Compiled Written Public Comments

NIH Workshop on *Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer*

June 28, 2023 – July 30, 2023

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Submission Date: 6/26/2023

Name: Frank Cullen

Name of Organization: Council for Innovation Promotion

Comment:

Dear Director Jorgenson,

I hope you're doing well. I've attached comments from the Council for Innovation Promotion -- a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere -- on the 7/31 Office of Science Policy technology transfer workshop.

The Council for Innovation Promotion appreciates your attention to these important issues, and also the opportunity to share our views. Please contact me should you have any questions or require additional information.

Sincerely,
Frank Cullen

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Frank Cullen
Executive Director, Council for Innovation Promotion

Additional Comment (attachment):

Council for Innovation Promotion
C4IP

Andrei Iancu, Co-Chair
David Kappos, Co-Chair
Judge Paul Michel (Ret.), Board Member
Judge Kathleen O'Malley (Ret.), Board Member
Frank Cullen, Executive Director

July 26, 2023

Lyric Jorgenson, PhD.
Office of Science Policy
6705 Rockledge Drive, Suite 630,
Bethesda, MD 20892

Dear Director Jorgenson,

C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. C4IP appreciates the opportunity to offer comments on the importance of strong intellectual property protections in leveraging the power of NIH-backed research to improve health outcomes and advance U.S. interests in other areas, such as national security.

C4IP stands second to none in our appreciation for the work scientists at the NIH do in advancing basic research. The knowledge gained through this work provides the foundation for partnerships with private-sector enterprises able to bring forth breakthrough medical advances from the research lab all the way to patients.

The work done at NIH is essential. But NIH itself has neither the charter nor the expertise to develop its work into commercial products such as FDA-approved life-saving medications. It is only through licensing arrangements with private companies possessing such experience and expertise that NIH research ultimately reaches the public in the form of new medical treatments and other useful products.

Through purchase agreements between the NIH and the private sector, for example, scientists at Pfizer and BioNTech were able to bring their breakthrough mRNA Covid vaccine to patients in record time. Treatments for HIV/AIDS, the hepatitis vaccine, and countless other products also trace their roots to NIH-licensed research.

But these roots do not mature and bear fruit on their own. They require careful nurturing. Intellectual property protection is the key to the continued success of this system.

Without secure patents and other IP protections, investors and private sector innovators will have insufficient incentive to pursue these risky and expensive research projects. These protections include the ability to sell the ultimate product developed out of patented technology at a price agreed to between the patent holder/developer and any buyer for as long as the patent is in effect.

Any restriction on this ability diminishes the value of a patent -- and, therefore, the willingness of any potential developer to license it and invest in it given the uncertain nature of any returns on the investment at all. Unfortunately, it is the case that many products will fail in the later stages of research and development. Indeed, approximately 90% of drugs don't make it through clinical trials to receive full approval.

Yet discounting that risk and undermining investment incentives is just what some advocates have in mind when they call for the inclusion of a "fair pricing" clause in licenses of NIH research for development. The ability of an outside party, in this case, the government, to decide whether the price of a developed consumer product is "fair" will not lead to less expensive consumer products but to an end to the willingness of private companies to license NIH or other government research discoveries for development (to say nothing over the likely and costly litigation over what is “fair and reasonable”). Government research will sit on shelves gathering dust, to the benefit of no one.

This is not a speculative conclusion but one borne out by the historical record. Past attempts at the NIH and elsewhere in government to institute similar "fair pricing" policies were ultimately repealed because they chilled private sector investment without "providing an offsetting benefit to the public."

Conversely, when policymakers act to preserve and strengthen our IP system, Americans reap the benefits in the form of new medical treatments and stronger national security, economic growth, and job creation. Fully 50% of yearly GDP growth in the United States comes from expanded innovation.

The partnerships forged between the NIH and the private sector transform valuable research findings into new medical treatments and commercial products. These partnerships are prime examples of the power of intellectual property to advance public health and encourage commercialization that benefits all Americans.

The system as currently constituted works well, not least because of its stability and predictability. NIH should not leave the door open to ongoing uncertainty through further consideration of "fair pricing" or other measures that would undermine intellectual property protection. On the contrary, NIH should close that door firmly to ensure Americans continue to enjoy the fruit of government research through private-sector development.

The Council for Innovation Promotion appreciates your attention to these important issues, and also the opportunity to share our views. Please contact me should you have any questions or require additional information.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion

Submission Date: 6/29/2023

Name: Fred Reinhart

Name of Organization: Not Provided

Comment:

As a 38-year veteran of academic technology transfer and Past President of AUTM, I would like to comment on the upcoming workshop.

The role of NIH, including its internal research and funding of extramural research is at the heart of America's successful medical, biomedical and pharmaceutical sectors. Americans benefit from access to a wide range of leading-edge diagnostics, vaccines and therapeutics. It is no secret that the U.S. is the leading innovator in these fields. One factor that supports these outcomes is the model that draws public and private stakeholders into cooperative partnerships in which each can contribute based on their strengths and resources.

NIH is the world's leader in medical research and awards funding to both research institutions and companies. Academia performs basic and applied research, identifies, protects and licenses promising inventions to new and existing companies. Industry does developmental and applied research and supplies the majority of funding to carry new Dx, Rx , vaccine and other innovations through the developmental and regulatory phases and into the commercial realm.

With respect to inventions derived from research in academia and teaching hospitals, over 300 important vaccines and therapeutics have reached the public as a result of academic licenses to industry. It would be foolish and counterproductive to undermine such an effective model yet several groups (specifically KEI and UAEM) are trying to do just that. They are doing so by making one blatantly false claim: that drugs like Xtandi, a prostate cancer drug, were developed with government money. They weren't. The federal government provided several million dollars to UCLA which resulted in early results that two companies built upon and brought to market after investing over $900,000,000. Thus, to say Xtandi was developed by the government and its price should be regulated by the government is simply not true. Such claims conveniently ignore the realities of the U.S. drug development model in which industry invests the majority of time and money that creates a new therapeutic.

The critics mentioned and others also have chosen to creatively and deliberately misinterpret Bayh-Dole law to claim that its "march-in" provision can be used to set prices. It cannot and the reasons have been widely detailed already. Yes, we need to ensure affordability and wide access to all new Dx, Rx and vaccines. We need to find ways to do that without undoing the remarkably effective system already in place.

Fred Reinhart
Plymouth, MI

Additional Comment (attachment): None

Submission Date: 7/8/2023

Name: Josh Sarnoff

Name of Organization: DePaul University College of Law

Comment:

Request to comment at the 7/31 workshop on transforming discoveries into products. FWIW, some of what I will say is included in the attached, discussing the ability of NIH to compel trade secrecy sharing should it develop the political will to do so.

Thanks.

Josh Sarnoff

Joshua D. Sarnoff (he, him, his)
Professor of Law
DePaul University College of Law
Center for Intellectual Property Law and Information Technology

Additional Comment (attachment): Available at https://hastingslawjournal.org/wp-content/uploads/1-Levine-final.pdf

Submission Date: 7/15/2023

Name: John Fraser

Name of Organization: Burnside Development and Associates

Comment:

Written submission as I am unavailable during the scheduled time of the July Workshop.

regards

John A. Fraser, RTTP, CLP
President
Burnside Development and Associates
Past President, AUTM

Additional Comment (attachment):

One more example of Tax Payers' Dollars at work though the National Labs, the Stevenson Wydler Act and the Bayh-Dole Act.

My name is John Fraser, a former President and Chair of AUTM. I have headed 4 academic technology commercialization offices – 2 in the US, 2 in Canada of which 2 were for-profit, 2 were not-for-profit.

I am unavailable during the schedule Workshop time, so I want to point out one more example of a very high profile drug and how research at a National laboratory and an academic center lead to the new, now widely known drug (**Ozempic and Wegovy**).

This occurred in the environment supportive of innovation provided by both the Stevenson-Wydler Technology Innovation Act of 1980 and the Bayh-Dole Act of the same year.

The following is verbatim from an article in the Wall Street Journal June 23, 2023

Monster Diet Drugs Like Ozempic Started With Actual Monsters

By Rolfe Winkler and Ben Cohen June 23, 2023 7:53 am ET

Before there was Ozempic or Mounjaro, there were fish guts and Gila monsters.

The blockbuster diabetes drugs that have revolutionized obesity treatment seem to have come out of nowhere, turning the diet industry upside down in just the past year. But they didn't arrive suddenly. They are the unlikely result of two separate bodies of science that date back decades and began with the study of two unsightly creatures: a carnivorous fish and a poisonous lizard.

In 1980, researchers at **Massachusetts General Hospital** wanted to use new technology to find the gene that encodes a hormone called glucagon. The team decided to study Anglerfish, which have special organs that make the hormone, simplifying the task of gathering samples of pure tissue.

They hired a Cape Cod fisherman to find the slimy bottom-feeders known for their sharp teeth and lightbulb-like lure. The fisherman tossed his catch on the dock, where two young scientists dissected “the ugliest fish you could ever imagine,” said Dick Goodman, one of those postdocs.

After plucking out organs the size of Lima beans with scalpels, they dropped them into liquid nitrogen and drove back to Boston. Then they determined the genetic sequence of glucagon, which is how they learned that the same gene encodes related hormones known as peptides. One of them was a key discovery that would soon be found in humans, too.

It was called glucagon-like peptide-1 and its nickname was GLP-1.

After they found GLP-1, others would determine its significance. Scientists in Massachusetts and Europe learned that it encourages insulin release and lowers blood sugar. That held out hope that it could help treat diabetes. Later they discovered that GLP-1 makes people feel fuller faster and slows down emptying of food from the stomach.

But there was a problem: GLP-1 vanishes from the human body nearly as fast as it is secreted, chewed up by enzymes and washed away by the kidneys in minutes. That meant there was little chance of developing the magic peptide into a drug.

To investigate whether it helped diabetics, scientists had to infuse GLP-1 intravenously. Studies showed it worked, lowering blood sugar. But some also foreshadowed the main side effect that plagues today’s GLP-1-mimicking drugs: nausea.

The early research that led to GLP-1 drugs included an experiment on Anglerfish.

David Nathan, a **MassGen** physician scientist who led a 1991 study, still remembers what happened when they increased the dose: “One person leaned over the side of his chair and threw up on my shoes.”

The key to the first drug would come from a serendipitous discovery inside another odd-looking animal.

Around the time Goodman was cutting open fish, Jean-Pierre Raufman was studying insect and animal venoms to see if they stimulated digestive enzymes in mammals. “We got a tremendous response from Gila monster venom,” he recalled.

It was a small discovery that could have been forgotten, but for a lucky break nearly a decade later when Raufman gave a lecture on that work at the **Bronx Veterans Administration**. John Eng, an expert in identifying peptides, was intrigued. The pair had collaborated on unrelated work a few years before. Eng proposed they study Gila monsters.

Gila monsters are poisonous lizards with powerful jaws and beaded skin.

Native to the U.S. southwest, Gila monsters (pronounced: HEE-luh) are poisonous lizards measuring 20 inches with powerful jaws and black-and-orange beaded skin. Adults eat four

meals per year, and live most of their lives below ground, slowly digesting energy stored in their tails.

Eng and Raufman studied powdered Gila monster venom ordered from the Miami Serpentarium, whose owner survived 172 snake bites over the years as he produced venom for research.

Eng isolated a small peptide that he called Exendin-4, which they found was similar to human GLP-1.

Eng then tested his new peptide on diabetic mice and found something intriguing: It not only reduced blood glucose, it did so for hours. If the same effect were to be observed in humans, it could be the key to turning GLP-1 into a meaningful advance in diabetes treatment, not just a seasickness simulator in an IV bag. Hoping that he could sell it to a pharmaceutical company that would develop it into a drug, Eng filed for a patent in 1993.

Jens Juul Holst, a pioneering GLP-1 researcher, remembers standing in an exhibit hall at a European conference next to Eng. The two had put up posters that displayed their work, hoping top researchers would stop by to discuss it. But other scientists were skeptical that anything derived from a lizard would work in humans.

"He was extremely frustrated," recalled Holst. "Nobody was interested in his work. None of the important people. It was too strange for people to accept."

After three years, tens of thousands of dollars in patent-related fees and thousands of miles traveled, Eng found himself standing with his poster in San Francisco. This time, he caught the attention of Andrew Young, an executive from a small pharmaceutical company named **Amylin.**

"I saw the results in the mice and realized this could be druggable," Young said.

When an Eli Lilly executive leaned over his shoulder to look at Eng's work, Young worried he might miss his chance. Not long after, Amylin licensed the patent.

They worked to develop Exendin-4 into a drug by synthesizing the Gila monster peptide. They weren't sure what would happen in humans. "We couldn't predict weight loss or weight gain with these drugs," recalled Young. "They enhance insulin secretion. Usually that increases body weight." But the effect on slowing the stomach's processing of food was more pronounced and Young's team found as they tested their new drug that it caused weight loss.

To get a better understanding of Exendin-4, Young consulted with Mark Seward, a dentist raising more than 100 Gila monsters in his Colorado Springs, Colo., basement. The lizard enthusiast's task was to feed them and draw blood. One took exception to the needle in its tail, slipped its restraint and snapped its teeth on Seward's palm—the only time he's been bitten in the decades he's raised the animals. "It's like a wasp sting," he said, "but much worse."

