

## Comments of Robert Sachs on Guidance Framework for Considering Exercise of March-In Rights

### Introduction

I am Robert Sachs, one of the three prostate cancer patients who petitioned Health & Human Services (HHS) Secretary Xavier Becerra on November 18, 2021 to exercise march-in and/or other federal patent rights to reduce the excessive price of the prostate cancer drug Xtandi. The petition focused on a single issue, the reasonableness of charging US cancer patients for Xtandi 3 to 6 times more than residents of other countries. (Attachment 1).

Secretary Becerra delegated our petition to the National Institutes of Health (NIH). In January 2022, NIH Deputy Director Tara Schwetz advised us that NIH's review would take "about a month." On March 21, 2023, 15 months later and after repeated assurances from Dr. Schwetz that NIH was "carefully reviewing" the petition, NIH issued a two-page letter denying a march-in hearing. The decision made no mention of the Bayh-Dole requirement that taxpayer funded inventions be made "available to the public on reasonable terms." (35 U.S. Code Sec. 201). Acting NIH Director Lawrence A. Tabak held that Xtandi is "widely available as a prescription drug" ignoring clear evidence of the discriminatory price drug maker Astellas charges for Xtandi in the US—RED BOOK 2022 US average wholesale price (AWP) of \$189,900/year—as well as Astellas's obligation to make Xtandi "available to the public *on reasonable terms.*"

On March 23, 2023 petitioners appealed NIH's ruling to HHS Secretary Becerra. Today, more than 10 months after filing our appeal, HHS has yet to take any action. Copies of the appeal and a December 19, 2023 follow-up request are attached. (Attachments 2 and 3)

As a US taxpayer and metastatic prostate cancer patient, I offer this experience with the current march-in review process to underscore the reality that cancer patients and other American citizens have been denied any meaningful opportunity to obtain relief from discriminatory prices for taxpayer funded inventions. After having been presented with clear evidence of the unreasonable price Xtandi is sold for in the US, NIH has refused to even grant a hearing.

#### White House December 7th Announcement on Drug Pricing

Recent statements by President Biden and his top advisors offer hope that the guidance to be issued by the Interagency March-in Taskforce will remedy this. On December 7, 2023, the White House announced "new actions to promote competition in health care and support lowering prescription drug costs for American families, including [this] proposed framework for the exercise of march-in rights on taxpayer funded drugs and other inventions. Most significantly, according to the White House, "the framework specifies that price can be a factor in considering whether a drug is accessible to the public."

In a short video released to You Tube, President Biden declared, "Today we're taking a very important step toward ending price gouging so you don't have to pay more for the medicine you need."

During a press call prior the announcement, National Economic Advisor Lael Brainard stated, “when drug companies won’t sell taxpayer funded drugs at reasonable prices, we will be prepared to let other companies provide those drugs for less.” And Domestic Policy Advisor Neera Tanden stated, “For the first time ever, the high price of that taxpayer funded drug is a factor in determining that the drug is not accessible to the American public for a reasonable price.”

Against this backdrop, **I offer the following comments on the Draft Interagency Guidance Framework:**

#### Defining Sales Price

In discussing criterion for whether a contractor or assignee has taken effective steps to achieve practical application, the draft framework suggests on page 13 that agencies may want to consider “reasonableness of the price and other terms at which the product is made available to end-users.” This formulation lends itself to confusion.

In considering this criterion, its crucial that the cost burden on private insurers and government health programs like Medicare, Medicaid and the VA, as well as the out-of-pocket costs borne by end-users must be fully accounted for.

Framing this question solely in terms of “end-user” costs, fails to account for the public burden that excessively priced drugs place on Medicare, Medicaid, the VA as well as private insurers—all of which are paid for by US taxpayers.



For instance, in the case of Xtandi, Medicare alone currently pays Astellas more than \$2 billion/year and has paid the drug maker more than \$20 billion since 2012. (Astellas claims it invested \$1.4 billion to bring Xtandi to market).

In Section VI D of the framework, the taskforce poses the price question more clearly: “At what price and on what terms has the product utilizing the subject invention been sold or offered for sale in the U.S.?” This is the appropriate formulation.

Information about drug pricing is available to HHS from industry and a number of reliable health industry sources such as RED BOOK which covers FDA-approved drugs and publishes an annual Average Wholesale Price (AWP) survey, and the World Health Organization. It should not be difficult for federal agencies to review these and other authoritative information sources.

#### International Reference Pricing

Since the discoveries underlying the subject inventions were paid for by US taxpayers, this question should be expanded to invite comparison with the price and terms at which the contractor or licensee makes the product available in other highly developed countries. The concept of international reference pricing is neither new nor radical. (In fact in some contracts such as the contract between the Army and Pfizer [W58P0522C0001] for purchase of the Covid-19 treatment Paxlovid, the Government included a “most favored nation clause” requiring Pfizer to offer the US the lowest price it sells Paxlovid for to Canada, France, Germany, Italy, Japan, the UK or Switzerland.)



In 2017, the Republican controlled Senate Armed Services Committee (ASC) directed the Department of Defense as follows:

The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.

*115<sup>th</sup> Congress, 1<sup>st</sup> Session, 2017, Senate Report 115-125. National Defense Authorization Act for Fiscal Year 2018, Report to accompany S. 1519, on page 173. July 10, 2017.*

On November 19, 2022, nineteen not-for-profit organizations wrote to HHS in support of granting our march-in hearing request, suggesting the federal government consider that international reference price caps on prices is appropriate when a product meets each of the following standards:

- (1)The product is for a non-rare disease,
- (2)The product has already generated very large revenues,
- (3)The US Government funded each of the primary patented inventions, and
- (4)The pricing disparities are enormous.

Although less restrictive than the Army's contract for Paxlovid or the Senate Armed Services Committee's 2017 directive to the Department of Defense, this formulation offers another example of how the Interagency Task Force can and should include comparison to international pricing of subject inventions in its march-in guidance to

federal agencies. Federal agencies would still have discretion to choose the appropriate comparator(s). (Attachment 4)

### Defining “Reasonable Terms”

**The most glaring omission from the draft framework is the absence of a definition of “reasonable terms.”** Given a four-decade history of federal agencies ignoring price as a factor in determining whether a product is “available to the public on reasonable terms,” this omission easily could undermine President Biden’s and top advisors’ commitment to make taxpayer funded drugs accessible to the American public at reasonable prices.

Although “reasonable terms” is not defined in the Bayh Dole Act, U.S. courts have generally deemed undefined terms in a statute to have their “ordinarily understood meaning” and the words “reasonable terms” have uniformly been interpreted to include price. See *Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed on Patents Derived in Whole or in Part from Federally Funded Research* by Professor of Law Michael H. Davis and health economist Peter S. Arno, PhD, in the July 2001 Tulane Law Review. Ph.D. (75 Tul. L. Rev. 631 (2001)). See especially, the authors’ discussion about “the meaning of ‘reasonable terms’” at p.p. 649-653. (Attachment 5)

To avoid any confusion going forward, the definition of “reasonable terms” should explicitly include price and other terms that the subject invention is offered for sale and sold for in the US, reflecting the total costs incurred by public agencies including Medicare, Medicaid and the VA, private insurance carriers and end-users.



