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Federal March-in Rights: What do the proposed changes mean?

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What is the Bayh-Dole Act?



Enacted in 1980 to “use the patent system to promote the utilization of inventions arising from federally supported research..., to promote collaboration between commercial concerns and nonprofit organizations...[and] to ensure that inventions made by nonprofit organizations...are used in a manner to promote free competition and enterprise.”

Gives title to subject inventions to “contractors”.



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When can government currently march in?

When action is necessary to address any of the following:

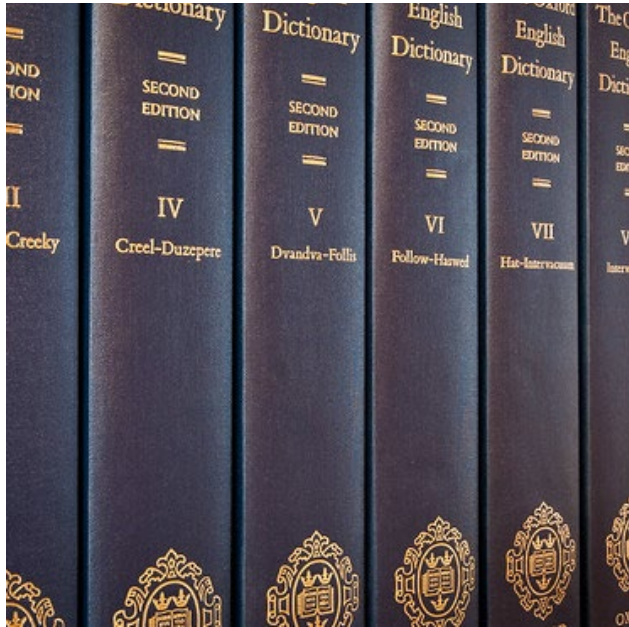
- 1) To ensure practical application of the invention;
- 2) To address health or safety needs not reasonably satisfied by contractor, assignee or licensees;
- 3) To meet requirements for public use specified by federal regs;
- 4) To address domestic manufacturing requirements.

What are the important changes in the proposed Dec 8, 2023 draft?



- Agency can focus on “reasonable” pricing of the product to assess public availability.
- Agency can consider whether product price appears to be “extreme, unjustified or exploitative” in determining whether health and safety needs are being addressed.

So, what's the problem?



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“Reasonable” pricing isn’t defined in the proposed changes; standard is arbitrary.

How will different federal agencies and administrations interpret “reasonable”?



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Wait, hasn't this been tried before?



Yes! In 1989, PHS adopted the requirement for a **reasonable pricing** clause in all CRADAs and exclusive licenses to subject inventions.

In 1995, PHS removed it, because:

“...the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists...”

Dr. Harold Varmus, former NIH Director

What else could go wrong?

- Creates substantial uncertainty for startup investors
- Affects all techs, incl. biotech, climate tech, agtech, telecom, etc.



What about US competitiveness?

- Foreign research partners expressing concern.
- Foreign IP not burdened by same reasonable pricing requirements.



What can I do about this if I have concerns?



Submit concerns and comments to NIST!

- Go to www.regulations.gov and enter NIST-2023-0008 in the search field.
- Click the “Comment” icon, complete required fields, and enter/attach your comments.

THANK
YOU!

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