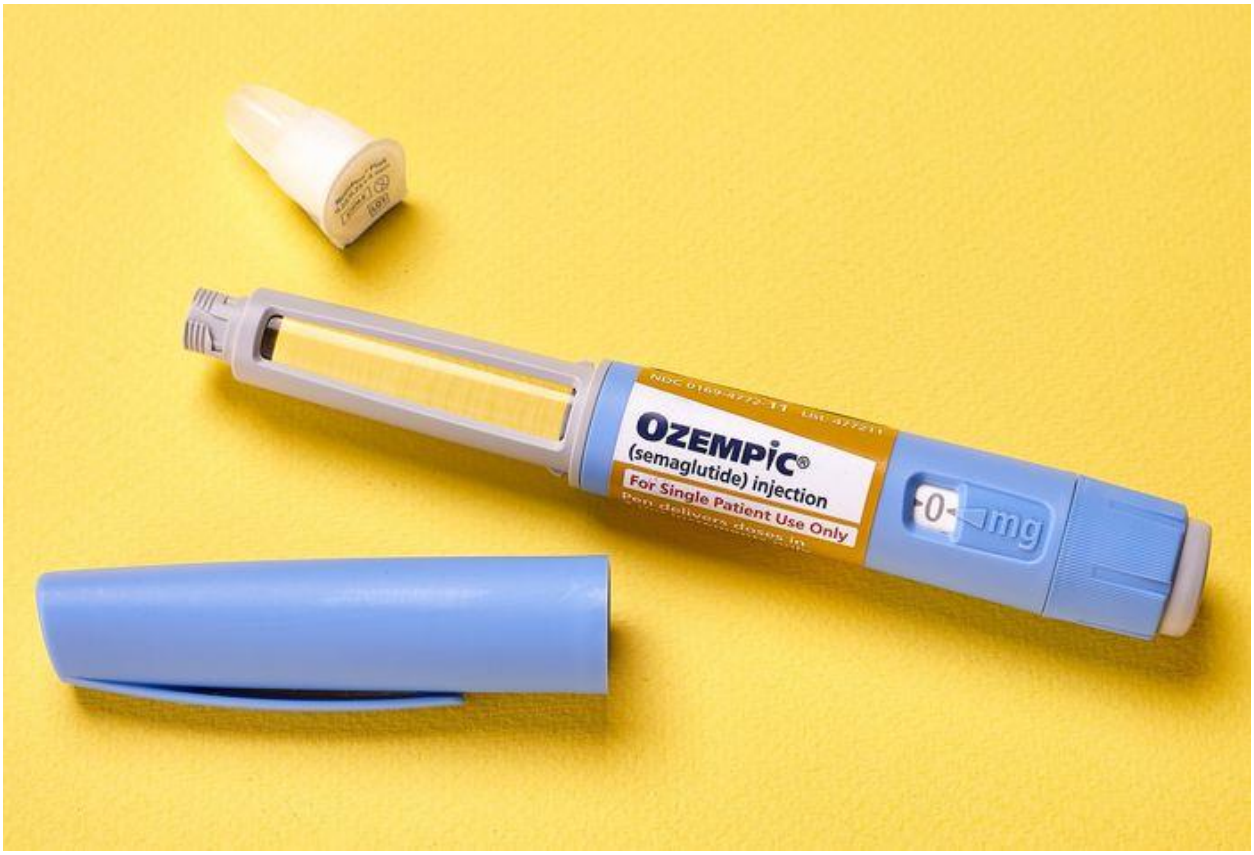
Nine years after the chance San Francisco meeting between Eng and Young, **the Food and Drug Administration approved the first GLP-1-based treatment in 2005.**

The twice-daily injection remained in the bloodstream for hours, helping patients manage Type 2 diabetes. Eng would be paid royalties as high as $6.7 million per year for the drug, according to federal government data available after 2015. “It was a long journey,” said Eng.

The proof of concept pushed other pharmaceutical companies to make more-effective and longer-lasting GLP-1 drugs.

At first, **Novo Nordisk** executives had little interest in GLP-1 drugs. They gave priority to Novo’s main business of selling insulin. “A lot of people didn’t believe in it,” says Jens Larsen, international medical director for the Danish company. He stopped his own mid-1990s study of IV-infused GLP-1 when patients on a higher dose started vomiting. The research was shelved until 2001.

The Gila monster-derived drug gave them a push, said Larsen: “It made companies more aware that this could be a serious competitor and we had to step up and put more people on it.”



An Ozempic pen by Novo Nordisk. PHOTO CREDIT: F. Martin Ramin/The Wall Street Journal
Photo: F. Martin Ramin/The Wall Street Journal

Novo kept at it, working on its own drug that more closely resembled the human peptide. With some clever chemistry it bumped up this drug’s time in the body to a day. Its first GLP-1 drug, the once-daily shot liraglutide, would receive FDA approval in 2010.

Seven years later came its longer-lasting diabetes drug, the once-weekly shot semaglutide. As it turned out, it was also the best of the drugs for weight loss, making it the first blockbuster in the category. A higher dose was approved in 2021 to treat obesity.

Those two approved doses are better known today by their brand names: Ozempic and Wegovy.

Submission Date: 7/24/2023

Name: Sarah Kaminer Bourland

Name of Organization: Patients for Affordable Drugs

Comment:

Hello,

Attached are comments from Patients for Affordable Drugs for the upcoming workshop on “Maximizing NIH’s Levers to Catalyze Technology Transfer.” We were unable to sign up in time to share oral comments, so please keep our organization in mind if any slots become available.

Thank you,

Sarah Kaminer Bourland Legislative & Policy Director (she/her)
Patients For Affordable Drugs, Patients For Affordable Drugs NOW

Additional Comment (attachment):

PATIENTS FOR AFFORDABLE DRUGS™

Patients For Affordable Drugs Comments on
Transforming Discoveries into Products:
Maximizing NIH's Levers to Catalyze Technology Transfer
July 24, 2023

Thank you for inviting comments ahead of the Workshop on *Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer*. Patients For Affordable Drugs (P4AD) is the only national patient advocacy organization focused exclusively on policies to lower prescription drug prices. We are bipartisan, independent, and do not accept funding from any organizations that profit from the development or distribution of prescription drugs.

It is critical that the National Institutes of Health (NIH) is convening stakeholders to discuss policies relating to biomedical innovation and policies to maximize NIH's levers to catalyze technology transfer. In our view, however, the discussion is limited given that it does not invite an explicit discussion of access and affordability. Drugs don't work if people can't afford them, and if NIH maximizes tech transfer but the products it invents are overpriced and do not reach patients, it will have failed in its mission to "seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability". That is why, since P4AD was launched in 2017, our organization has advocated for fair pricing for all NIH and taxpayer-funded drugs, including by working with and supporting members of Congress to introduce legislation to ensure fair pricing and maximization of public health.

Many United States government agencies — especially the NIH — are engines of innovation, driving research and development (R&D) leading to medicines with meaningful public health impact. Indeed the NIH is the largest public funder of biomedical research in the world. But too often, the very taxpayers who fund the riskiest research into these life-saving inventions are themselves denied access due to the exorbitantly high launch prices when eventually commercialized. The NIH and its critical role in biomedical R&D have been at the center of this debate since 1995, when the agency chose to remove the requirement for reasonable pricing in contracts with external entities. At that time, the average monthly price for a drug was $50. Since then, the NIH has continued to fuel innovation in the field, but has also contributed to exorbitant and unjustified pricing and profits for drug corporations. The current system socializes the research and development while privatizing the gain. One study estimates that each dollar in NIH investment can result in up to $2.13 in pharmaceutical sales. Now, nearly 30 years after

removing the reasonable pricing clause, the median annual price of a new drug is $222,000 and three in ten adults in the United States are forced to ration medication due to price. People of color are disproportionately harmed by high drug prices, which contribute to the fact that uninsured Latinos and Black Americans use 10-40% fewer medications than their White counterparts. **The NIH's approach to ensuring taxpayer-funded inventions are available on reasonable terms for all who need them is long overdue for change.**

We are also very disappointed at the orientation of the meeting; the agenda for the meeting betrays a perspective that is not at all patient-focused. **While purporting to be a convening of stakeholders this workshop does not include a single representative of the most important stakeholder for NIH-developed technologies: the patient.** This is completely unacceptable. There is still time to include patient voices, and this workshop will have much greater credibility with those whose lives and communities you seek to impact if you include patients in this discussion.

Background

Pharmaceutical companies argue high drug prices are required to attract investment and reward the industry for the financial and scientific risk they take on during research and development. In reality, the U.S. government takes on most of those early risks, undermining the industry's argument for high prices.

The government's involvement in COVID-19 vaccine development illuminates this point with crystal clarity. For years, drug companies were unwilling to invest their own money in emerging vaccine technologies they considered too risky. Instead, the U.S. government stepped up and made investments into the technologies that led to mRNA-based COVID-19 vaccines. We now know the unprecedented and rapid development of vaccines was driven by more than $300 million in public investments in mRNA technology prior to COVID-19 and $31.6 billion more to support the development and manufacturing of COVID-19 vaccines. Vaccine manufacturers have made record-breaking profits off products that were de-risked by the U.S. government:

- Pfizer sales of the vaccine reached $37.8 billion in 2022, making it the best-selling drug in history.
- The COVID-19 pandemic created more than 40 new pharmaceutical billionaires, including four from Moderna, a company that had never marketed a product prior to the federal government standing up Moderna's manufacturing capability and providing advance purchase agreements for COVID-19.
- According to nonprofit Oxfam, "Pharmaceutical giants are making over $1,000 a second in profit from vaccines alone and they are charging governments up to 24 times more than it would cost to produce vaccines on a generic basis."

While the COVID-19 case study involves numerous agencies, the NIH is no stranger to this phenomenon. A recent study of R&D expenditures revealed that the NIH's spending on R&D matches that of the biopharmaceutical industry. In fact, between 2010 and 2019, the NIH spent $187 billion for basic or applied research related to 354 of the 356 drugs approved by the Food and Drug Administration (FDA), which was at least as much or more than investment by the pharmaceutical industry when considering basic research contributions. A recent HELP Committee report highlighted the government's key role in basic research, invention of new medicines, clinical trials, and even manufacturing. The report found that the median "price of new treatments that NIH scientists helped invent over the past twenty years is $111,000." As an agency dedicated to "the application of that knowledge to enhance health, lengthen life, and reduce illness and disability," the NIH can no longer turn a blind eye when its investments are turned into blockbuster profits at the expense of patients and public health.

Striking the right balance between technology transfer to commercialize innovation and affordable access is possible and should be the driving force behind NIH policy changes. At minimum, P4AD recommends the following:

- **Address price at the point of technology transfer:** The NIH should implement a new reasonable pricing requirement in cooperative research agreements and licensing agreements or establish a multi-disciplinary entity for negotiation terms of technology transfer that would be required to consider the public health implications of inventions, especially if they were to be priced unaffordably for patients, taxpayers, and society as a whole. NIH grantees should be required to address access and affordability as a requirement for funding; for example, NIH grants to research institutions, medical schools and universities could require the inclusion of concrete and transparent strategies and policies to ensure equitable access to health technologies as a primary purpose of technology transfer.

- **NIH Grantees must be required to disclose funding in patent applications:** A May 2023 GAO study found that NIH awardees "did not consistently disclose NIH support in patents arising from research funded by the agency" and among those that did, the funding was inaccurately or incorrectly reported. This lack of disclosure contributes to ambiguity over intellectual property rights and makes it difficult to quantify taxpayer contributions to biomedical inventions. Without data on taxpayer contribution to commercialized inventions, it is difficult to quantify the public's stake in affordable pricing. In addition to requiring disclosure of all taxpayer funding in patent applications, the NIH and other agencies—including the U.S. Patent and Trademark Office—should have enforcement mechanisms at their disposal for violations of these disclosures.

Submission Date: 7/25/2023

Name: Andrew Schlafly

Name of Organization: Eagle Forum Education and Legal Defense Fund

Comment:

To whom it may concern:

Eagle Forum Education and Legal Defense Fund, a nonprofit organization founded by Phyllis Schlafly in 1981, is pleased to comment on the National Institutes of Health's (NIH) invitation to comment regarding the “Workshop on Transforming Discoveries into Products: Maximizing NIH’s Levers to Catalyze Technology Transfer.”

Please accept our comments, which are attached as a pdf file.

Thank you!

Andrew L. Schlafly
Counsel for Eagle Forum Education and Legal Defense Fund

Additional Comment (attachment):

July 25, 2023

National Institutes of Health
VIA EMAIL: SciencePolicy@od.nih.gov

RE: Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

To whom it may concern:

Eagle Forum Education and Legal Defense Fund, a nonprofit organization founded by Phyllis Schlafly[1] in 1981, is pleased to comment on the National Institutes of Health's (NIH) invitation to comment regarding the "Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer."

Our organization's decades of work on patent policy, including the Bayh-Dole Act, provides perspective on the topic at hand. Fundamentally, secure, reliable intellectual property (IP) rights are the foundation for transforming discoveries into products. Since the Bayh-Dole Act became law in 1980, the NIH has generally played an important part in technology transfer, primarily as a funder of research at universities and other nongovernmental research institutions. Those entities own the discoveries, determine the appropriate IP protection, decide the best terms and partners for specific technology transfer efforts, and transfer technology as they deem appropriate, without interference from Washington. This model has worked extraordinarily well and successfully. Thus, the goal of NIH's present initiative should be "First, do no harm."

Bayh-Dole is intended to move taxpayer-funded discoveries from concept to commercial use. This law employs the certainty of IP rights in the resulting inventions to foster practical benefit from federally funded basic research. Each technology, license, and licensee face specific circumstances that affect the pace of commercialization and progress in achieving milestones. It is crucial to understand that royalties are the principal payment for the licensee to use the technology. As is widely recognized, the beauty of Bayh-Dole is that it puts incentives such as royalties in the right place, where these payments reward inventors and researchers and fund additional research. Such patent-centered, democratized decisionmaking directly bears

[1] Phyllis Schlafly was an outspoken advocate of the rights of inventors, emphasizing the importance of their traditional rights to our national prosperity and security. She wrote often about this topic. A compilation of her writings on this subject is *Phyllis Schlafly Speaks, Vol. 4, Patents & Inventions*. Skellig America, 2018 (Ed Martin, Editor).

upon technology transfer, translation, and resulting commercialization—and, therefore, end products.