## Conclusion

As a 38-year non-Hodgkins lymphoma and eight year advanced prostate cancer survivor who has personally benefited from the fruits of federally funded research, I deeply appreciate the role the Bayh-Dole Act has played in fostering innovation and bringing new drugs to market. But often overlooked or ignored is the fact that the Bayh-Dole Act also included provisions “to alleviate health and safety needs not being met by the contractor or licensee” and to ensure that taxpayer funded inventions are made “available to the public on reasonable terms.” Innovation and accessibility *on reasonable terms* are **not** mutually exclusive concepts. Contractors and licensees are entitled to a period of exclusivity to recoup their reasonable costs to develop, market and distribute the product and to earn a reasonable risk-adjusted return on their investment. At the same time the public interest requires that inventions paid for by US taxpayers be affordable and broadly accessible. Excessive drug prices that result in American citizens being charged several times more than residents of other countries for the very same products their tax dollars financed are incompatible with these goals and the terms of the patents that contractors were granted. Drug manufacturers can earn healthy returns on their investments in taxpayer funded discoveries without profiteering at the expense of the American public. As President Biden has declared, the “price gouging” of American consumers must stop.

If the Interagency Guidance Framework is to deliver on the President's promise, the framework must be clear that price is a factor to be considered in determining whether or not a taxpayer funded invention is made "available to the public on reasonable terms." Likewise, the framework should provide clear guidance on how price should be calculated and price discrimination determined.

Thank you for this opportunity to submit my comments.

Submitted by:

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Attachments (5)



**Attachments to**

**Comments of Robert Sachs on Guidance Framework  
For Considering Exercise of Federal March-In Rights**

**February 1, 2024**

## **Attachment 1**



November 18, 2021

Xavier Becerra  
Secretary  
Department of Health & Human Services  
United States of America

Via Email: [xavier.becerra@hhs.gov](mailto:xavier.becerra@hhs.gov)

Dear Secretary Becerra:

The undersigned individuals are writing to formally ask the Department of Health and Human Services (HHS) to grant march-in rights for the patents on the prostate cancer drug enzalutamide (marketed as Xtandi).

As prostate cancer patients we have previously petitioned the U.S. Department of Defense (DoD) to grant march-in rights for the patents on this life saving drug.

Clare Love and David Reed submitted a petition to the DoD on February 4, 2019, following a Directive from the Senate Armed Services Committee to the DoD to grant such march-in requests when the price of a drug developed with a DoD grant is higher than the median price in seven large high income economies. That is the case in this petition, in which enzalutamide—which was invented at UCLA on grants from the U.S. Army and the National Institutes of Health (NIH)—are roughly 3 to 5 times more expensive in the United States than in other high income countries. The drug, which is inexpensive to manufacture, is priced in the United States at \$106.865 per 40 mg pill. With a required dose of four pills per day, Xtandi costs \$427.50 per day and more than \$156,000 per year. The price in other high income countries generally ranges from \$20 to \$40 per 40mg pill. A Canadian generic manufacturer has offered to sell enzalutamide to the U.S. government for \$3 per pill.

(See: <https://www.drugs.com/price-guide/xtandi> and <http://drugdatabase.info/drug-prices/>)

Robert Sachs wrote to the DoD on April 12, 2021 to join the Love and Reed march-in request. To date, the DoD has not acknowledged nor acted on these petitions.

Clare Love is a Vietnam veteran. David Reed is an accomplished computer scientist,<sup>1</sup> best known for developing the concept of the end to end principle for the Internet. Robert Sachs is an attorney, former Board Chair of the National Coalition for Cancer Survivorship (NCCS), and member of the board of trustees of the Dana Farber Cancer Institute.

We ask that our petition be adjudicated by an impartial decision maker. Under two previous Administrations, HHS has been petitioned to grant a march-in request for the patents on enzalutamide. Each time HHS delegated the case to the NIH, and each time, including on the

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<sup>1</sup> [https://en.wikipedia.org/wiki/David\\_P.\\_Reed](https://en.wikipedia.org/wiki/David_P._Reed).

administrative appeals, such requests and appeals were summarily rejected, in line with a then standing policy position that the NIH would not question the reasonableness of company pricing of NIH funded inventions. It is our understanding that HHS is now willing to consider the merits of a march-in request, when the basis is that the price is demonstrably unreasonable.

Attached are copies of the 2019 and 2021 march-in petitions DoD. We are asking that HHS address this issue in a timely manner, which has dragged on for years at this point. A first step is to grant a hearing on the petition, where the patent holders and the persons supporting the march-in petitions can present evidence. This was done once by NIH for a march-in petition on the HIV/AIDS drug ritonavir in 2004.

A group known as the Bayh-Dole Coalition has lobbied against any use of the march-in rights to deal with pricing concerns. This well resourced and powerful group of patent holders has generated a steady stream of misleading information about the march-in rights issue. We welcome their input in any evaluation of our march-in petitions, and only ask that the facts are actually addressed by HHS. We also ask that any groups or individuals interested in the petition be allowed to provide evidence for the record.

We are pleased that the HHS Comprehensive Plan for Addressing High Drug Prices and the President's Executive Order on Competition recognize the use of march-in rights to address abusive pricing of drugs.

Xtandi was invented with NIH funding. The Orange Book lists three patents for enzalutamide: U.S. Patent Nos. 7709517, 8183274, and 9126941, and all three acknowledge support from NIH grant number 5 P50 CA092131. The patent expiration dates are from May 2026 to August 2027.

In the past, the use of march-in rights for enzalutamide has been supported by more than a dozen organizations (see Annex 1) and several members of Congress in both the U.S. Senate and the House of Representatives. When the Trump Administration made a last minute attempt to change the Bayh-Dole regulations to eliminate pricing concerns as a sole ground for a march-in petition, more than 80 thousand persons submitted comments in opposition.

Thank you for considering our request. We ask HHS to move forward and incorporate the two previous march-in petitions to the DoD, which are attached.

Sincerely,

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Robert Sachs  
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**ANNEX 1: Organizations that have previously supported march-in rights on enzalutamide**

Alliance for Retired Americans  
American Medical Students Association (AMSA)  
Center for the Study of Responsive Law  
Community Catalyst  
Essential Information  
Knowledge Ecology International (KEI)  
National Physicians Alliance (NPA)  
Public Citizen  
RxRights  
The Other 98%  
U.S. PIRG  
Union for Affordable Cancer Treatment (KEI)  
Universities Allied for Essential Medicines (UAEM)

**ANNEX 2: Members of the Bayh-Dole Coalition**





1. Association of University Research Parks
2. AUTM
3. BIOCUM
4. BIO
5. BIOHealth Innovation
6. Bio NJ
7. California Life Sciences Association
8. Carnegie Mellon University
9. Center for Innovation and Free Enterprise (CIFE)
10. Conservatives for Property Rights
11. Council on Government Relations
12. Columbia Technology Ventures
13. Council on Competitiveness
14. CSU Ventures
15. Duke Licensing & Ventures
16. Eagle Forum



17. ExploraMed
18. Funtek
19. US Chamber of Commerce Global Innovation Policy Center
20. Incubate
21. India University
22. Innovation Associates
23. IPWatchdog
24. Information Technology and Innovation Foundation
25. International Economic Development Council
26. K2 Biotechnology Ventures
27. Licensing Executives of USA and Canada
28. Lehigh University
29. LSU Business and Technology Center
30. Magee-Womens Research Institute and Foundation
31. NVCA
32. Patent Docs
33. PhRMA
34. Pristine Surgical
35. Purdue University
36. Small Business and Entrepreneurship Council
37. Stanford University Office of Technology Licensing
38. UNM Rainforest Innovations
39. Taxpayer Protection Alliance
40. UNEMED - Technology Transfer for Nebraska
41. University of Notre Dame
42. USIJ Alliance for U.S. Startups & Inventors for Jobs
43. University of Michigan Tech Transfer
44. VirginiaBio
45. Wisconsin Alumni Research Foundation
46. Yale Office of Cooperative Research

<https://bayhdolecoalition.org/about/>

## **Attachment 2**



March 21, 2023

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Clare Love  
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Dear Mr. Sachs and Mr. Love:

On November 18, 2021, Health and Human Services (HHS) Secretary Xavier Becerra, received your petition requesting the exercise of the march-in authority under the Bayh-Dole Act (35 USC §203) to lower the price of Xtandi (enzalutamide). Additional requests to join the petition were received in November and December from Eric Sawyer, Knowledge Ecology International (KEI), and Universities Allied for Essential Medicines (UAEM). HHS referred this petition to the National Institutes of Health (NIH).

