.
H.R. 2414 Rodino, Edwards, AuCoin	February 26, 1979	"(f) The term 'practical application' means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.	invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.
H.R. 5343 McDade	September 19, 1979	"(f) The term 'practical application' means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.	invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.
H.R. 5427 Ertel	September 27, 1979	(12) "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method or to operate in the case of a machine or system, and, in	invention is being worked and that its benefits are available to the public either on reasonable terms or through

		each case, under such conditions as to establish that the invention is being worked and that its benefits are available to the public either on reasonable terms or through reason- able licensing arrangements; and	reasonable licensing arrangements;
S. 1860 Nelson, Weicker, Bayh, Dole, etc	October 4 (legislative day, June 21), 1979	"(f) The term 'practical application' means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.	invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.
H.R. 5607 Smith and McDade	October 16, 1979	"(f) The term 'practical application' means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.	invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.
H.R. 5715	October 26, 1979	(g) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine or system, and, in each case, under such conditions as to establish that the invention is being worked and that its benefits are available to the public either on reasonable terms or through reasonable licensing arrangements.	invention is being worked and that its benefits are available to the public either on reasonable terms or through reasonable licensing arrangements.
H.R. 6533, 96th Railsback	February 19, 1980	"(f) The term 'practical application' means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.	invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

H.R. 6933, 96th Kastenmeier, Rodino, Railsback	March 26, 1980	"(10) 'Practical application' means manufacture of a machine, composition, or product, or practice of a process or system, under conditions which establish that the invention is being worked and its benefits are available to the public on reasonable terms.	invention is being worked and its benefits are available to the public on reasonable terms.

For more discussion of the legislative history, see: James Love, The Bayh-Dole Act definition of "practical application, *Medium,* May 3, 2022.
https://jamie-love.medium.com/the-bayh-dole-act-definition-of-practical-application-92a7cc18f28c

Additional commentary

One final note. The 1980 version of the Bayh-Dole Act only gave contractors the automatic right to grant exclusivity for five years after market entry. Anything beyond that required permission from the funding agency. That was changed in 1984, but only after HHS used that authority to lower the price of the cancer drug cisplatin. The five year cap on exclusivity was a far greater constraint on monopoly pricing than the march-in right.