March-In Rights

The Bayh-Dole Act includes a "march-in rights" provision. Its purpose is of an "in case of fire, break glass" nature. March-in is authorized, pursuant to statute, for very few, very narrow grounds. If initiated, patent holders whose inventions were derived from federally funded research and development (R&D) would have to issue a license for the IP to another. The specified grounds for such "march-in" licensing are when the patentee has failed to pursue timely commercialization of the invention, has not reasonably satisfied public health or safety needs, has failed to ensure the invention is substantially made in the United States, or can't meet or hasn't met specified federal requirements for public use. There is no legal authority under the Bayh-Dole Act for march-in to be used on the basis of a resulting product's price.

Counterproductively, activists seek to force unlawful application of this emergency-only measure for extra-statutory purposes. Their efforts risk injecting uncertainties and threaten to disrupt technology transfer and commercialization. We applaud NIH for consistently declining to misuse Bayh-Dole's march-in provision, as sought in several rejected product-price-based petitions over the decades. Yet, activists continue to play on people's emotions and gain unwarranted sympathy.

That Bayh-Dole omits price of products from the few grounds for march-in is intentional. The law's authors, Senators Birch Bayh and Robert Dole, affirmed this fact in the Washington Post, where they rebutted the preposterous notion of march-in over product price that was first asserted in a law review article:

> 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. . . . The [law reviewers'] article also mischaracterizes 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 the 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.[2]

[2] Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," Washington Post, April 11, 2002, p. A28.

The futility of price-based march-in is displayed in the fact that a march-in license recipient would have to expend enormous resources to set up manufacturing, supply, distribution, and marketing channels—duplicating the patent owner's commercialization. The recipient of such a license would have to meet all applicable regulatory requirements. All that would come at great cost and time. It is questionable, therefore, whether such expense would achieve activists' product price aims.

NIH's CRADA Disaster

NIH briefly bowed to political pressure in 1989, when it required a "reasonable pricing" provision in its Cooperative Research and Development Agreements (CRADAs). This condition for an exclusive license to NIH-developed inventions inserted uncertainty, deterring interest by those who otherwise might license the IP. The price-control requirement resulted in NIH CRADAs dropping off from 42 in 1989 to 32 on average per year. The pricing clause's discouragement of industry partnerships eventually caused NIH to drop the CRADA requirement. Thereafter, NIH saw CRADAs increase to about 90 agreements in 1996 and more than 160 in 1997.

In removing the contract language, then-NIH Director Harold Varmus noted "the pricing clause has driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public. . . . Eliminating the clause will promote research that can enhance the health of the American people."[3]

Director Varmus further observed, "The [product pricing] clause attempts to address the rare breakthrough product at the expense of a more open research environment and more vigorous scientific collaborations. One has to have a product to price before one can worry about how to price it, and this clause is a restraint on the new product development that the public identified as an important return on their research investment."

This important lesson should not be lost on NIH, especially given the agency's 2021 confirmation of the chilling effect of its product-pricing requirement.[4]

Constructive Alternatives

NIH could take multiple steps to facilitate technology transfer and practical commercial benefit, thereby fostering more products from more patents. One, NIH should ensure

[3] NIH news release, April 11, 1995. Available at https://bayhdolecoalition.org/wp-content/uploads/2023/05/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

[4] NIH, "The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995," Nov. 15, 2021. Available at https://bayhdolecoalition.org/wp-content/uploads/2023/06/CRADA-QA-Nov-2021-FINAL.pdf

the ability of IP owners and licensees to rely on the IP exclusivity that is critical to achieving commercial success and that incentivizes private investors to assume the risk involved in bringing an invention to market. This means vigilantly making certain that march-in is never to be twisted into a means of enacting government price controls.

NIH could enact guidance or a rule warning that future march-in petitions on essentially the same grounds (i.e., product price) will be treated as a nuisance. Petitioners who assert the rejected basis could be barred from having similar, future petitions considered. Also, such nuisance petitioners could be charged the costs the petition had imposed on government resources, i.e., tapping taxpayers' money.

Two, partnering vehicles, such as CRADAs and SBIRs/STTRs, could permit a portion of the R&D funding to be used to secure IP protection. This would help more IP-centered startups gain commercial traction and more early-stage firms become going concerns faster. Such faster growth would expedite product and market development.

Three, NIH could adopt or strengthen a confidentiality duty that would require the agency and agency personnel not to disclose confidential, privileged, or proprietary information through the Freedom of Information Act (FOIA) or by other means. This policy would help assure contractors that the confidential business information in their submissions will remain secure and protected.

In conclusion, Bayh-Dole's march-in provision has never been invoked in the law's more than 40 years. Further, officials of both Democratic and Republican administrations have uniformly refused to base march-in on price. Bipartisan prudence rejecting this power's use on the basis of a product's price over four decades is strong evidence of the illegitimacy of activist petitioners' assertions to the contrary. Those public servants have found no basis in the law; that should be good enough.

Sincerely,

/s/ Ed Martin

Ed Martin
President

/s/ Andrew L. Schlafly

Andrew L. Schlafly
Counsel
939 Old Chester Rd.
Far Hills, NJ 07931
(908) 719-8608

/s/ James Edwards

James Edwards
Patent Policy Advisor

Submission Date: 7/26/2023

Name: James Edwards

Name of Organization: Conservatives for Property Rights

Comment:

Attached please find comments from the coalition Conservatives for Property Rights (CPR) regarding the National Institutes of Health's (NIH) July 31 "Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer."

Kindest regards,

James Edwards

Additional Comment (attachment):

Conservatives
for
Property Rights

July 26, 2023

National Institutes of Health
VIA EMAIL: SciencePolicy@od.nih.gov

RE: Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

To whom it may concern:

Conservatives for Property Rights (CPR), a coalition of policy organizations representing thousands of Americans, writes in response to the National Institutes of Health's (NIH) request for comments in connection with the "Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer."

CPR acknowledges NIH's taking stock of "policies and practices that shape biomedical innovation and promote access to NIH-funded discoveries." We recognize that NIH has a "role in the broader biomedical research enterprise in promoting the application of knowledge to enhance human health." In NIH's consideration of "how NIH, as a research institution, approaches the patenting and licensing of biomedical inventions," CPR cautions the agency to consider what is working and keep in mind how shifts away from what is working are likely to be steps backward, causing unintended consequences. Failing to proceed with caution in this exercise would have serious, counterproductive effects that harm patients, weaken our economy, and even give adversarial competitors such as China an advantage in technological leadership.

NIH's Sweet Spot

NIH has an important role in biomedical research as a funder of basic research. NIH grants and its in-house biomedical research advance understanding of scientific and biomedical concepts and relationships. While some may be patentable, these initial discoveries are typically not readily translatable and certainly not ready for commercialization. Rather, NIH's or NIH-funded discoveries require orders of magnitude greater funding in applied research and development (R&D) to have a prospect for a commercial product.

The latter stages appropriately rely on private investment because the failure rate is approximately 9 out of 10. One study reported it "underscore[d] that the development of basic discoveries requires substantial additional investments, partnerships, and the shouldering of financial risk by the private sector if therapies are to materialize as FDA-

approved medicine."[1] For NIH to assume the enormous risk of failure that comes with development of the basic research discoveries, where its investment is more fertile, would be the height of misuse of taxpayer money.

NIH should stay in its lane underwriting basic research. This is NIH's most effective, efficient means of transforming discoveries into products. NIH's core competency (grantmaking) seeds basic scientific discoveries, which in turn hold promise for more technology, whose patents and intellectual property (IP) are held by grantees (universities and research institutions), to transfer. More embryonic technologies actively being commercialized means more products and more competition. More consumer choice and competition constrain product price increases, even before patent expiration. This indirect role on NIH's part in product and market development make the best use of taxpayer dollars and produce the best prospects of technology transfer and commercialization efforts succeeding.

IP and Bayh-Dole

IP ownership and having more IP-protected technology incentivize institutions to transfer inventions to willing entities capable of attempting commercialization. The key to this success is secure, reliable IP rights.

The 40-plus year experience of the Bayh-Dole Act of 1980 bears recounting. Bayh-Dole solved the problem of wasted expenditure of taxpayer money. Prior to Bayh-Dole, federally funded research led to many discoveries. The U.S. government owned 28,000 patents from research it funded. But only 5 percent were commercialized. Taxpayers received no practical benefit from all the research for which their taxes paid.

Pre-Bayh-Dole, the government tightly controlled the IP from its funded research in Washington, D.C. Some 26 agencies' rules controlled commercial use of federally owned IP. Grantees often were not allowed to take title of their discoveries. The government only gave nonexclusive licenses to patents. Thus, very little new knowledge was ever transformed into products.

This success-story law changed all that failure. It has facilitated commercialization by providing reliable property rights. Bayh-Dole has unleashed thousands of inventions that otherwise would have never moved to commercial application.

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[1] Duane Schulthess, Harry P. Bowen, Robert Popovian, Daniel Gassull, Augustine Zhang, and Joe Hammang, "The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals," Therapeutic Innovation & Regulatory Science, January 2023; 57(1):160-169.

For instance, university inventions bring about more than two new products and two jobs every single day.[2] Bayh-Dole made possible the creation of the biotech industry. Its decentralized tech transfer has contributed $1 trillion to U.S. GDP from 1996-2020. Its patent licensing is responsible for about $2 trillion of industry gross output and supports 6.5 million jobs.[3] In the 1970s, most medicines Americans used were developed in Europe; since Bayh-Dole, the United States leads the world in drug discovery, R&D, commercialization, and the development of new innovative medicines.[4]

The stark contrast between the pre-Bayh-Dole barriers and central command-and-control policies, resulting in radically stunted benefits from the millions and millions of taxpayer dollars poured into research over four decades, and the post-Bayh-Dole democratization of ownership and IP decisionmaking by grant recipients over the fruits of their labors, must not be missed. The difference is night and day. Bayh-Dole spurs widespread invention; efficient, smart technology transfer and commercialization; and the outpouring of new products, startup companies, new jobs, invigorated innovation ecosystems across the country, and even new industries.

The Bayh-Dole Act provides the government "march-in" rights in certain narrow, extraordinary circumstances. March-in would require the patent owner or exclusive licensee to issue a license to the patented invention. The statute specifies the grounds for such march-in licensing: when the contractor has failed timely to pursue commercialization of the invention, has not reasonably satisfied public health or safety needs, has failed to ensure the invention is substantially made in the United States, or can't meet or hasn't met specified federal requirements for public use. None of these extremely limited exceptions for "march-in" relates to product prices. In more than 40 years, march-in has never been exercised despite a number of petitions requesting it. In denying march-in petitions, NIH has always acted appropriately and in accord with the statute. NIH has repeatedly, consistently declined the requested misuse of march-in. CPR commends this fidelity to the spirit and letter of this important law. We urge NIH to resolve to continue doing the right thing as the agency has heretofore done.

Catalyzing Technology Transfer

Again, NIH has far less involvement in technology transfer, where decisionmaking was revolutionized when Bayh-Dole democratized technology transfer decisionmaking to the grantee institutional level and away from Washington. Because

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[2] Eagle Forum Education & Legal Defense Fund, summary of remarks by Joseph P. Allen, "Benefiting from Federal Research Funding: Technology Transfer, the Bayh-Dole Act, Patent Rights, and Society," Proceedings of Capitol Hill Briefing, Oct. 18, 2018, p. 5.

[3] AUTM and BIO, "The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2020," June 14, 2022.

[4] Stephen Ezell, "The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System," Information Technology & Innovation Foundation, March 4, 2019.

of the localized prerogative to decide whether to obtain IP protection and how best to license it, this now properly locates and brings about the most effective, informed commercialization decisions.

As discussed, the benefits of the Bayh-Dole regime could hardly be clearer. Thus, NIH's (or any other federal government agency's) interference in or imposition of inadvisable conditions on IP, technology transfer, or commercialization would cause tremendous damage to the turning of discoveries into products and beyond.

NIH's policy levers to catalyze tech transfer include licensing commercially promising discoveries made by NIH researchers. This should be done efficiently, with minimized red tape, in keeping with Bayh-Dole's framework. In that context, NIH could seek to ensure that its policies and practices are user-friendly, "speed-of-business" for federal agency tech transfer processes and procedures. The agency should make certain that any such levers enable partnerships for translational R&D, technology maturation, and commercialization under existing partnership mechanisms (e.g., SBIR/STTR, CRADA).

With respect to CRADAs and other licensing vehicles and in light of the vast majority of public participants given speaking slots at the workshop, it is imperative that NIH remember and not forget the lesson of its Cooperative Research and Development Agreement (CRADA) experience in the 1990s. In 1989, NIH began requiring a "reasonable pricing" provision in its CRADAs as a condition for an exclusive license to NIH-developed technologies. That price-control clause injected uncertainty, diminished intellectual property value, and undermined property rights over eventual products.

The "reasonable pricing" requirement caused a significant drop in NIH CRADAs, which fell from 42 in 1989 to an average of 32 the next six years. This dramatic fall-off led NIH to eliminate the provision. CRADAs with NIH immediately rose to about 90 agreements in 1996 and more than 160 in 1997. The agency confirmed this lesson in 2021.[5]

When the government price control was removed, NIH Director Harold Varmus said "the pricing clause has driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public. . . . Eliminating the clause will promote research that can enhance the health of the American people." New price controls today would do the same harm. Instead of catalyzing tech transfer or turning discoveries into products, NIH would repeat the failures of the past and radically diminish the stated aim of this exercise.