NIH shares your concern about the high price of drugs and the burden it places on patients and their families, particularly the uninsured and the underinsured. Nearly one in four Americans struggle to afford prescription drugs. Understandably, members of the public are concerned that the prices they pay are higher than those in other high-income countries. President Biden's Executive Order 14036 "Promoting Competition in the American Economy,"<sup>1</sup> Executive Order 14087 "Lowering Prescription Drug Costs for Americans,"<sup>2</sup> and the HHS "Comprehensive Plan for Addressing High Drug Prices" ("the Plan")<sup>3</sup> provide approaches to address the high cost of prescription drugs through implementation of one of the three guiding principles for drug pricing reform laid out in the Plan. One of them—"to foster scientific innovation to promote better health care and improve health"—falls within the mission of NIH to uncover new knowledge that

<sup>1</sup> [www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/](https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/) (July 9, 2021).

<sup>2</sup> <https://www.whitehouse.gov/briefing-room/presidential-actions/2022/10/14/executive-order-on-lowering-prescription-drug-costs-for-americans/> (October 14, 2022).

<sup>3</sup> [https://aspe.hhs.gov/sites/default/files/2021-09/Drug\\_Pricing\\_Plan\\_9-9-2021.pdf](https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf) (September 9, 2021).



will lead to better health for everyone. With the support of the President and Congress, NIH-funded research has and will continue to lead to improved health outcomes.

The purpose of the Bayh-Dole Act is to promote the commercialization and public availability of government-funded inventions, 35 U.S.C. § 200, et seq., and the overarching framework of the Act is to allow government funding recipients to own patent rights and to encourage them to seek and commit to partnering with the private sector for commercialization of these technologies. Section 203 of the Act, governing march-in, outlines residual rights retained by the government. In the last 18 years, much analysis has been published and discussed at public meetings concerning the application of the march-in authority. Diverse views on the use of march-in have been explored by the Congressional Research Service<sup>4</sup> and presented at a National Academies' workshop.<sup>5</sup> The National Academies' Consensus Study Report from 2018, "Making Medicines Affordable," recommends a variety of governmental actions.<sup>6</sup>

NIH's analyses in response to the petition request have found Xtandi to be widely available to the public on the market. In addition, given the remaining patent life and the lengthy administrative process involved for a march-in proceeding, NIH does not believe that use of the march-in authority would be an effective means of lowering the price of the drug. For these reasons, NIH has determined that initiation of a march-in proceeding is not warranted in this case. This decision is consistent with NIH's determination in 2016, in which KEI and the Union for Affordable Cancer Treatment requested NIH and the Department of Defense march-in based on the price of Xtandi, but each declined.<sup>7,8</sup> In responding to the march-in request for Xtandi in 2016, NIH explained that, consistent with march-in determinations for Cell Pro (1997), Norvir (2004, 2013) and Xalatan (2004),<sup>9</sup> practical application is evidenced by the "manufacture, practice, and operation" of the invention and the invention's "availability to and use by the public...." Astellas, the maker of Xtandi, estimates that more than 200,000 patients were treated with Xtandi from 2012 to 2021.<sup>10</sup> Therefore, the patent owner, the University of California, does not fail the requirement for bringing Xtandi to practical application, as the drug is manufactured and on the market in the manner of other prescription drugs. NIH has reviewed the information submitted by the current petitioners, which is substantially the same as that submitted in 2016, and reached the conclusion that Xtandi is still widely available as a prescription drug.

NIH and HHS will pursue a whole of government approach informed by public input to ensure the use of march-in authority is consistent with the policy and objective of the Bayh-Dole Act,

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<sup>4</sup> March-in rights under the Bayh-Dole Act (2016) <https://sgp.fas.org/crs/misc/R44597.pdf> (2016)

<sup>5</sup> The role of NIH in drug development innovation and its impact on patient access (2020) <https://www.nap.edu/read/25591/chapter/2> ,

<sup>6</sup> <https://www.nap.edu/catalog/24946/making-medicines-affordable-a-national-imperative>

<sup>7</sup> See Army March-In Response at [https://www.keionline.org/wp-content/uploads/USArmy\\_Response\\_Xtandi\\_Request\\_5Aug2016.pdf](https://www.keionline.org/wp-content/uploads/USArmy_Response_Xtandi_Request_5Aug2016.pdf)

<sup>8</sup> See NIH March-In Response at [https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/Final\\_Response\\_Goldman\\_6.20.2016.pdf](https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/Final_Response_Goldman_6.20.2016.pdf)

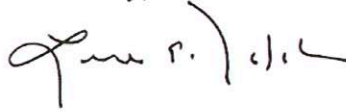
<sup>9</sup> See previous NIH March-In Responses at [www.ott.nih.gov/policy/policies-reports](http://www.ott.nih.gov/policy/policies-reports)

<sup>10</sup> Estimate based on Astellas sales and use data September 2012 to June 2021. [www.Xtandi.com](http://www.Xtandi.com)



promotes commercialization of research results, maximizes the potential for HHS-funded technologies to become products, and serves the broader interest of the American public.

Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence A. Tabak". The signature is fluid and cursive, with a large initial "L" and a distinct "A" and "T".

Lawrence A. Tabak, D.D.S., Ph.D.  
Performing the Duties of the NIH Director

cc:

James Love, Director, Knowledge Ecology International  
james.love@keionline.org

Merith Basey, Universities Allied for Essential Medicines  
merith@essentialmedicine.org

Eric Sawyer, via his attorney Kathryn Ardizzone  
kathryn.ardizzone@keionline.org

## **Attachment 3**

March 23, 2023

Xavier Becerra  
Secretary  
Department of Health & Human Services  
Washington, DC

Via Email: [xavier.becerra@hhs.gov](mailto:xavier.becerra@hhs.gov)

Re: Appeal of NIH decision to reject petition that HHS use Federal rights in patents on Xtandi to address pricing discrimination against US cancer patients

Dear Secretary Becerra:

The undersigned petitioners hereby appeal the March 21, 2023 decision by the National Institutes of Health (NIH), acting on your behalf, to reject our petition asking the Department of Health and Human Services (HHS) to use its rights in patents on the prostate cancer drug Xtandi in order to enable generic competition to lower the price.

Our petition to HHS was filed on November 18, 2021, by prostate cancer patients Clare Love and Robert Sachs, and later joined by prostate cancer patient Eric Sawyer, and Universities Allied for Essential Medicines (UAEM). The November 18, 2021 petition followed an earlier petition filed with the Department of Defense (DoD) on February 4, 2019, by Love and prostate cancer patient David Reed that Robert Sachs subsequently joined. If you consider both of these requests together, a petition to exercise the government's march-in or other rights in the Xtandi patents has been pending before the federal government for more than four years. The HHS petition was filed 16 months ago.

The petitions were filed with the DoD and HHS instead of the NIH because the NIH has repeatedly demonstrated its unwillingness to even acknowledge that the Bayh-Dole Act includes an obligation to make products invented with federal funds "available to the public on reasonable terms." This is demonstrated by a track record of dismissing multiple requests to use the government's Bayh-Dole safeguard to address pricing abuses and access restrictions, including those concerning the federal government's march-in rights under 35 USC § 203, and the federal government's global royalty-free license, under 35 USC § 202(c)(4). There are also extensive email records between Mark Rohrbaugh, currently NIH Special Advisor for Technology Transfer who is a long-time agency official, and lobbyists for drug companies and university rights holders, obtained through Freedom of Information Act requests, which not only express opposition to any safeguards regarding unreasonable pricing but organize public relations efforts against using a march-in request to address the pricing of products.

HHS chose to assign to the NIH the evaluation of our petition regarding Xtandi. We request HHS to consider this appeal directly, and not assign NIH to review its own decision. The latter would be tantamount to no review at all.

The petition focused on a single issue: the reasonableness of charging US cancer patients 3 to 6 times more than residents of other high-income countries for the drug Xtandi. There is no dispute



about the following facts: Xtandi was invented on grants from the US Army and the NIH at UCLA, a public university. The patents were licensed eventually to Astellas, a Japanese drug company, with a partnership share now held by Pfizer, following its 2016 \$14 billion acquisition of Medivation, UCLA's original licensee, that occurred just after the NIH rejected an earlier march-in request on Xtandi. The prices in the United States have consistently been far higher than the prices in other high-income countries.

The legal basis for a march-in case to address this price discrimination against US residents was the obligation in 35 USC § 203(a)(1) that the patent holder takes "effective steps to achieve practical application of the subject invention in such field of use."

As the NIH is well aware, "practical application" is defined in the statute, as follows:

35 U.S. Code § 201 - Definitions

(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.

The central issue in the case has always been about the last seven words in the definition: "available to the public on reasonable terms."

The staff of the NIH have repeatedly ignored these critical seven words, the most recent example being the March 21, 2023 letter from Acting NIH Director Lawrence A. Tabak, D.D.S., Ph.D. which misleadingly described the practical application issue as follows:

. . . practical application is evidenced by the "manufacture, practice, and operation" of the invention and the invention's "availability to and use by the public..." Astellas, the maker of Xtandi, estimates that more than 200,000 patients were treated with Xtandi from 2012 to 2021. /10/ Therefore, the patent owner, the University of California, does not fail the requirement for bringing Xtandi to practical application, as the drug is manufactured and on the market in the manner of other prescription drugs. NIH has reviewed the information submitted by the current petitioners, which is substantially the same as that submitted in 2016, and reached the conclusion that Xtandi is still widely available as a prescription drug.

10 Estimate based on Astellas sales and use data from September 2012 to June 2021.  
[www.Xtandi.com](http://www.Xtandi.com)

Absent from the letter is any mention of "reasonable terms" or the price for which Xtandi is sold in the U.S. The quotes from Dr. Tabak's letter do not track the statute or the regulations on march-in rights, and specifically, omit the central issue in the case, that the patent holder must make the product "available to the public on reasonable terms." This blatant omission cannot and should not be ignored.

Clearly, this is a case about “reasonable terms” and the question is: can a company charge US cancer patients 3 to 6 times more than they charge residents of other high-income countries, for a drug invented on US federal government grants? The NIH letter does not once use the words “reasonable” or “terms.” The NIH justifies the rejection of the petition on the grounds that Astellas and Pfizer are selling the product and it is “widely available as a prescription drug,” an issue that, of course, was never in dispute. However, never did NIH even address the reasonableness of that price discrimination. Nonetheless, one could reasonably ask *how* widely available is the drug, given the restrictive nature of formularies for drugs as expensive as Xtandi? In any case, the Bayh-Dole Act does not set “availability” by itself as a standard.

NIH’s March 21, 2023 letter effectively declares that drug prices are irrelevant, and more specifically, that price discrimination against US cancer patients is irrelevant. This whole case is about price discrimination, and the NIH’s only acknowledgment of this was to say “Understandably, members of the public are concerned that the prices they pay are higher than those in other high-income countries.” After 16 months of foot dragging and repeated assurances by NIH that our petition was being “carefully considered,” petitioners deserve an unbiased legal determination based upon the facts and the issue presented in our petition. However, never did NIH even discuss the reasonableness of that price discrimination, in the context of the Bayh-Dole statutory obligation for patent holders to make inventions based upon taxpayer-funded discoveries “available to the public on reasonable terms.”

A second justification used to reject the petition is that a march-in proceeding would be “lengthy” relative to the remaining patent life and would not be “an effective means of lowering the price of the drug.”

“In addition, given the remaining patent life and the lengthy administrative process involved for a march-in proceeding, NIH does not believe that use of the march-in authority would be an effective means of lowering the price of the drug.”

It is ironic that our petition, first filed in 2019 and later filed in 2021, is considered not timely, in March 2023, by an agency that promised a decision more than a year ago. But has the opportunity for government action actually run out on the Xtandi monopoly? The FDA Orange Book patents on Xtandi expire in 2027, four years from now, and every year of monopoly pricing is not only worth billions to Astellas and Pfizer, but more importantly imposes high costs and restricted access to a life extending treatment for many advanced prostate cancer patients.

The ‘clock has run’ argument might have some weight if NIH had not totally ignored the federal government’s parallel authority, cited by petitioners, to use its royalty-free rights in the patents under 35 USC § 202(c)(4), which gives the US government a “paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.” This license, which does not even require the payment of royalties to Astellas, gives the US government the legal ability to authorize a generic version of Xtandi at any time, the only issue being a question of the breadth of the authorization. If the authorization is extended to Medicare and Medicaid, and put on the Federal Supply Schedule (FSS), it would have a rapid impact on Xtandi’s price in the United States. This gives HHS tremendous leverage, and makes the combination of rights, march-in under §203 or the royalty-free license under § 202, a powerful tool to address this clear abuse in



pricing in the near term. Curiously, HHS fails to use all the tools currently available to it while at the same time the Biden Administration publicly decries the excessive cost of prescription drugs in the U.S.

It is particularly offensive that NIH has been unwilling to even consider the overriding legal issue presented by our petition, and conveys disrespect for us as American citizens exercising legitimate rights while insulting the intelligence of anyone who has followed this issue. As noted in a separate HHS press release, also dated March 21, 2023, more than 80,000 persons had provided comments in a related 2021 rulemaking proceeding on Bayh-Dole regulations, on the very topic of the definition of "practical application." This is not some minor technical issue. The overwhelming majority of those opposed eliminating the Bayh-Dole Act's "reasonable terms" protection. The requirement that patent holders make products "available to the public on reasonable terms" was and is a widely discussed topic and of course is one of the subjects of the Presidential Executive Order 14036 on Competition cited by NIH. And yet, NIH cited the Executive Order while rejecting our petition on the grounds that mere availability at any price satisfies the definition of practical application, a position at odds with the Executive Order.

There are now four companies that have filed ANDA applications for enzalutamide, two of which have received tentative approval from the FDA. To act as if the federal government is powerless to address this abusive price discrimination against US residents is appalling and a dereliction of our Government's duty to enforce the terms of patents arising out of taxpayer-funded discoveries.