In closing, CPR applauds the successes NIH has had in technology transfer, particularly by funding research at research institutions and universities and respecting the

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[5] NIH, "The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995," Nov. 15, 2021. https://www.techtransfer.nih.gov/sites/default/files/CRADA Q&A Nov 2021 FINAL.pdf

boundaries of Bayh-Dole. We urge NIH to stay true to its lane and abide by the law. We urge rejection of the siren song of government price controls, "reasonable pricing," abuse of march-in, and any other scheme that would violate the provisions of the Bayh-Dole statute and ignore the clear lessons of secure IP held by grantee institutions, inventors, or licensees.

Sincerely,

James Edwards, Ph.D.
Executive Director
Conservatives for Property Rights

Kevin L. Kearns
President
U.S. Business & Industry Council

James L. Martin
Founder/Chairman
60 Plus Association

Saulius "Saul" Anuzis
President
60 Plus Association

George Landrith
President
Frontiers of Freedom

Gerard Scimeca
Chairman
Consumer Action for a Strong Economy

Dick Patten
President
American Business Defense Council

Ashley Baker
Director of Public Policy
The Committee for Justice

Richard Manning
President
Americans for Limited Government
Americans for Limited Government Foundation

Submission Date: 7/26/2023

Name: Joseph P. Allen

Name of Organization: Bayh-Dole Coalition

Comment:

Dear Director Jorgenson,

My name is Joseph P. Allen, and I serve as executive director of the Bayh-Dole Coalition. The Bayh-Dole Coalition is a diverse group of research and innovation-oriented individuals and organizations committed to preserving the Bayh-Dole law, and informing policymakers and the public of its many benefits.

I am submitting the attached comments on behalf of the Bayh-Dole Coalition to the NIH ahead of their workshop: "Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer." Please let me know if you need any additional information and I look forward to the upcoming workshop.

Best,
Joseph P. Allen

--

Joseph P. Allen
Executive Director

Additional Comment (attachment):

July 26, 2023

Lyric Jorgenson, Ph.D.
NIH Office of Science Policy
6705 Rockledge Dr #750
Bethesda, MD, 20817

Dear Director Jorgenson,

The Bayh-Dole Coalition appreciates the opportunity to submit comments to the National Institutes of Health (NIH) in advance of the agency's workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer on July 31, 2023.

Perhaps the easiest way for the NIH to continue promoting successful technology transfer is to uphold the agency's longstanding commitment and respect for the Bayh-Dole Act of 1980. Partnerships under Bayh-Dole have made the U.S. the unquestioned leader in the life sciences. When the Covid-19 pandemic hit, the world looked to us for a solution, and we didn't let them down. NIH should be very proud of your role in that achievement.

As you are aware, NIH advances America's scientific progress and well-being not only by conducting research in its own labs, but also by funding R&D at universities and nonprofits across the country. For over 40 years, resulting discoveries have been turned into breakthrough therapies thanks to the Bayh-Dole Act. The law gives universities, small companies, and federal laboratories the ability to retain the patents on their discoveries and license them for their development and commercialization. That process is extremely risky and expensive. Most times even the best efforts fail. When they do, companies take the hit. But under our system, taxpayers receive a tremendous return on their investment in public research in the form of life-saving and life-improving technologies, medical devices, and drugs, benefitting people here and around the world.

We should keep in mind the critical factor in our success—finding private sector companies, primarily small businesses, which are willing to assume the risk and expense of turning NIH-supported inventions into useful therapies. As you know all too well, many times it is very difficult to attract even one company as a potential licensee because most of the resulting discoveries are at such an early stage. It was to help bridge this gap that NIH created your newest institute, the National Center for Advancing Translational Sciences, which states the realities you all face very well: "A novel drug can take 10 to 15 years and more than $2 billion to develop, and failure rates occur in about 95 percent of human studies." (https://ncats.nih.gov/about). Many academic institutions have created programs to move their technologies further down the R&D pipeline, reducing the risk of development for their industrial partners. Finding effective means to lessen the risk of developing new therapies would be the most significant improvement we could make to increase the impact of NIH-funded R&D.

More times than not, the companies who take on the burden of commercializing NIH-funded inventions are entrepreneurial start-ups, which risk everything to get a product to market. These are also the entities which should be consulted about how NIH is performing and where improvements can be made.

As you consider today's recommendations, it would be well to keep in mind this criteria for evaluating the comments you are receiving -- does this make it easier or harder to find industry partners which drive our innovation system?

It might also be well to keep in mind why the Bayh-Dole Act has worked day in and out for 43 years. When we were creating the law, we didn't go to people with theories, we went to people with decades of hands-on experience funding and managing federally-funded inventions. Indeed, the experience we particularly drew upon was that of NIH. Two of the principal architects were Norman Latker, NIH's patent counsel, and Howard Bremer of the Wisconsin Alumni Research Foundation, one of the creators of the profession of academic technology management. Both Latker and Bremer knew from personal experience why the pre Bayh-Dole era failed to commercialize NIH-funded inventions and how to create the authorities and incentives to correct the problem. The resulting success of the Bayh-Dole Act and its extension to the federal laboratories through the Federal Technology Transfer Act (which Latker wrote) speaks for itself.

Thus, you would do well to put the recommendations you are receiving into two buckets -- one for those with theoretical knowledge and another for those who have actually licensed, managed, and most importantly, commercialized federally funded inventions. Hopefully, it goes without saying which bucket deserves greater weight.

More than any other agency, NIH should be commended for preserving Bayh-Dole. NIH has consistently rejected attempts to undermine the law through the misuse of "march-in" rights by opponents who claim it allows the government to set prices on successfully developed products. As someone who was in the room when Bayh-Dole was conceived, who staffed the bill for Senator Birch Bayh, putting together the hearings of the Senate Judiciary Committee, writing the Committee's report on the legislation, and later overseeing its implementation at the Department of Commerce, I can say with some authority that is not how the law works. But you don't have to take my word for it. Every Administration which has received petitions to "march in" for price controls has rejected them as not sanctioned under the statute. The Biden Administration is only the latest to confirm that view.

NIH deserves considerable credit for your steadfast commitment to the rule of law, even though incredible political pressures have been applied against you. Some of you have even been attacked personally for not giving in to those who seek to overturn Bayh-Dole. At a time when many have lost faith in our institutions, your conduct illustrates what public service is all about.

Now those who oppose Bayh-Dole have disinterred a failed policy last seen in the 1990s. Then bowing to political pressures, NIH inserted "reasonable pricing clauses" stipulating how resulting products would be priced if they were based on inventions arising from its Cooperative R&D Agreements (CRADAs) or exclusive licenses. Contrary to the predictions of its proponents, this provision didn't lower drug costs -- it collapsed industry partnerships.

Realizing the disaster unfolding before its eyes, NIH scrapped this policy in 1995 declaring "the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS [public health service] scientists without providing an offsetting benefit to the public." The number of CRADAs increased fourfold in the years following that repeal. NIH knows firsthand that "reasonable pricing" provisions are

counter-productive. They will only deny the public access to new discoveries protecting the public health.

Our system works. It deserves to be preserved and defended. Hopefully, today's exercise will help make NIH commercialization even more effective. The Bayh-Dole Coalition stands ready to help achieve that goal in any way that we can.

Again, thank you for all that you have done -- and continue to do -- to protect and defend public health.

Thank you,

Joseph P. Allen
Executive Director
Bayh-Dole Coalition

Submission Date: 7/27/2023

Name: Walter Copan

Name of Organization: N/A

Comment:

Dear Director Jorgenson:

Thank you for the opportunity to submit comments regarding the National Institutes of Health's forthcoming workshop, Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

These are attached. Best wishes for a productive workshop. Please fee free to reach out if I can provide additional support.

Kind regards,
Walt

Walter G. Copan, PhD
Vice President for Research and Technology Transfer

COLORADOSCHOOLOFMINES | https://research.mines.edu/

Additional Comment (attachment):

Walter G. Copan, Ph.D.
Vice President for Research and Technology Transfer
Colorado School of Mines
1500 Illinois Street, Golden, CO 80401

July 25, 2023

Lyric Jorgenson, Ph.D.
Acting Associate Director for Science Policy
National Institutes of Health Office of Science Policy
6705 Rockledge Dr #750
Bethesda, MD 20817

Dear Director Jorgenson:

Thank you for the opportunity to submit comments regarding the National Institutes of Health's forthcoming workshop, *Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer*.

I currently serve as the vice president for research and technology transfer at Colorado School of Mines. I am also the co-founder of the Renewing American Innovation Project at the Center for Strategic and International Studies, where I serve as a senior adviser.

From 2017 to 2021, I served as Under Secretary of Commerce for Standards and Technology and 16th Director of the National Institute of Standards and Technology (NIST), a position to which I was confirmed unanimously by the Senate.

I write to you in my personal capacity. The comments below do not necessarily reflect the views of my current or former employers or any organization with which I am affiliated.

For much of its history, the United States has been the most innovative country in the world. Our leadership is no accident. It is the direct result of a carefully constructed set of policies -- dating back to the nation's founding -- that protect intellectual property (IP) rights and incentivize the inventiveness of our citizens to push the boundaries of what is considered possible.

One of the most influential of these policies is the Bayh-Dole Act. Prior to Bayh-Dole's passage in 1980, U.S. scientists were making many important discoveries at universities and research laboratories with the help of federal research investments, including funding provided by NIH.

However, the government retained the patent rights to those discoveries -- and, for the most part, these inventions added no direct benefit to the people of America nor to the Nation’s economy. Of the 30,000 patents the government held as of 1980, only about 5% were licensed to innovative

companies that would ultimately turn them into products.[1] Further, due to the government's practice to principally grant non-exclusive licenses to federal inventions, firms were reluctant to take the risk to invest their capital for development, and entrepreneurs were unable to secure financing for their new companies, knowing that others could also readily access the same technology.

The Bayh-Dole Act of 1980 changed all of that. For the first time, the law allowed universities and research institutions to retain the rights to their federally funded discoveries -- and to have the opportunity to exclusively license these rights to private companies with the necessary expertise to bring them to market.

Bayh-Dole launched an entire era of U.S. global innovation and industrial competitiveness, catalyzing collaborations and technology transfer between public and private sector partners. This framework has been a driving force behind the nation's most innovative breakthroughs ever since. Between 1996 and 2021, exclusive licensing partnerships between academic institutions and private companies were responsible for launching 15,000 new startups and contributing $1 trillion to the U.S. GDP. Technology partnerships arising from federally funded inventions brought more than 200 new life-changing medicines to patients.[2]

The Bayh-Dole law works because it establishes key incentives for innovation and for private sector investment through reliable access to intellectual property rights. Without secure access to the necessary IP, investors simply will not take the high risk of investing in a firm or a technology lacking a protectable IP position. Most notably, the Bayh-Dole system incentivizes firms to enter into exclusive licensing agreements with academic and research institutions for early-stage inventions arising from federally funded research by allowing the institutions to own the patents on their inventions. This crucial incentive grants companies the opportunity to achieve a return on investment for successfully commercialized products stemming from the license, and from investing in related development collaborations.

It's imperative that agencies like the NIH, which is the single largest government funder of biomedical research in the world, uphold these incentives and the integrity of the Bayh-Dole Act.[3] Critically, the NIH must continue to resist pressure from the well-meaning but ultimately ill-informed parties and lawmakers, who do not understand the balanced workings of the U.S. innovation system, of the consequences of misusing Bayh-Dole to impose price controls on prescription drugs and other products that resulted, in part, from research supported by federal dollars. The Bayh-Dole Act allows federal officials to "march-in" and relicense patents in only an extremely limited set of circumstances, where the original licensee fails to diligently invest and turn the government-funded discovery into a real-world product available in the marketplace. But

[1] https://techtransfer.syr.edu/abouThe Bayh-Dole Act - Office of Technology Transfert/bayh-dole/
[2] https://bayhdolecoalition.org/wp-content/uploads/2023/04/Driving-the-Innovation-Economy-Academic-Technology-Transfer-in-Numbers-2021.pdf pg. 1
[3] https://www.nih.gov/about-nih/what-we-do/impact-nih-research/serving-society/direct-economic-contributions

certain individuals claim that even if a discovery has been developed into a successful product, and widely available, march-in is still justified if the price of that product is considered too high.

This premise is entirely false. The Bayh-Dole Act was never intended to be a mechanism for government price control, as the Act's authors made crystal clear.[4] The law's narrowly tailored march-in provision was meant to ensure that society benefited from discoveries made with the help of taxpayer dollars -- not to negate current exclusive licenses nor to empower the government to create a controlled economy.

Granting such misguided requests would severely damage confidence in U.S. intellectual property rights and our stock markets, and in the Bayh-Dole Act's protections that have sparked the creation of so many technological breakthroughs. Few companies would license inventions that came from even a penny of federal funding contribution if the government could simply nullify their exclusive license if the price of the resulting product is deemed by some party as unsatisfactory. Misusing march-in rights in this manner would undermine the successful public-private innovation pipeline that Bayh-Dole generated, and that the NIH and other agencies are striving to expand. The provisions of the Bayh-Dole Act enable American entrepreneurs and existing companies to create value for the people of the U.S. and contribute to our economic development and vitality. The consistent voice of NIH for U.S. innovation is important to be maintained at this time because the integrity of Bayh-Dole Act is not just an NIH and healthcare cost issue. The Bayh-Dole Act applies to all products, in all markets, from all U.S. federal science and technology investments. The inventions and national economic benefits arising from each federal agency's research funding would ultimately be affected by misuse of the Bayh-Dole Act, including the innovations arising from NIST, the agency I had recently led.