In considering the appeal, we ask HHS to also include in its review the evidence and analysis included in the memorandum in support of the petition to HHS to exercise the march-in or paid up royalty right in patents on the prostate drug Xtandi, which was submitted to HHS and NIH on January 25, 2022. (See: <https://www.keionline.org/xtandidocs/xtandi-25jan2022.pdf>) Among other things, this memorandum provides:

- Table 1, a review of "Prices of 40 mg capsules of Xtandi in 16 high income countries compared to FSS, Medicaid, Medicare Part D, Drugs.Com coupon, AWP and WAC prices.
- Table 2, a review of the annual cost of Xtandi for patients in the United States and eight high income countries with large economies, and the ratio of the cost to GNI per capita in each of the countries.
- Evidence of restrictive placement of Xtandi on US formularies.
- Table A1, A list of recent U.S. government COVID-19 contracts that contain a reference price constraints on resultant products.

HHS is also asked to take note of our letter of February 3, 2022 to you and Acting NIH Director Dr. Tabak providing information on a contract between the Army and Pfizer (W58P0522C0001) to purchase the Covid-19 treatment Paxlovid that contains a most favored nation clause requiring that if Pfizer charges a "Covered Nation" a lower price than it charged the United States for Paxlovid, then Pfizer must offer that lower price to the United States. The clause, located at section H.7 of the contract, states that if the government accepts the lower price, the contract is thereby amended to reflect the lesser cost. A "Covered Nation" is Canada, France, Germany, Italy, Japan, the United Kingdom, the United States, or Switzerland. The terms of this contract are a more strict international reference pricing standard than we had endorsed.



We also ask HHS to reflect on the recommendation of 19 organizations that wrote to HHS on November 19, 2022 seeking to create a narrow standard to justify granting our petition. They suggested that the federal government consider that an international reference pricing cap on prices is appropriate, without prejudice to other cases with different facts, when a product meets each of these standards,

- (1) the product is for a non rare disease
- (2) the product has already generated very large revenues
- (3) the government funded all of the primary patented inventions and
- (4) the pricing disparities are enormous,

Given the government's unnecessarily long delays reviewing these petitions, which the NIH has now invoked as one of its excuses to reject our petition, we respectfully request HHS decide our appeal within 30 days. We realize this may be an ambitious timetable but for tens of thousands of American men living with advanced prostate cancer, every month truly matters when it comes to their lives and the availability "on reasonable terms" of life-extending drugs like enzalutamide. We also request you appoint as the reviewing authority an impartial HHS official not involved in preparing the March 21 NIH decision.

Sincerely,

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December 19, 2023  
Xavier Becerra  
Secretary  
Department of Health & Human Services  
Washington, D.C.  
Via email: [xavier.becerra@hhs.gov](mailto:xavier.becerra@hhs.gov)

Re: Appeal of NIH decision rejecting petition for HHS to exercise Federal rights in patents on Xtandi in order to address price discrimination against US cancer patients

Dear Secretary Becerra:

This letter is to renew the [March 23, 2021 appeal](#) to HHS of NIH's March 21, 2023 decision rejecting the November 18, 2021 petition submitted by the undersigned prostate cancer patients, Clare Love and Robert Sachs, later joined by prostate cancer patient Eric Sawyer (collectively, "cancer patients") and Universities Allied for Essential Medicines (UAEM). In renewing our appeal to HHS to review and reverse NIH's decision, we take note of the White House's recent announcement that the high price of taxpayer funded drugs is a factor to be considered in determining cases involving the exercise of Federal patent rights. A copy of our appeal is attached.

In it we point out that NIH took 16 months to issue a perfunctory decision ignoring the provision of the Bayh-Dole Act requiring US taxpayer funded inventions be made available to the public "on reasonable terms." (See [35 USC Sec. 203, and 35 USC Sec. 201\(f\)](#)), defining "practical application.") It's been an additional nine months since we filed our appeal and based upon Medicare's 2021 total spending for Xtandi, it has paid almost \$5 billion for the drug just since our petition was submitted in November 2021.

Since then, HHS has taken no action to address the excessive and discriminatory price at which Xtandi is sold in the US. In fact, NIH review and the current appeal process have now consumed more than two years—even though HHS had recognized in a report issued two months before we submitted our petition that "march-in" rights were a tool that could be used to address excessively priced taxpayer funded drugs. The September 9, 2021 [report](#), titled "Comprehensive Plan for Addressing High Drug Prices," states, "The federal government may grant a license to use the intellectual property arising from government funding without the permission of the rights-holder including when 'action is necessary to alleviate health and safety needs which are not reasonably satisfied' or when the benefits of the patented product are not 'available to the public on reasonable terms.'"

NIH justified its rejection of our petition on the grounds that Xtandi is "widely available as a prescription drug." This was never at issue but, more importantly, the Bayh-Dole Act does not set "availability" alone as a standard. Despite HHS's September 2021 guidance, then Acting NIH Director Lawrence Tabak refused to acknowledge that government-funded drug discoveries need to be made publicly available "on reasonable terms." Indeed, the last three words of the requirement— "on reasonable terms"—were totally ignored in NIH's March 21 decision, as if they had been excised from the Bayh-Dole Act. As we state in our appeal, "NIH's decision effectively declares that drug prices are irrelevant, and more specifically that price discrimination against US cancer patients is irrelevant."

A second reason NIH cited for rejecting our petition was that a march-in proceeding would be "lengthy" in view of the remaining patent life and therefore not be "an effective means of lowering the price of the drug." But as we explain in our appeal, "the 'clock has run' argument might have some weight if NIH had not totally ignored the government's parallel authority, cited by petitioners, to use its royalty-free rights in the patents under [35 USC Sec. 202\(c\)\(4\)](#), which gives the US government a "paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."



If this acquisition authority is extended to Medicare and Medicaid, and a generic form of Xtandi is put on the Federal Supply Schedule (FSS), it would have a rapid impact on Xtandi's US price, saving the Federal government and American taxpayers billions of dollars during each of the next several years. Clearly, the potential exercise of the government's royalty-free rights gives HHS another powerful tool to address the excessive and discriminatory price of Xtandi paid by US prostate cancer patients.

Against this backdrop, the [White House](#) announced on December 7, 2023 "new actions to promote competition in health care and support lowering prescription drug costs for American families, including the release of a proposed framework for agencies on the exercise of march-in rights on taxpayer funded drugs and other inventions, which specifies that price can be a factor in considering whether a drug is accessible to the public."

In a short [video](#) released to YouTube the night before the announcement, President Biden declared, "Today we're taking a very important step toward ending price gouging so you don't have to pay more for the medicine you need."

During a press call before the announcement, National Economic Advisor Lael Brainard stated, "When drug companies won't sell taxpayer funded drugs at reasonable prices, we will be prepared to let other companies provide those drugs for less." Emphasizing this point she went on to say, "If American taxpayers paid to help invent a prescription drug, the drug companies should sell it to the American public for a reasonable price."

And domestic Policy Adviser Neera Tanden said, "For the first time, ever, the high price of that taxpayer-funded drug is a factor in determining that the drug is not accessible to the public on reasonable terms."

Cancer patients fully agree with these statements and fervently hope the White House's announced drug price control efforts do not result in dashed hopes about lowering excessive costs for potentially life-saving drugs. To this end, petitioners urge HHS to consider our appeal directly, and not assign NIH to review its own decision. (This is consistent with guidance contained in the proposed framework.) As explained in our appeal, NIH has a long track record "of dismissing requests to use the government's Bayh-Dole safeguard to address pricing abuses and access restrictions including the federal government's march-in rights under [35 USC Sec. 203](#), and the federal government's global royalty-free license under [35 USC Sec. 202\(c\)\(4\)](#)."

In contrast to the White House's and HHS' recognition that drug prices are a factor to be considered in reviewing such requests, NIH has totally ignored the Bayh-Dole Act requirement that taxpayer funded drugs be "made available to the public on reasonable terms." In the case of Xtandi, which has a Redbook average US wholesale price of \$189,900/year as of January 12, 2022, the excessive price of the drug should be a major factor in determining whether the Bayh-Dole "on reasonable terms" mandate has been met. To appreciate the arbitrariness of the US price for Xtandi, compare it with the situation in other highly developed markets, where Astellas sells Xtandi for one-sixth to one-third its US price. Had Astellas sold Xtandi in the US for even one third its price, Medicare alone would have saved more than \$3.3 billion over the two years since we filed our petition.

As President Biden declared, the "price gouging" of American consumers has to stop. In keeping with the President's and his top advisors' embrace of exercising government patent rights to control excessive drug prices, we respectfully ask you to rule expeditiously on our appeal and exercise HHS's authority to ensure Xtandi is made available to the public "on reasonable terms."

Sincerely,

Robert J Sachs

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[Petitioners March 23,2023 Appeal to HHS of NIH's March 21, 2023 Xtandi Decision](#)

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## Attachment 4



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Home (<https://www.keionline.org>) » Blogs (/blog) » Letter from 19 groups asking HHS to take action on the request that HHS use the federal government rights in patents on the prostate drug enzalutamide, marketed by Astellas under the brand name Xtandi. (<https://www.keionline.org/38148>)

## Letter from 19 groups asking HHS to take action on the request that HHS use the federal government rights in patents on the prostate drug enzalutamide, marketed by Astellas under the brand name Xtandi.

Posted on November 29, 2022 (<https://www.keionline.org/38148>) by James Love (<https://www.keionline.org/author/james-love>)

Attached is a letter from 19 groups asking HHS Secretary Xavier Becerra to take action on the request that HHS use the federal government rights in patents on the prostate drug enzalutamide, marketed by Astellas under the brand name Xtandi.

HHS-asked-act-Xtandi-29Nov2022 (<https://www.keionline.org/wp-content/uploads/HHS-asked-act-Xtandi-29Nov2022.pdf>)

---

November 29, 2022

Xavier Becerra

Secretary

Department of Health & Human Services

Washington, DC

Via Email: [xavier.becerra@hhs.gov](mailto:xavier.becerra@hhs.gov)

Dear Secretary Becerra:

We are writing to urge action on the request that HHS use the federal government rights in patents on the prostate drug enzalutamide, marketed by Astellas under the brand name Xtandi. The request to HHS, by four prostate cancer patients, was made on November 18, 2021. More than one year has passed, and HHS has yet to decide the case.

The central issue in the case is the fact that Astellas charges U.S. residents three to six times more for this drug than the company charges in any other high income country.

If there are members of the administration who are reluctant to set a standard for the pricing of drugs that use federally funded patented inventions, this case involves facts that should make this decision easy.

The drug, Xtandi, is for a common rather than a rare disease. Xtandi has already generated massive revenues, including more than \$10 billion from the Medicare program alone. The US government funded each of the three patented inventions in the FDA Orange Book. The pricing disparities are enormous.

If a product meets each of these standards, (1) the product is for a non rare disease (2) the product has already generated very large revenues (3) the government funded all of the patented inventions and (4) the pricing disparities are enormous, then the federal government should state it will use its rights to remedy the pricing abuse. This is a modest but important step toward addressing the excessive pricing of drugs that can be taken now.

In Australia, Xtandi costs less than \$31 thousand per year. The 2021 price in Japan, where Astellas is headquartered, is less than \$25 thousand a year at current exchange rates. The January 2022 Redbook Average Wholesale Price (AWP) for the U.S. was \$189,800 per year.

If the Administration rejects the Xtandi petition, it sets a precedent on pricing, that the Biden Administration will permit a company to charge exorbitant prices, even when the drug is invented on a government grant, and is subject to a statute that requires products to be made "available to the public on reasonable terms." (35 USC 201.f)

A rejection of the petition will encourage more aggressive pricing of drugs.

HHS needs to bring this case to a conclusion, either by deciding now, based upon the evidence before it, that the use of federal government's rights in the patent are warranted, or at the very least, granting a public hearing on the petition.

signed

(in alphabetical order).

ACA Consumer Advocacy  
Arkansas Community Organizations  
Beta Cell Foundation  
Church World Service,  
Health Care Voices  
Just Care USA  
Knowledge Ecology International  
People's Action  
Physicians for a National Health Program  
Progressive Maryland  
Public Citizen  
R2H Action [Right to Health], USA  
Salud y Farmacos  
Social Security Works  
T1International USA  
Tennessee Health Care Campaign

## Attachment 5



# 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

Peter S. Arno\*  
Michael H. Davis†

*This Article discusses drug pricing in the context of federally funded inventions. It examines the "march-in" provision of the Bayh-Dole Act, a federal statute that governs inventions supported in whole or in part by federal funding. It discusses technology-transfer activity as a whole and the often-conflicting roles of the government, academia, and industry. The Article discusses the mechanisms of the Bayh-Dole Act and examines its legislative history. It notes that the Act has had a powerful price-control clause since its enactment in 1980 that mandates that inventions resulting from federally funded research must be sold at reasonable prices. The Article concludes that the solution to high drug prices does not involve new legislation but already exists in the unused, unenforced march-in provision of the Bayh-Dole Act.*

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\* Professor of Epidemiology and Social Medicine, Albert Einstein College of Medicine/Montefiore Medical Center. Ph.D., Economics 1984, Graduate Faculty of the New School for Social Research. We would like to thank Dr. Karen Bonuck for providing much of the early historical research for this Article. We owe a special debt of gratitude to Margaret Memmott, who for months has painstakingly tracked down hundreds of documents and citations. This work was supported in part by grants from the National Science Foundation (SBR-9412966) and the Henry J. Kaiser Family Foundation, but the views and mistakes reflect those of the authors alone.

† Professor of Law, Cleveland State University College of Law; Registered to Practice Before the U.S. Patent & Trademark Office in Patent Matters. J.D. 1975, Hofstra Law School; LL.M 1979, Harvard Law School. I would like to thank Dr. Arno for teaching me about co-authorship. Having co-authored less than a handful of pieces at the time Peter and I started this collaboration, I thought of co-authorship as a convenient way to share the work; as time passed, I came to think of it as a way to share the blame; as even more time passed and the work was completed, I finally realized that it was really a way to share the pain, for which I apologize. I must also express my sincere appreciation to C.S.U. law library's Marie Rehmar, one of the world's two greatest reference law librarians. This Article owes much of its completion to two generous grants from the Cleveland-Marshall Fund, for whose patience I am most grateful.