Fortunately, the NIH has consistently refused to go down the path to undermine the Bayh-Dole Act, and NIH has appropriately denied all march-in petitions that have come across its desk. NIH must remain resolute in upholding the Bayh-Dole Act to achieve its mission for the public good. March-in advocates have continued to call for this misuse of the law, and further recently called for the NIH to re-implement a "reasonable pricing" clause in NIH agreements, not just for Cooperative Research and Development Agreements (CRADAs) but "in all future collaboration, funding, and licensing agreements for biomedical research."[5] Any requests of this nature must also be denied -- or risk disastrous consequences for American innovation. At a crucial time for U.S. innovation and competitiveness, the Bayh-Dole Act bedrock of our innovation system must not be undermined.

This is not just a hypothetical concern. In 1989, the NIH inserted a "reasonable pricing clause" in the required language of its CRADAs and certain exclusive licenses.[6] The clause required companies engaged in CRADAs or exclusive licenses to set "reasonable prices" for any resulting commercial products.

[4] Birch Bayh and Robert Dole, "*Our Law Helps Patients Get New Drugs Sooner,"* Washington Post, April 11, 2002, p. A28.
[5] https://www.sanders.senate.gov/in-the-news/sanders-vows-to-oppose-nih-nominee-until-biden-produces-drug-pricing-plan/
[6] https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system/

The well-intentioned "reasonable pricing" clause backfired miserably. Under the policy -- which created ongoing uncertainties of government intervention in the outcomes of high-risk R&D -- undermined the economic incentive of exclusive licensing. The result was an immediate dramatic decline of private sector partnerships with NIH research. The data was clear that public-private partnerships collapsed due to the risks of investment uncertainty. The private sector no longer saw that NIH research partnerships were worth the inevitable commercial risks. Just six years after it came into effect, NIH Director Harold Varmus declared that NIH had to scrap the "reasonable pricing" clause. In 1996, a year after the provision was repealed, the number of private sector CRADAs with NIH once again surged.

The U.S. has run this experiment – and I trust we have learned an important lesson about the underpinnings of our innovation system. The delicate balance between the early-stage federally funded research conducted by universities and research institutions and conditions for high risk late-stage development undertaken by the private sector relies heavily on the predictability of rules for IP rights provided in exclusive licensing. Without this essential component, the entire technology transfer framework unravels to the detriment of the American public. The U.S. otherwise steps onto a downward slope for government intervention and control in all markets, as the Bayh-Dole Act applies to funding from all federal agencies.

Indeed, during my time at the NIST, the agency published a roadmap for "Unleashing American Innovation" in the NIST Green Paper that had resulted from the nation's most comprehensive review ever of the U.S. innovation system. We concluded that federal officials must, among other things, better engage with the private sector, strengthen IP protections, incentivize technology transfer, and maintain the integrity of the Bayh-Dole Act.[7] Today, my recommendations for the NIH and for all federal science and technology agencies remain consistent. We must remember the vision of Vannevar Bush on the importance of national investment in *"Science: The Endless Frontier,"* and that of Senators Birch Bayh and Bob Dole, who saw the important incentive of reliable intellectual property rights as essential to America gaining a return on federal science investments for our people and for our economic prosperity.

I appreciate the opportunity to provide comments in support of these important discussions. I would be pleased to provide any further assistance and data in supporting your considerations.

Sincerely yours,

/ S / Walter G. Copan, Ph.D.

[7] https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf pg. 5

Submission Date: 7/27/2023

Name: Stephen Heinig

Name of Organization: Association of American Medical Colleges

Comment:

Attached, please find written comments of the Association of American Medical Colleges for consideration at the NIH's July 31 workshop and for inclusion in the record.
Please let us know directly if further information would be helpful, or if there is any difficulty in transmission.
Thank you.

Stephen Heinig
Director, Science Policy
Association of American Medical Colleges

Additional Comment (attachment):

Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400 F 202 828 1125
www.aamc.org

July 27, 2023

Lyric Jorgenson, PhD
Acting Associate Director for Science Policy
Office of Science Policy
National Institutes of Health
Bethesda, MD

Re: Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

Submitted electronically to SciencePolicy@od.nih.gov

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide feedback to the National Institutes of Health (NIH) for the workshop, *Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer*.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

The AAMC's member institutions perform more than half of the extramural research sponsored by the NIH, and the Association is mindful that the American people invest substantial resources in medical research, especially relative to other areas of science. While profound social and economic benefits accrue from scientific research generally, our advocacy in support of investment in the NIH emphasizes the potential for research discoveries to translate into new treatments and cures for disease. The topic of this workshop is therefore extremely important to fulfilling this promise, and to strengthening our shared, continuing commitment to the social contract supporting medical research. Our comments here focus on several points that we believe should frame productive discussions on catalyzing technology transfer:

I. While the workshop's deliberations necessarily focus on patenting and licensing practices, the most beneficial "product" of NIH research is the scientific knowledge generated and widely disseminated.

Once, a case needed to be made before the public for how laboratory basic research was relevant to advances in health and medicine, but now, after generations, there is a demonstrable track record – from virology to cancer to CRISPR – that discovery and shared understanding of fundamental biology has made nearly miraculous impacts on human health. Along with discovering new molecular entities and pathways that may become targets for pharmaceutical development, NIH-funded scientists have developed new research platforms, new techniques and methods, data resources, and insights into the mechanisms of health and disease. Behavioral and social science research have similar impacts on improvements to human health, although such advances may not typically be reflected in patentable inventions.

Another vitally important form of knowledge transfer are NIH-supported trainees and scientific personnel. Students and post-doctoral scientists at medical schools and universities, often with NIH funding, participate in the leading edge of scientific exploration, and carry this experience across to other economic sectors. Scientists and leaders in US industry and elsewhere are often the products of NIH support and provide the nation with an ample base of human capital to support medical innovation.

II. The current NIH innovation system has seen spectacular successes.

In a recent study, Stevens and colleagues identified 364 FDA-approved drugs and vaccines over more than 40 years to which specific intellectual property (IP) was held by public sector research institutions, including the NIH and US medical schools, universities, hospitals, and research institutions largely funded by NIH.[1] The tally does not include research platforms or similar resources developed by these institutions that enable drug discovery but were not identified with a particular approved drug. In comparing the relative success of the nation's drug development ecosystem, Stevens et al. noted:

> In the context of the global public sector landscape, the US dominates drug discovery, accounting for two-thirds of these drugs and many of the important, innovative vaccines introduced over the past 30 years. Contributions by Canada, UK, Germany, Belgium, Japan, and others each amount to 5.4% or less of the total.[2]

The persistence of disease and burden in so many areas, including orphan diseases, and in areas like addiction, depression, obesity, etc., challenge us to improve and catalyze the innovation process. But reforms should not undermine what has been shown to work well. The success during the pandemic of a public-private partnership building on decades of mRNA research to develop and deploy COVID-19 vaccines in record time, and avert potentially millions of deaths, should be an inspiration for future action.

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[1] Stevens AJ, Benson DE, Dodson SE, Jensen JJ, Rohrbaugh ML. Role of global public sector research in discovering new drugs and vaccines. *Journal of Technology Transfer*, 2023, Apr 27, published ahead of print.
[2] Ibid, p. 1.

III. Intellectual property protections serve many uses, but an essential feature is that IP protections like patents make it possible for private capital to be used to develop a new pharmaceutical or device.

A promising new molecular entity or pathway discovered by academic researchers usually requires much more effort to be developed into an approved drug. Further R&D is required to assess the chemical properties of a drug candidate, to confirm its effectiveness, identify potential interactions and adverse events, and conduct the extensive preclinical and clinical testing necessary for FDA approval. It remains a notoriously expensive, time-consuming process that only a small percentage of promising drug candidates survive, and is therefore a very high-risk investment. Patent protection and exclusivity rights are necessary to attract the private investment that supports most drug development. Even philanthropic, non-profit organizations have used patents in this way; to simply put an entity in the public domain would likely ensure that it remains undeveloped, just as no contractor would build on a vacant city lot without clear title. That said, not every valuable entity or process needs to be patented; the AAMC has supported NIH positions on research tools, biological samples, genomic and other data sharing encouraging use of these resources with or without proprietary encumbrances as possible. The AAMC was also one of the original organizations drafting the Nine Points document on socially responsible licensing of university technology.[3]

The National Institute of Standards and Technology (NIST) within the Department of Commerce recently studied the entire federal system for promoting innovation, including looking at the implementation regulations for the Bayh-Dole and Stevenson-Wydler Acts, and other controlling authorities. The AAMC joined other organizations in this review, and we highly recommend the report for the NIH workshop deliberations.[4] Overall, we agree with the review that the Bayh-Dole Act has been highly effective in promoting tech transfer from sponsored, extramural research.

On the question of exercising Bayh-Dole's march-in authorities over pharmaceutical pricing, the AAMC has consistently supported the NIH and the Federal Government's interpretation of its authority, which we noted most recently in a joint letter with other higher education associations to Secretary Becerra last year.[5] The AAMC has three central concerns over the proposed use of march-in to influence drug pricing. First, the outcome from granting a march-in petition would be uncertain; any exercise over pricing would likely be challenged in the courts, given the legislative record and express statements by Senators Bayh and Dole that the Act's march-in provisions were not intended for inventions widely available on market. Moreover, march-in would not be a comprehensive solution to the problems of excessive drug prices, as it would apply only to the subset of drugs covered by university patents arising from NIH sponsored research, and to which no other significant IP applies. Price issues exist for many drugs that are not related to university patents, including many essential drugs that have been on the market for decades. Our third and most central concern is that the precedent of exercising march-in over market pricing would create disincentives for industry and private investors to license university inventions. In calculating potential risks and returns, private investors might favor non-university, non-NIH funded inventions, even if the target results are less

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[3] https://autm.net/about-tech-transfer/principles-and-guidelines/nine-points-to-consider-when-licensing-university

[4] NIST. Return on Investment Initiative for Unleashing American Innovation. April 2019. https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf

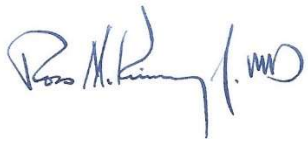
[5] https://www.aamc.org/media/61966/download?attachment

innovative. Rather than incentivizing tech transfer, the action would chill future licensing or industry collaboration, and undermine Bayh-Dole's intent.

In short, we are skeptical that pharmaceutical prices can or should be controlled from the laboratory and would look for alternative solutions to this problem. For example, the Inflation Reduction Act provides the Secretary of Health and Human Services the authority to negotiate drug prices under relevant sections of the Medicare program, and those negotiations are now in process. The USPTO and FDA are also looking at ways the patent system and approval process may be abused to indefinitely extend patent protections and impede the entry of generics to the market.

We are grateful for the opportunity to provide comments, and for continuing engagement with the research community. Please feel free to contact me or my colleagues Stephen Heinig, Director of Science Policy (sheinig@aamc.org) or Heather Pierce, JD, MPH, Senior Director of Science Policy and Regulatory Counsel (hpierce@aamc.org), with questions about these comments.

Sincerely,



Ross McKinney, Jr., MD
Chief Scientific Officer

cc: David J. Skorton, MD, AAMC President and Chief Executive Officer

Submission Date: 7/27/2023

Name: Adam Mossoff

Name of Organization: George Mason University

Comment:

Dear Director Jorgenson,

Please find attached my written comment for consideration by the NIH in its Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

If you have any questions, please feel free to contact me via email or by telephone at (703) 993-9577.

Best regards,

Adam Mossoff

Adam Mossoff
Professor of Law
Antonin Scalia Law School
George Mason University

Additional Comment (attachment):

GEORGE MASON UNIVERSITY
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Adam Mossoff
Professor of Law

July 27, 2023

Via Email Submission

Lyric Jorgenson, Ph.D.
Office of Science Policy
6705 Rockledge Drive, Suite 630
Bethesda, MD 20892

Re: Written Submission for Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

Dear Director Jorgenson,

I respectfully submit this written comment to the National Institutes of Health (NIH) for consideration in the workshop, *Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer*. In support of evidence-based analysis and policymaking by the NIH, I have attached for consideration by the Office of Science Policy my article, *The False Promise of Breaking Patents to Lower Drug Prices*, ST. JOHN'S L. REV. (forthcoming 2023).[1]

My article explains why proposals for the NIH to use the Bayh-Dole Act or 28 U.S.C. § 1498 to impose price controls on patented therapeutics and diagnostics contradict the plain text and function of these two federal statutes. This is important for the NIH to consider in its workshop concerning tech transfer policies and licensing practices, because these "price-control theories of the Bayh-Dole Act and § 1498" have been asserted in numerous petitions to the NIH and in recent letters sent to the NIH by Senators Elizabeth Warren and Bernard Sanders.

Moreover, some speakers at the workshop, such as James Love, have incorrectly argued the price-control theories of the Bayh-Dole Act and § 1498 to the NIH and to other federal officials. Mr. Love has also mischaracterized federal contract regulations and provisions implementing § 1498, such as 48 C.F.R. § 52.227-1(a) (2020), as an alleged "compulsory licensing" mandate.[2] As I have

[1] This article is available for download at https://papers.ssrn.com/abstract=4348499.