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## I. INTRODUCTION

It is widely believed that advances in drug development and biomedical technology over the next few decades will revolutionize the delivery of health care, reduce mortality and morbidity, and improve the quality of life for individuals afflicted by many life-threatening conditions.<sup>1</sup> An apparent nirvana of high technology seems within reach, and yet the dark shadow of exploitation and a growing disparity of access lurks, threatening a loss of democratic control over the necessities of life through corporate domination of economic and political freedoms. Increasingly, the combined efforts of government, industry, and academia are advancing free trade in both domestic and international fora. However, the immediate, financial fruits of these achievements appear, for the most part, to adduce to private participants. The relationships among these players have an enormous impact on the costs of health care, the health of the American public, the nation's competitive position in the global economy, and the integrity, quality, and independence of science. In light of the controversies, the evolving approach to these public-private relationships in health-related research demands scrutiny.<sup>2</sup>

1. RUTH E. BROWN ET AL., *THE VALUE OF PHARMACEUTICALS: AN ASSESSMENT OF FUTURE COSTS FOR SELECTED CONDITIONS* 3 (1991).

2. It is difficult to call such often one-sided relationships partnerships. Not only is there little question that the real winners here are private entities, but the government, when reviewing the results, reports these private gains in what can only be characterized as a contentedly sanguine manner:

Two major beneficiaries of this federal spending have been universities and U.S.-based corporations. The universities benefited because the government was



resulted in a kind of land grab in which researchers receive funding but uniformly fail to include the Bayh-Dole legend in any resulting patents.<sup>105</sup> Ironically, although the goal of the Bayh-Dole Act was to make policies for government inventions uniform, the fact that each agency imposed its own rules seriously undermined and balkanized the statute until the uniform Commerce Department rules were enacted. The result is possibly worse, however, under the Commerce Department rules, because the Commerce Department issued implementing regulations with no facilities for oversight,<sup>106</sup> leaving the agencies to enforce the Act with no direction and little expertise.<sup>107</sup>

### B. *The Meaning of "Reasonable Terms"*

What "*available to the public on reasonable terms*"<sup>108</sup> means is not jurisprudentially troublesome, even absent the clear legislative history of the term.<sup>109</sup> U.S. law has always held that, absent a clearly explicit statutory intent to the contrary, ordinary words such as these

105. Wendy Baldwin, Deputy Director for Extramural Research for the NIH, noted evidence of this land grab in her statement to Congress:

As a pilot project to further evaluate reporting compliance, we have contacted 20 institutions to reconcile our records with theirs and to provide additional utilization information. Fifteen of these institutions are among those that report the greatest number of patents supported by Federal funding agreements and their responses will help to determine the completeness of their previous reporting. Five of the institutions report few patents with Federal support even though they are among our top 100 recipients.

*Underreporting Federal Involvement in New Technologies Developed at Scripps Research Institute: Hearing Before the Subcomm. on Regulation, Bus. Opportunities, & Tech. of the House Comm. on Small Bus.*, 103d Cong. 104 (1994) [hereinafter *Underreporting Federal Involvement*] (statement of Wendy Baldwin, Ph.D., Deputy Dir. of Extramural Research, Nat'l Insts. of Health).

106. The lack of oversight is both total and somewhat shocking: "Despite the perception that Bayh-Dole is working well, none of the federal agencies or universities we contacted evaluated the effects of Bayh-Dole." ADMINISTRATION OF THE BAYH-DOLE ACT, *supra* note 2, at 15.

107. The GAO reported:

The administration of the [Bayh-Dole Act] is decentralized. Each federal agency awarding R&D funds is required to ensure that the universities receiving such funds abide by the [A]ct's requirements. The agency that comes closest to coordinating the Bayh-Dole Act is the Department of Commerce. The [A]ct, as amended, provided that Commerce could issue regulations for the program and establish standards for provisions in the funding agreement entered into by federal agencies and universities, other nonprofit institutions, and small businesses. Commerce did so in 1987. Commerce is looked upon by the other agencies as a type of coordinator and may be consulted when questions arise. However, Commerce does not maintain any overall Bayh-Dole database.

*Id.* at 6.

108. 35 U.S.C. § 201(f) (1994) (emphasis added).

109. See *infra* notes 146-266 and accompanying text.



must be interpreted with their ordinary meaning.<sup>110</sup> The Supreme Court has said, "When we find the terms of a statute unambiguous, judicial inquiry is complete except in rare and exceptional circumstances."<sup>111</sup> Justice Scalia has stated the rule succinctly:

[F]irst, find the ordinary meaning of the language in its textual context; and second, using established canons of construction, ask whether there is any clear indication that some permissible meaning other than the ordinary one applies. If not—and especially if a good reason for the ordinary meaning appears plain—we apply that ordinary meaning.<sup>112</sup>

Lower courts, following the Supreme Court, have noted that the "ordinary meaning" rule is binding. The Federal Circuit, quoting Supreme Court cases, has stated the rule thus: "[L]egislative purpose is expressed by the ordinary meaning of the words used . . . ."<sup>113</sup> The court also noted that "[i]t is a basic principle of statutory interpretation . . . that undefined terms in a statute are deemed to have their ordinarily understood meaning."<sup>114</sup>

In the United States in similar contexts, the words "reasonable terms" have uniformly been interpreted to include price. In *Byars v. Bluff City News Co.*, the United States Court of Appeals for the Sixth Circuit, recognizing that establishing "reasonable terms" is necessary to remedy a monopolistic market, noted that "[t]he difficulty of setting reasonable terms, especially price, should be a substantial factor" in how to proceed.<sup>115</sup> Similarly, in *American Liberty Oil Co. v. Federal Power Commission*, the United States Court of Appeals for the Fifth Circuit, interpreting a statute that allows the Federal Power Commission to establish "reasonable terms and conditions," concluded that this meant that the "price . . . must be reasonable."<sup>116</sup> In *Commercial Solvents Corp. v. Mellon*, the United States Court of Appeals for the D.C. Circuit addressed prices under a statute that demanded "reasonable terms as to quality, price and delivery"; this language shows that the word "terms" includes, as a matter of common sense, the element of price.<sup>117</sup> In *United States v. Mississippi Vocational Rehabilitation for the Blind*, the United States District

110. See *Smith v. United States*, 508 U.S. 223, 232 (1993).

111. *Demarest v. Manspeaker*, 498 U.S. 184, 190 (1991).

112. *Chisom v. Roemer*, 501 U.S. 380, 404 (1991) (Scalia, J., dissenting).

113. *Cook v. Brown*, 68 F.3d 447, 451 (Fed. Cir. 1995) (internal quotations omitted) (quoting *Ardestani v. INS*, 502 U.S. 129, 136 (1991)).

114. *Id.* (alteration in original) (internal quotations omitted) (quoting *Best Power Tech. Sales Corp. v. Austin*, 984 F.2d 1172, 1177 (Fed. Cir. 1993)).

115. 609 F.2d 843, 864 n.58 (6th Cir. 1979) (emphasis added).

116. 301 F.2d 15, 18 (5th Cir. 1962).

117. 277 F. 548, 549 (D.C. Cir. 1922).

Court for the Southern District of Mississippi similarly interpreted a statute that allowed organizations to operate vending machines on “reasonable terms” at the Stennis Space Center.<sup>118</sup> Such reasonable terms, the court implied, include “prices and vending operations.”<sup>119</sup> In *Topps Chewing Gum, Inc. v. Major League Baseball Players Ass’n*, the United States District Court for the Southern District of New York resolved a dispute between baseball players and a playing card company that had agreed to pay “commercially reasonable terms”; the court said, “I assume [commercially reasonable terms] means at a price higher than Topps currently pays under its player contracts.”<sup>120</sup> In *United States v. United States Gypsum Co.*, the United States District Court for the D.C. Circuit held that “reasonable terms and conditions” includes prices.<sup>121</sup> Finally, in *South Central Bell Telephone Co. v. Louisiana Public Service Commission*, the Louisiana Supreme Court considered the meaning of “reasonable terms” and concluded that, although such things as timing and performance might be important, the most important and central factor is, of course, price:

Thus . . . regulation must make it possible . . . to compete . . . . The utility’s earnings, i.e., its *return*, both actual and prospective, must be sufficient . . . so that it can attract . . . capital on reasonable terms. The rate of return is but an intermediate factor; the basic requirement is a fair and reasonable dollar return.