[2] *See* In re COVID-19 Diagnostics and Therapeutics; Supply, Demand, and TRIPS Agreement Flexibilities, Investigation No. 332-596, at 62-63 (March 29, 2023) (Testimony of James Love).

explained in written testimony submitted to the International Trade Commission, this is incorrect.[3] Lastly, the mistaken view that Bayh-Dole or § 1498 authorize the NIH to enact regulations or engage in licensing practices to expand "access" through some form of price controls on patented therapeutics and diagnostics is proposed in a recent white paper, *Making Genetic Therapies Affordable and Accessible*, authored by many speakers at the workshop.[4]

To assist the NIH in evidence-based policymaking in implementing its specific powers granted under federal statutes and regulations in licensing patented therapeutics and diagnostics derived from upstream research supported in part by federal grants, I am submitting my article, *The False Promise of Breaking Patents to Lower Drug Prices*.

Thank you for your consideration. If you have any questions, please do not hesitate to reach out via email (amossoff@gmu.edu) or by telephone (703-993-9577).

Sincerely,

Adam Mossoff

/attachment

[3] *See* In re COVID-19 Diagnostics and Therapeutics; Supply, Demand, and TRIPS Agreement Flexibilities, Investigation No. 332-596 (May 5, 2023) (Final Written Submission of Adam Mossoff), https://edis.usitc.gov/external/attachment/795809-1992655.pdf.

[4] *See Making Genetic Therapies Affordable and Accessible* 42-43 (Innovative Genomics Institute, 2023), https://innovativegenomics.org/making-genetic-therapies-affordable-and-accessible/.

The False Promise of Breaking Patents to Lower Drug Prices

97 ST. JOHN'S LAW REVIEW __ (forthcoming 2023)

Adam Mossoff*

ABSTRACT

Congressional leaders, policy activists, and scholars contend that patents are a principal cause of rising drug prices. They argue that a solution exists in two federal statutes that allegedly authorize agencies to impose price controls on drug patents: 28 U.S.C. § 1498 and the Bayh-Dole Act. These "price-control theories of § 1498 and the Bayh-Dole Act" maintain that Congress has already endorsed the unprecedented and controversial policy of breaking patents to lower drug prices in private transactions in the healthcare market.

Neither § 1498 nor the Bayh-Dole Act authorize agencies to impose price controls, as confirmed by their plain text and by their interpretation by courts and agencies. Section 1498 is an eminent domain statute that applies only when a patent is used by and for the government, such for the military, the Post Office, or the Veterans Administration. The Bayh-Dole Act promotes commercialization of patented inventions derived from federal funding of upstream research; consistent with this commercialization function, this law specifies four delimited conditions when a federal agency may "march in" and license a patent when a patented product is not sold or available in the marketplace. Applying canons of statutory interpretation, the meaning of these two statutes is clear. Neither specifies that "price" triggers regulatory controls over private market transactions. Congress knows how to enact price-control laws, such as the Emergency Price Control Act of 1942 or when it specifies "reasonable price" as a goal of legislation. The price-control theories of § 1498 and the Bayh-Dole Act profess unprecedented agency powers lacking any authorization in existing statutes. Yet academic scholarship, as well as policy and legal work based on this scholarship, continue to promote the price-control theories of § 1498 and the Bayh-Dole Act. These are policy arguments masquerading as statutory construction.

* Professor of Law, Antonin Scalia Law School, George Mason University. Thank you to the participants at the 2022 Intellectual Property Scholars Conference at Stanford Law School for comments, and to attendees at many professional conferences and panel presentations over the past several years. Thank you also to Joseph Allen, Eric Claeys, and Joshua Sarnoff for comments on earlier drafts. A portion of this article is based on my comment submitted to the National Institute of Standards and Technology in April 2021 for its Notice of Proposed Rule Making for amending regulations implementing the march-in power in § 203 of the Bayh-Dole Act. Kent Hess, Peter Abernathy, Brandon Merrill, and Suzanne Johnson provided invaluable research assistance.

I. Introduction

The cost of medical care in the United States has long been debated in healthcare policy.[1] The causes of healthcare prices are complex and multi-varied, if only because the U.S. healthcare system is complex. The modern healthcare system comprises a myriad of legislative, administrative, and regulatory regimes enacted by the federal government and all fifty states, which are intertwined with equally complex commercial institutions built through private rights in property and contract.[2] In policy discussions about drug prices, though, some scholars and policymakers reduce this legal and institutional complexity to a single cause—patents.

The patent system is now at the center of policy debates and academic discussions about drug prices. Scholars blame patents for "rising drug prices."[3] Activists have filed at least ten petitions to federal agencies requesting that they break patents in order to lower drug prices in the healthcare market—petitioning the agencies to authorize through regulatory fiat a generic drug company to make and sell lower-priced drugs protected by patents owned by innovator drug companies.[4] These petitions have all been denied, with the most recent rejection on March 23, 2023 by the National Institutes of Health (NIH) in response to a petition seeking to impose price

[1] *See, e.g.*, *Consumer Group Decries Rise in Drug Prices*, LOS ANGELES TIMES (Mar. 16, 1995) ("Prices of the 20 top-selling prescription drugs are rising faster than inflation, despite drug company promises to slow the increases, a consumer group charged Wednesday."); *Uncertain Progress on Health Costs*, N.Y. TIMES, B20 (July 17, 1984) ("The Reagan Administration is declaring victory over 'the health care inflation monster' because medical costs are rising less feverishly. Any celebration, however, should wait until all the causes of the decline are better understood."); E. RICHARD BROWN, ROCKEFELLER MEDICINE MEN: MEDICINE AND CAPITALISM IN AMERICA 1 (1979) ("The crisis in today's health care system is deeply rooted in the interwoven history of modern medicine and corporate capitalism. The system's most obvious problems are cost, inflation, and inaccessibility of medical care in the United States.").

[2] *See* Douglas A. Hastings, *Foreword: The Changing Face of Law and Medicine in the New Millennium*, 26 AM. J.L. & MED. 135, 135 (2000) ("For over 200 years, our healthcare system has been, in effect, a mixed public and private system, essentially built on a private chassis with a great deal of public funding, regulating and prodding. It also has been a profoundly federalist system, generating fifty-one health regulatory schemes.").

[3] S. Sean Tu, *FDA Reexamination: Increased Communication Between the FDA and USPTO to Improve Patent Quality*, 60 HOUS. L. REV. (forthcoming 2022), at 2, https://papers.ssrn.com/abstract=4149718 ("Patients, doctors and insurers have all felt the distress of rising drug prices over the past decade. Underlying much of these cost increases are the exclusive rights granted by patents."); *see also* Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH. 275, 277 (2016) ("Drug prices in the United States are among the highest in the world . . . . . [T]hey result from . . . our patent system . . . [and its] grant of a monopoly [that] allows a manufacturer to charge any price . . . ."); Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 33 HEALTH AFFAIRS 791, 791 (2015) (claiming that "new medicines . . . are expensive not because they are expensive to manufacture but because they are protected by patents").

[4] *See Return on Investment Initiative for Unleashing American Innovation* 29 (NIST Special Publication 1234, April 2019) (identifying 10 petitions to break patents solely for the purpose of imposing price controls on drug patents).

controls on a patented drug that treats a prostate cancer.[56] A group of activists and academics also lobbied Congress to break patents in order to lower drug prices, arguing that drug prices "are high primarily because brand-name drug companies use government-granted exclusivities, such as patents, to prevent competition and charge high prices."[7]

These agency petitions and lobbying activities over several decades urging the federal government to break patents to lower drug prices assert that two federal statutes authorize this regulatory action. The first is a century-old statute that secures the right of patent owners to sue the federal government when it violates a patent right through its eminent domain power (28 U.S.C. § 1498).[8] Section 1498 requires the government to pay "reasonable and entire compensation" if a patented invention "is used or manufactured by or for the United States."[9] The second is the Bayh-Dole Act of 1980, a statute that declared definitively that inventors had a right to obtain patents if federal funding was used in the discovery or creation of their inventions.[10] To facilitate commercialization of new innovations, the Bayh-Dole Act affirmed that inventors whose research is funded even in part by the federal government may receive patents for their innovations.[11] In

[5] *See* Letter from Lawrence A. Tabak, Performing the Duties of the NIH Director, to Robert Sachs and Clare Love (Mar. 23, 2023), https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-12march2023.pdf (rejecting petition to impose price controls on Xtandi); *see also Return on Investment Initiative for Unleashing American Innovation*, *supra* note 4, at 29 ("NIH determined that the use of march-in to control drug prices was not within the scope and intent of its authority."); John R. Thomas, *March-In Rights Under the Bayh-Dole Act*, CONGRESSIONAL RESEARCH SERVICE 8-9 (Aug. 22, 2016), https://sgp.fas.org/crs/misc/R44597.pdf (As of 2016, "six petitions have been filed requesting that the NIH 'march in' with respect to a particular pharmaceutical. Each petition was denied. A common theme of each of the denials was the agency's views that concerns over drug pricing were not, by themselves, sufficient to provoke march-in rights.").

[6] *See* Letter from Clare Love & Robert Sachs to Xavier Becerra, Secretary of the Department of Health and Human Services 2 (Nov. 18, 2021), https://www.keionline.org/wp-content/uploads/Love-Sachs-HHS-Xtandi-Request-18Nov2021.pdf (proposing "a march-in request" for the drug, Xtandi, on the basis "that the price is demonstrably unreasonable"); Letter from Knowledge Ecology International and Union for Affordable Cancer Treatment to the National Institutes of Health, Department of Health and Human Services & Department of Defense 21 (Jan. 14, 2016), https://www.keionline.org/wp-content/uploads/Xtandi-March-In-Request-Letter-14Jan2016.pdf (making "march-in request" that "the federal government grant an open license to any generic drug manufacturer" due to "an excessive price" for Xtandi).

[7] Letter from Amy Kapczynski, Aaron S. Kesselheim, et al. to Senator Elizabeth Warren, at 1 (Apr. 20, 2022), https://tinyurl.com/yt62wt4t.

[8] *See* Decca Ltd. v. United States, 544 F.2d 1070, 1082 (Ct. Cl. 1976) ("It is [the government's] taking of a license, without compensation, that is, under an eminent domain theory, the basis for a suit under § 1498."); Carter-Wallace, Inc. v. United States, 449 F.2d 1374, 1390 (Ct. Cl. 1971) (Nichols, J., concurring) (stating that § 1498 authorizes a claim in court "to recover just compensation for a taking under the power of Eminent Domain"); Irving Air Chute Co. v. United States, 93 F. Supp. 633, 635 (Ct. Cl. 1950) (stating that § 1498 is "an eminent domain statute").

[9] 28 U.S.C. § 1498(a).

[10] *See* University and Small Business Patent Procedures Act of 1980, Pub. L. 96–517, 94 Stat. 3018 (Dec. 12, 1980) (codified in 35 U.S.C. §§ 200-212). This statute is popularly known as the "Bayh-Dole Act," as set forth in its Short Title. *See id.*, 94 Stat. at 3018.

[11] *See* 35 U.S.C. § 200 ("It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development . . . to promote the commercialization and public availability of inventions made in the United States by United States industry and labor . . . .").

further promoting commercialization of patented inventions, the Bayh-Dole Act also authorizes federal agencies to "march in" and license a patent without authorization from the patent owner if the patented invention is not commercialized in the marketplace.[12]

Advocates for the price-control theories of § 1498 and the Bayh-Dole Act also make policy arguments, but these arguments are based on a core legal claim: the federal government has the existing statutory authority to lower drug prices by breaking patents on drugs.[13] In sum, the price-control theories of § 1498 and the Bayh-Dole Act maintain that Congress long ago resolved in the affirmative the debate over the highly controversial policy whether the federal government should impose price controls on drug patents. The only remaining policy question, its advocates contend, is whether federal agencies will act on their existing statutory authority.

This article addresses this purported *legal foundation* supporting the argument that breaking patents is the best governmental policy to lower drug prices. Contrary to claims of the price-control theories of § 1498 and the Bayh-Dole Act, these statutes do not authorize the federal government or any federal agencies to break patents solely for the purpose of lowering drug prices. This article derives this conclusion from the text of § 1498 and the Bayh-Dole Act and the consistent judicial and agency interpretations of these statutes. These statutory analyses are essential to the broader policy debates occurring in Congress and in agencies because these statutes define and delimit federal officials' authority to achieve policy goals. As the legal realists reminded us in the early twentieth century, policy arguments "empty without *objective description* of the causes and consequences of legal decisions."[14] They were speaking of court decisions, but this key insight applies equally to the objective description of the meaning of statutes.

In explaining why the price-control theories of § 1498 and the Bayh-Dole Act are a false promise to lower drug prices via price controls on patents, this article proceeds in three parts. First, it details the text and longstanding judicial interpretation of § 1498. Both its text and its interpretation by courts establish that § 1498 does not authorize the federal government to impose price controls on products manufactured and sold by private companies, such as drugs made by pharmaceutical companies and sold to patients in the healthcare market. This was confirmed by a district court's recent decision rejecting Moderna's attempt to use § 1498 as an affirmative defense from a patent infringement lawsuit brought against Moderna for its manufacture and use of its mRNA COVID-19 vaccine in the U.S. healthcare market.[15] Second, the article explicates the march-in provision of the Bayh-Dole Act, which is a more complex statute than § 1498, but the conclusion is the same: It does not authorize unprecedented agency actions to break drug patents

[12] *See* 35 U.S.C. § 203(a)(1)-(4).

[13] *See, e.g.*, Alfred B. Engelberg, Jerry Avorn, & Aaron Kesselheim, *A New Way to Contain Unaffordable Medication Costs – Exercising the Government's Existing Rights*, 386 N. ENGL. J. MED. 1104, 1104 (2022), https://www.nejm.org/doi/full/10.1056/NEJMp2117102 (stating that "existing laws" provide the government with the authority to lower drug prices and identifying § 1498 and the Bayh-Dole Act); Brennan, Kapczynski, et al., *supra* note 3, at 279 (claiming that "a legal remedy that has been hiding in plain sight" in § 1498 to lower drug prices).

[14] Felix S. Cohen, *Transcendental Nonsense and the Functional Approach*, 35 COLUM. L. REV. 809, 849 (1935) (emphasis added).

[15] *See* Arbutus Biopharma Corp. v. Moderna, Inc., No. CV 22-252, 2022 WL 16635341 (D. Del. Nov. 2, 2022).

to impose price controls on drugs manufactured and sold in the healthcare market. Similar to § 1498, the Bayh-Dole Act does not expressly authorize an agency to impose price controls on products produced and sold by private companies to private consumers in the marketplace, and it has never been used for this purpose. Such a power not only contradicts the commercialization function of the Bayh-Dole Act, it runs afoul of Supreme Court jurisprudence that unprecedented grants of power to an agency, such as imposing price controls on drug patents made and sold by private companies, must be expressly authorized by statute.[16] This construction of the march-in power in the Bayh-Dole Act is further confirmed by agency interpretations of this statutory provision over many decades, including the recent decision by the NIH not to invoke the march-in power on the patents covering Xtandi,[17] that have concluded that this statute does not authorize agencies like the NIH to impose price controls on drug patents.

II. As an Eminent Domain Statute, § 1498 Does Not Authorize Breaking Patents to Impose Price Controls on Private Transactions in the Marketplace

The price-control theory of § 1498 proposes to use this statute as an "important tool" to lower drug prices charged by private companies to private purchasers,[18] but § 1498 is not a price-control statute. It is an eminent domain statute based in nineteenth-century eminent domain cases in which the government directly used patented inventions without authorization of the patent owners. When the federal government did this, nineteenth-century courts responded by protecting patents as constitutional private property under the Takings Clause of the Fifth Amendment.[19] In one key case in 1876, the Supreme Court recognized that "[a]gents of the public have no more right to take such private property [in a patent] than other individuals" who may infringe a patent because the Constitution mandates that "[p]rivate property . . . shall not be taken for public use without just compensation."[20] In the early twentieth century, Congress enacted § 1498 to resolve confusion about the jurisdiction of courts to hear takings claims by patent owners, foreshadowing the enactment of the Bayh-Dole Act in 1980 to eliminate confusion about the patentability of inventions based in research supported by even a modicum of federal monies. The provenance of § 1498 is important, because it establishes that it is an eminent domain statute, as well established by court decisions, and thus its text precludes its use as a legal tool for imposing price controls on drug patents.

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[16] *See* West Virginia v. Environmental Protection Agency, 142 S. Ct. 2587, 2609 (2022) ("[B]oth separation of powers principles and a practical understanding of legislative intent make us 'reluctant to read into ambiguous statutory text' the delegation claimed to be lurking there. . . . The agency instead must point to "clear congressional authorization" for the power it claims.") (citations omitted).

[17] *See supra* notes 5-6, and accompanying text.

[18] *See* Letter to Senator Elizabeth Warren from Amy Kapczynski, Aaron S. Kesselheim, et al., *supra* note 7, at 1.

[19] *See* U.S. CONST. amend. V ("[N]or shall private property be taken for public use, without just compensation."); Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents under the Takings Clause*, 87 B.U. L. REV. 689, 701-11 (2007) (discussing case law).

[20] Cammeyer v. Newton, 94 U.S. 225, 234-35 (1876).

A. Section 1498 is an Eminent Domain Statute

In the patent-takings cases in the nineteenth century, courts rejected numerous defenses by federal officials when called to account for their unauthorized uses of patented inventions. This included their arguments that patents are mere regulatory privileges that can be used by the government without authorization and that government officials are immune from lawsuits given sovereign immunity.[21] In rejecting a federal official's claim to sovereign immunity, one federal court held in 1879 that "[t]his property, like all other private property recognized by law, is exempt from being taken for public use without just compensation, by the supreme law of the land. Const. U. S. art. 5. . . . The property in a patented invention stands the same as other property, in this respect."[22] Unfortunately, the Supreme Court sowed confusion two decades later when the Court blithely stated in an 1894 decision that patent owners lacked a jurisdictional basis to sue the government for its unauthorized uses of their property.[23] Notably, the Court issued this decision without even acknowledging the existence of the earlier precedents in the lower courts and in its own decisions that patent owners had the right to sue the federal government for an unconstitutional taking of their property when officials used their patents without authorization.[24]

In 1910, Congress brought an end to this constitutional confusion by enacting § 1498 to reestablish the previously secure constitutional protection afforded to patents by the Supreme Court under the Takings Clause.[25] The House committee report for the bill that became § 1498 expressly stated that the federal government was using patents without authorization "in flat violation of [the Takings Clause] and the decisions of the Supreme Court."[26] During the congressional debates leading up to the enactment of § 1498, the bill's sponsor, Representative Currier, emphasized that the legislation "does not create any liability; it simply gives a remedy upon an existing liability."[27] (This is the same function of 42 U.S.C. § 1984 and 42 U.S.C. § 1988, which establish jurisdiction for a court to hear a constitutional claim and provide a remedy for a violation of a citizen's constitutional rights.) Throughout the debates in Congress in 1910, legislators repeatedly referenced the earlier Supreme Court decisions that had already secured to

[21] *See* Mossoff, *supra* note 19, at 701-11 (detailing the defenses against the takings or infringement claims).

[22] Campbell v. James, 4 F. Cas. 1168, 1172 (C.C.S.D.N.Y. 1879) (No. 2,361), *rev'd on other grounds*, James v. Campbell, 104 U.S. 356 (1881). Since the Supreme Court held on appeal that the patent is invalid, it did not reach the infringement or sovereign immunity issues as a matter of law. But the *James* Court still thought it important to state in dicta that the "exclusive property in the patented invention . . . cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land." *James*, 104 U.S. at 358.

[23] *See* Schillinger v. United States, 155 U.S. 163 (1894).

[24] Justice Brewer's majority opinion and Justice Harlan's dissenting opinion in *Schillinger* clashed over the legal fiction of an "implied contract" that the Supreme Court had long employed to establish jurisdiction for courts to hear claims for unconstitutional takings of property in both real estate and patents under the enabling legislation that created the Court of Claims in 1855. But the majority opinion does neither acknowledges nor engages with any of the takings cases involving patents. *See* Mossoff, *supra* note 19, at 713 and n.130.

[25] *See* Act of June 26, 1910, ch. 423, 36 Stat. 851, 851-52 (1910) (codified as amended in 28 U.S.C. § 1498).

[26] H.R. REP. NO. 61-1288, at 3 (1910).

[27] Mossoff, *supra* note 19, at 712-13 (quoting 45 CONG. REC. 8755, 8756 (1910)).

patent owners their constitutional remedy under the Takings Clause.[28] In 1918, in the midst of federal procurement efforts with contractors, Congress amended § 1498 to provide jurisdiction to hear claims by patent owners for compensation when federal contractors infringe their patents.[29]

The text of § 1498 establishes that it is a jurisdiction-conferring statute for claims for compensation arising from exercises of the government's eminent domain power. Section 1498 states that a patent owner can sue the federal government in the Court of Claims (now-styled as the Court of Federal Claims) for "recovery of his reasonable and entire compensation" when a patented invention is "used or manufactured by or for the United States without license of the owner."[30] Judge Philip Nichols thus stated as a truism in a 1971 decision that § 1498 authorizes a court to hear a claim by a patent owner "to recover just compensation for a taking under the power of Eminent Domain."[31] A couple decades earlier, the Court of Claims succinctly stated in 1950 that § 1498 is "an eminent domain statute."[32]

B. Section 1498 Does Not Apply to Market Transactions Between Private Parties

As an eminent domain statute, the text of § 1498 provides that a patent owner may sue the federal government for "reasonable and entire compensation" when its patented "invention . . . is used or manufactured by or for the United States."[33] The nineteenth-century takings cases that underscored the enactment of this statute by Congress confirm that it applies to the classic case of an exercise of eminent domain by the federal government over a patented invention—the government acquires or uses a patented without authorization by the patent owner. Two such prominent nineteenth-century cases, for example, arose from the unauthorized use by the U.S. military of patented tents and patented cartridge (bullet) cases carried by soldiers.[34] The twentieth-century cases brought by patent owners under § 1498 are no different,[35] including a famous twentieth-century case arising from the U.S. military's unauthorized use of a patented battery during World War Two.[36] In sum, the plain text of § 1498 makes clear that it is not a grant of power to the federal government to impose price controls on products sold by private companies

[28] *See* Mossoff, *supra* 19, at 712 (citing H.R. REP. NO. 61-1288, at 1-4 (1910)).

[29] *See* Act of July 1, 1918, ch. 114, 40 Stat. 704, 705 (1918) (codified as amended in 28 U.S.C. § 1498).

[30] 28 U.S.C. § 1498(a).

[31] *Carter-Wallace, Inc.*. 449 F.2d at 1390 (Nichols, J., concurring).

[32] *Irving Air Chute Co.*, 93 F. Supp. at 635.

[33] *Id.*

[34] *See, e.g.*, United States v. Burns, 79 U.S. 246 (1870) (patented tents used during Civil War); McKever v. United States, 14 Ct. Cl. 396 (1878) (patented cartridge boxes).

[35] *See, e.g.*, *Hughes Aircraft Co. v. Messerschmitt-Boelkow-Blohm*, 625 F.2d 580 (5th Cir. 1980); *Hughes Aircraft Co. v. United States*, 534 F.2d 889 (Ct. Cl. 1976); *Croll-Reynolds Co. v. Perini-Leavell-Jones-Vinell*, 399 F.2d 913 (5th Cir. 1968), *cert. denied*, 393 U.S. 1050 (1969).

[36] *See* United States v. Adams, 383 U.S. 39 (1966). This is a famous patent case that is in many patent casebooks. *See, e.g.*, ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 552-59 (7th ed. 2017).

to private consumers—it confers jurisdiction for a federal court to hear a lawsuit when a patented invention is "used or manufactured by or for the United States without license of the owner."

Despite this clear statutory text that a patented invention must be "used or manufactured" by the United States, a 2016 law journal article argued for a novel price-control theory of § 1498 as a solution to the problem of the "soaring cost" of drugs.[37] The scheme was both clever and simple: Congress enacts a law or a federal agency adopts a regulation that directs a private company to make and sell patented drugs at lower prices for private purchasers in competition with the owner of the drug patent. According to this argument, since the government authorizes the private company to sell the infringing drug at the lower price in the marketplace, the patent owner can only sue the federal government under § 1498 for compensation. It cannot sue the private company directly for patent infringement, because the federal government is the proximate cause of the patent infringement. In this lawsuit, a federal judge would set the "reasonable compensation" due to the owner of the drug patent that will be paid by the federal government. They argued that this "reasonable compensation" determined by a court would reflect a lower amount than the innovator would receive from sales of its patented drug, if only because it is a distinct remedy from the "lost profits" paid by infringing companies in run-of-the-mill patent infringement lawsuits between private companies. Thus, the federal government could impose price controls on drugs sold in the healthcare market with the price set at whatever federal judges think is "reasonable" compensation via a lawsuit against the government under § 1498.[38]

Perhaps recognizing that the government authorizing private parties to manufacture and sell products to private purchasers in the marketplace is not "used or manufactured by or for the United States," the proponents of the price-control theory of § 1498 also argue that federal agencies had done this before under § 1498 in the mid-twentieth century.[39] In an editorial, the *New York Times* repeated this claim that this has all happened before, and thus it can happen again, asserting that it was merely historical accident that the price-control theory of § 1498 "fell out of use."[40]

The problem with this "it's been done before" argument is two-fold. First, the text of § 1498 expressly authorizes lawsuits against the government only when an "invention . . . is used or manufactured by or for the United States."[41] In other words, the statute confers jurisdiction for lawsuits when the federal government exercises its eminent domain power, authorizing patent owners to receive "reasonable and entire compensation" for this unauthorized use—the patent law equivalent of the "just compensation" mandated by the Takings Clause. Even if federal agencies sporadically invoked § 1498 a few limited times during the initial decades of the nascent

[37] *See* Brennan, Kapczynski, et al., *supra* note 3, at 277.

[38] *Id.*; *see also* Joseph Adamczyk, Adrienne Lewis, Shivani Morrison, and Christopher Morton, *§ 1498: A Guide to Government Patent Use, a Path to Licensing and Distributing Generic Drugs* (Jan. 2021), https://dx.doi.org/10.2139/ssrn.3882823 (detailing similar proposal for the use of § 1498 to license generic drug companies to make and sell patented drugs at a lower price than that charged by the drug patent owner).

[39] *See* Brennan, Kapczynski, et al., *supra* note 3, at ___; Adamczyk, Lewis, et al., *supra* note 38, at ___.

[40] *How the Government Can Lower Drug Prices*, N.Y. TIMES (June 20, 2021), https://www.nytimes.com/2018/06/20/opinion/prescription-drug-costs-naloxone-opioids.html (repeating and endorsing the price-control theory proposed in the 2016 law journal article).

[41] *Id.*

administrative state and patent owners did not argue at the time that the agencies lacked authority under § 1498 to do this, these improper agency actions do not justify contradicting the plain statutory text today. As parents often remind their children: Two wrongs do not make a right.