In order to attract capital on reasonable terms, the utility [must] be able to pay the going price . . . . In the last analysis regulation seeks to set utility prices . . . .<sup>122</sup>

The requirement for “practical application” seems clearly to authorize the federal government to review the prices of drugs developed with public funding under Bayh-Dole terms and to mandate march-in when prices exceed a reasonable level. The terms required by the Bayh-Dole Act include, but are not limited to, reasonable prices.<sup>123</sup> Terms may be considered unreasonable if the unit price is too high or if its use over the long term makes it too costly with respect to the investment, costs, and profits of the manufacturer.<sup>124</sup> Despite somewhat unbelievable complaints from the NIH that this price review is beyond its ability, the traditional judicial and agency competence to

118. 812 F. Supp. 85, 87-89 (S.D. Miss. 1992).

119. *Id.* at 87.

120. 641 F. Supp. 1179, 1191 (S.D.N.Y. 1986).

121. 67 F. Supp. 397, 433-41 (D.D.C. 1946).

122. 373 So. 2d 478, 480-81 n.1 (La. 1979).

123. See *infra* notes 175-227 and accompanying text.

124. See *United States Gypsum Co.*, 67 F. Supp. at 433-41; *S. Cent. Bell Tel. Co.*, 373 So. 2d at 480-81 n.1.



determine reasonableness of prices is supported by countless cases and a host of statutes, including, for instance, the reasonable price provisions of the Uniform Commercial Code (UCC),<sup>125</sup> the reasonable royalty remedies of patent law,<sup>126</sup> the similar provisions of copyright law,<sup>127</sup> the compulsory licensing provisions of antitrust law,<sup>128</sup> the

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125. U.C.C. § 2-305(1)(a) (2000); see also Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 YALE L.J. 87, 95-97 (1989). See generally *Koch Hydrocarbon Co. v. MDU Res. Group, Inc.*, 988 F.2d 1529, 1534-35 (8th Cir. 1993) (determining what constitutes a "reasonable price" for natural gas after deregulation pursuant to U.C.C. § 2-305); *N. Cent. Airlines, Inc. v. Cont'l Oil Co.*, 574 F.2d 582, 592-93 (D.C. Cir. 1978) (determining what constitutes a "reasonable price" for aviation fuel in the wake of the early 1970s OPEC oil embargo and the resulting federal price controls, pursuant to U.C.C. § 2-305); *Kellam Energy, Inc. v. Duncan*, 668 F. Supp. 861, 877-879 (D. Del. 1987). The UCC, which governs commercial transactions in forty-nine states, gives courts the power to determine reasonable prices and even to enforce contracts on the basis of what a reasonable price would be, for instance, where the contract does not specifically state any price (the so-called open-price situation): "The parties if they so intend can conclude a contract for sale even though the price is not settled. In such a case the price is a reasonable price at the time for delivery . . ." U.C.C. § 2-305(1). The drafters of the UCC unabashedly placed their faith in the ability of a court to determine what a reasonable price would be: "In many valid contracts for sale the parties do not mention the price in express terms, the buyer being bound to pay and the seller to accept a reasonable price which the trier of the fact may well be trusted to determine." *Id.* § 2-201, cmt. n.1.

126. The Patent Act expressly grants a reasonable royalty, the amount to be determined by the court after hearing evidence, to an aggrieved patent owner: "Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court." 35 U.S.C. § 284 (1994).

127. The copyright statute, unlike the patent law, does not expressly grant a reasonable royalty. However, in many cases, assessing profits unlawfully garnered by an infringing defendant requires a court to determine what a reasonable royalty would be. See, e.g., *Sherry Mfg. Co. v. Towel King of Fla., Inc.*, 220 U.S.P.Q. (BNA) 855 (S.D. Fla. 1983), *rev'd on other grounds*, 753 F.2d 1565 (11th Cir. 1985). Furthermore, the assessment of reasonable royalties by courts and agencies is an integral part of the administration of the copyright regime. The copyright law, in section 118, grants public broadcasting a compulsory license for use of nondramatic literary and musical works, as well as pictorial, graphic, and sculptural works, subject to the payment of reasonable royalty fees to be set by the Copyright Royalty Tribunal. See H. REP. NO. 94-1476, at 116 (1976), *reprinted in* 1976 U.S.C.C.A.N. 5659, 5732.

128. A compulsory license, at reasonable royalty rates, is a remedy occasionally granted in response to antitrust violations. "The appropriateness of compulsory licensing at reasonable royalty rates as an antitrust remedy has long been recognized." A. Samuel Oddi, *Contributory Infringement/Patent Misuse: Metaphysics and Metamorphosis*, 44 U. PITT. L. REV. 73, 125 (1982); see Carlisle M. Moore, Note, *A Study of Compulsory Licensing and Dedication of Patents as Relief Measures in Antitrust Cases*, 24 GEO. WASH. L. REV. 223, 223-27 (1955).



price control provisions of the Orphan Drug Act,<sup>129</sup> and public utility rate regulation cases.<sup>130</sup>

The language of the Bayh-Dole Act implies that the contractor has the burden of providing, upon a good faith request by the government, data showing that it charged a reasonable price.<sup>131</sup> At present, the federal government may not grant a license on a federally owned invention unless it has been supplied with a development or marketing plan.<sup>132</sup> It would be appropriate to require the contractor to provide the data necessary to determine a reasonable price as part of the development or marketing plan.

C. *The Reach of the Act and the Broad Scope of "Subject Inventions"*

Determining whether an invention was made with government funds (and is therefore a "subject invention") is a complex task that can easily lead to, and be the subject of, unpredictable litigation.<sup>133</sup> The Bayh-Dole Act defines a subject invention as any invention that the "contractor conceived or first actually reduced to practice in the performance of work under a funding agreement."<sup>134</sup> However the implementing regulations of the legislation, which attempt to specify what is meant by "subject invention," do not settle the issue.<sup>135</sup> The regulations state that a closely related project that falls "outside the planned and committed activities of a government-funded project and does not diminish or distract from the performance of such activities . . . would not be subject to the conditions of these regulations."<sup>136</sup> The language here seems to invite litigation and almost defies comprehension.

129. Orphan Drug Act of 1983, Pub. L. No. 97-414, 1983 U.S.C.A.N. (96 Stat.) 2049-66.

130. See, e.g., *S. Cent. Bell Tel. Co. v. La. Pub. Serv. Comm'n*, 373 So. 2d 478, 480-81 n.1 (La. 1979) (discussing the importance of price controls).

131. There is some support in the legislative history for concluding that the contractor bears the burden of proof on this question. Cf. *Government Patent Policies: Institutional Patent Agreements: Hearings Before the Subcomm on Monopoly & Anticompetitive Activities of the Select S. Comm. on Small Bus.*, 95th Cong. 397 (1978) [hereinafter *1978 Hearings*] (statement of Howard W. Bremer, patent counsel, Wis. Alumni Research Found.).

132. 35 U.S.C.A. § 209(a) (West 1984 & Supp. 2000).

133. See *S. Research Inst. v. Griffin Corp.*, 938 F.2d 1249 (11th Cir. 1991); *Johns Hopkins Univ. v. CellPro*, 978 F. Supp. 184 (D. Del. 1997); *Gen-Probe Inc. v. Ctr. for Neurologic Study*, 853 F. Supp. 1215 (S.D. Cal. 1993); *Ciba-Geigy Corp. v. Alza Corp.*, 804 F. Supp. 614 (D.N.J. 1992).

134. 35 U.S.C. § 201(e) (1994).

135. See 37 C.F.R. §§ 401.1-17 (2000).

136. *Id.* § 401.1(a)(1).