Second, and perhaps more important, the claim by proponents of the price-control theory of § 1498 that the statute has been used in the past for this purpose is false. The federal government has not used § 1498 for the sole purpose of imposing price controls on *private companies* selling products to *private consumers* engaged in transactions in the marketplace. In a co-authored 2018 blog essay, we published the results of our own, independent review of the historical record on the use of this statute as alleged by the proponents of the price-control theory of § 1498.[42] The earlier agency actions that relied on § 1498 represented government procurement contracts, such as acquisition of medicines by the Veterans Health Administration of the U.S. Department of Veterans Affairs. This was not the scheme proposed by the price-control theory of § 1498 in which the federal government authorizes *private companies* to sell patented products or services solely to *private consumers* in the marketplace. In sum: "The historical record is absolutely clear that government agencies and courts have all applied § 1498 only to situations of government procurement and its own direct use. It has never been used to authorize private companies infringing patents for the sole purpose of selling the patented innovation to consumers in the free market."[43]

In a letter to Senator Elizabeth Warren in April 2022, advocates for the price-control theory of § 1498 broadened their argument that § 1498 should also apply to situations in which the use of the patented invention is merely for the general "benefit" of the government.[44] The letter derives this "benefit" language, not from the text of § 1498, but from a 2009 court opinion in *Advanced Software Design Corp. v. Federal Reserve Bank of St. Louis*, in which the court interpreted the phrase "by or for the United States" in § 1498.[45] In this case, the court held that regional Federal Reserve banks acted "for the government" when they used a process for detecting fraudulent Treasury checks that infringed a patent. The court concluded that "the benefits to the government of using the [patent-infringing fraud-detection] technology on Treasury checks are not incidental effects of private interests."[46] *Advanced Software* concluded that the patent owner had to proceed in its lawsuit against the federal government under § 1498, and not in a patent infringement lawsuit against the specific Federal Reserve bank. Given the formal relationship between the federal government and the Federal Reserve System in managing the official currency printed by the U.S.

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[42] *See* Adam Mossoff, Sean O'Connor & Evan Moore, *Proposal for Drug Price Controls is Legally Unprecedented and Threatens Medical Innovation* (Nov. 5, 2018), https://cpip.gmu.edu/2018/11/05/proposal-for-drug-price-controls-is-legally-unprecedented-and-threatens-medical-innovation/.

[43] Adam Mossoff, Sean O'Connor & Evan Moore, *Proposal for Drug Price Controls is Legally Unprecedented and Threatens Medical Innovation* (Nov. 5, 2018), https://cpip.gmu.edu/2018/11/05/proposal-for-drug-price-controls-is-legally-unprecedented-and-threatens-medical-innovation/.

[44] *See* Letter from Amy Kapczynski, Aaron S. Kesselheim, et al to Senator Elizabeth Warren, *supra* note 7, at 37.

[45] *Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371, 1373-74 (Fed. Cir. 2009). Judge Braden and Joshua Kresh similarly describe *Advanced Software* and *Larson v. United States*, *see* Susan G. Braden & Joshua A. Kresh, *Section 1498(A) is Not a Rx to Reduce Drug Prices*, 77 FOOD & DRUG L.J. 274, 284-85 (2022).

[46] *Id.* at 1379.

Bureau of Engraving and Printing in the U.S. Department of Treasury, this decision makes sense, both legally and commonsensically.

The Federal Reserve System, however, is not the same legal or commercial entity as a private company that manufactures and sells a drug to other companies or patients in the marketplace. In fact, the *Advanced Software* court distinguished an earlier decision, *Larson v. United States*, whose facts are similar to the proposed scheme to lower drug prices under the price-control theory of § 1498.[47] In *Larson*, a patent owner sued a private medical company for infringing its patent on a medical device (a splint); the splints were paid through government programs such as Medicaid or Medicare, or at least the purchase price was reimbursed.[48] Given that "the government reimbursed the cost [of the infringing splint] through Medicare and other federal programs," the defendant argued that the patent owner's lawsuit must proceed against the government under § 1498.[49] The *Larson* court definitively rejected this argument, stating that "government reimbursement of medical care expenses did not constitute a *use* of a medical patent *for* government purposes," as required by the text of § 1498 in authorizing lawsuits against the federal government.[50] Seventeen years later, the *Advanced Software* court reaffirmed the holding in *Larson*, stating that "[t]he fact that the government has an interest in the [healthcare] program generally, or funds or reimburses all or part of its costs, is too remote to make the government the program's beneficiary for the purposes underlying § 1498."[51]

The interpretation of § 1498 by *Advanced Software* and *Larson* that it applies only to eminent-domain actions by the government in its own unauthorized use of patented technologies was confirmed in a recent decision in *Arbutus Biopharma Corp. v. Moderna*.[52] In this case, Arbutus sued Moderna for infringing Arbutus' patents covering mRNA technology when Moderna produced and sold its famous mRNA vaccine for COVID-19. Moderna filed a motion to dismiss on the basis of § 1498, arguing that the federal government purchased Moderna's mRNA vaccines in response to the COVID-19 pandemic through federal programs like Operation Warp Speed. Thus, Moderna argued that Arbutus was required to sue the federal government under § 1498 for its "entire and reasonable compensation," which precluded it from suing Moderna for patent infringement. In effect, Moderna argued that, since it "contracted with the Government for production and delivery of the vaccine for use in combatting the pandemic," it was immune from a patent lawsuit and Arbutus' real legal dispute was with the federal government, not Moderna.[53]

The *Arbutus* court rejected Moderna's argument because its production and sale of its mRNA vaccines was not "for the Government," as required by § 1498. Moderna's contract with the federal government did not provide that the advance purchases of vaccine doses was for the

[47] *See* Larson v. United States, 26 Cl. Ct. 365 (1992)

[48] *Id.* at 367-68.

[49] *Advanced Software*, 583 F.3d at 1379 (describing the defendant's argument in *Larson*).

[50] *Larson*, 26 Cl. Ct. at 369 (emphases added).

[51] *Id.* (quoting *Larson*, 26 Cl. Ct. at 369).

[52] *See* Arbutus Biopharma Corp. v. Moderna, Inc., No. CV 22-252, 2022 WL 16635341 (D. Del. Nov. 2, 2022).

[53] *Id.*, at *4.

benefit of and use by the government; rather, the purchase contract provided only that the government was making these advanced purchases of vaccines as part of a "whole of nation effort" in response to a "national emergency."[54] The *Arbutus* court concluded that Moderna's "development and sale of the vaccines was for the benefit of the vaccine's recipients," not for the benefit of the federal government.[55]At best, the court observed that "the U.S. Government was an *incidental beneficiary* who bore an interest in ensuring the safety of its citizens,"[56] not a *direct beneficiary* as required by § 1498 and the consistent interpretation of this statute by courts.[57] Several months later, the *Arbutus* court reaffirmed its interpretation of § 1498 in response to a surprise Statement of Interest filed by the Biden Administration in support of Moderna's earlier argument that § 1498(a) shielded it from a patent infringement lawsuit by Arbutus.[58]

In its first decision, the *Arbutus* court also recognized that "Moderna's argument . . . could mean that every government-funded product used to advance any policy goal articulated by the U.S. Government—such as IV needles to fight HIV to cancer drugs to fight the war on cancer—would be subject to a § 1498(a) defense."[59] Given the federal government's widespread funding and regulating of healthcare, Moderna's argument about the broad-based applicability of § 1498 would convert every patent infringement lawsuit arising from patents covering drugs or other healthcare treatments into a suit for compensation against the federal government for the exercise of its eminent domain power. This lack of any limiting principle in Moderna's interpretation of § 1498 is another key insight into the plain meaning of this statute: it does not apply when a drug is made by a private company for use by private citizens in the healthcare market.

In sum, *Larson*, *Advanced Software*, and *Arbutus* establish that general payment from the public fisc to a private party that infringes a patent is not sufficient by itself to qualify as a use of the patented invention "by or for the United States" under § 1498.[60] Given the extensive federal funding of a myriad of private activities far beyond biomedical research, a contrary decision would result in every private lawsuit being converted into a constitutional claim for compensation. It is not the function of § 1498 as an eminent domain statute to wipe out all private patent infringement

[54] *Id.*, at *5-*6 (quoting Moderna's contract with the federal government).

[55] *Id.*, at *7.

[56] *Id.*, at *7 (emphasis added).

[57] Since this was a ruling on a motion to dismiss, the *Arbutus* court was required to "accept as true the allegations of the Complaint," and this was an additional reason why the court ruled against Moderna's attempt to use § 1498 to dismiss the infringement complaint. *Id.*, at 7*. It is conceivable that additional facts might be introduced into evidence in the litigation that would lead the court to revise its analysis of whether the government is a direct beneficiary of the mRNA vaccine purchase contract, as opposed to an incidental beneficiary. Even if the court changed its decision, it would be on the basis of a key distinction between *direct* and *incidental* benefits to the government rooted in the text of § 1498 that it applies only to unauthorized uses of patents "for and by the United States," 28 U.S.C. § 1498, not uses for and by private companies selling to private consumers in the marketplace.

[58] *See* Arbutus Biopharma Corp. v. Moderna, Inc., No. CV 22-252, 2023 WL 2455979 (D. Del. Mar. 10, 2023).

[59] *Id.*

[60] *See Larson v. United States*, 26 Cl. Ct. at 368 & n.3. These judicial rulings are also consistent with agency guidance on government use of licensed rights in patented inventions under the Bayh-Dole Act, as discussed in Part Three below. *See, e.g.*, 32 C.F.R. § 37.860(b) (Bayh-Dole license does not include the right to practice the invention for commercial purposes).

lawsuits in which federal monies (or regulatory controls) create government interests in the private activities underlying the legal claims of patent infringement.

In conclusion, § 1498 does not apply to private commercial activities in which private companies manufacture and sell products for use by private parties in the marketplace. By its express terms, as confirmed by its interpretation and application by courts, § 1498 is an eminent domain statute that is limited to unauthorized uses of patented inventions by or for the federal government, such as use of patented inventions by the military or by federal agencies, such as the Veterans Administration. Even scholars who support more direct federal government regulation or control of the healthcare market have recognized this legal fact. In fact, one of the monographs relied on by those advocating for the price-control theory of § 1498 acknowledges that § 1498 must be "modified" if it is "to apply to governmental payment for drugs prescribed for beneficiaries of such federal health programs as Medicare and Medicaid."[61]

C. As an Eminent Domain Statute, § 1498 Mandates Full Compensation of the Market Value of a Patent that Vitiates Any Proposed Cost Savings

Even if the price-control theory of § 1498 did not contradict the text and judicial interpretation of this statute as implementing the constitutional limitations imposed on the eminent domain power of the federal government, the use of this statute to impose price controls on drug patents would likely create massive financial liabilities for the federal government. This follows logically from § 1498 as an eminent domain statute in which the government must pay "reasonable and entire compensation"—the patent law version of "just compensation" in the Takings Clause—when a patented invention is "used or manufactured by or for the United States without license of the owner."[62] In eminent domain law, courts have long construed the payment of "just compensation" as tantamount to payment of the *market value* of the property.[63] Similarly in patent law, the basic rule for the statutorily authorized payment of damages is to award *lost profits* to patent owner who is manufacturing and selling the patented invention.[64] Under the scheme proposed by the advocates of the price-control theory of § 1498, these remedies principles would direct courts to award patent owners their lost profits due to the lost sales of their drugs from the unauthorized manufacture and sale of the infringing drug.

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[61] MILTON SILVERMAN & PHILIP R. LEE, PILLS, PROFITS, AND POLITICS 187 (1974). This monograph is cited in Letter to Senator Elizabeth Warren from Amy Kapczynski, Aaron S. Kesselheim, et al., *supra* note 7, at 2 n. 9.

[62] § 1498(a).

[63] *See* United States v. Miller, 317 U.S. 369, 374 (1943) ("In an effort . . . to find some practical standard [for awarding 'just compensation'], the courts early adopted, and have retained, the concept of market value.").

[64] *See* 35 U.S.C. § 284 (providing that "the court shall award the claimant damages adequate to compensate for the infringement"); General Motors Corp. v. Devex Corp., 461 U.S. 648, 654-55 (1983) ("Congress sought to ensure [in § 284] that the patent owner would in fact receive full compensation for 'any damages' he suffered as a result of the infringement."); Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc) ("[T]he general rule for determining actual damages to a patentee that is itself producing the patented item is to determine the sales and profits lost to the patentee because of the infringement."); Del Mar Avionics, Inc. v. Quinton Instrument Co., 836 F.2d 1320, 1326 (Fed. Cir. 1987) ("The general rule for determining the actual damages to a patentee that is itself producing the patented item, is to determine the sales and profits lost to the patentee because of the infringement.").

The advocates for the price-control theory of § 1498 argue that lost profits for the market value of their property should not be the baseline for compensation, because they believe that courts should not award "monopoly" profits. Instead, they maintain that "reasonable and entire compensation" requires only the payment of a court-determined "reasonable royalty" that would reward drug innovators for their investments in creating the new medical treatment plus some additional compensation, such as reimbursement at marginal cost pricing.[65] This is incorrect for several reasons based in well-established, foundational remedies principles as implemented in patent law, in § 1498, and in Takings Clause jurisprudence.

First, as a matter of remedies doctrine in patent law, when a patent owner has not licensed its patent to others, awarding anything less than the patent owner's lost profits falls short of the statutorily mandated award of "damages adequate to compensate for the infringement."[66] In the foundational case on lost profits and reasonable royalties, *Panduit Corp. v. Stahlin Bros. Fibre Works*, the 6th Circuit held that it is improper for a court to set a reasonable royalty solely as "the equivalent of ordinary royalty negotiations among truly 'willing' patent owners and licensee," especially in the context of a patent owner that does not licensee its patents.[67] This would convert remedies doctrine into a tool for "competitors to impose a 'compulsory license' policy on every patent owner."[68] In such an approach, according to the *Panduit* court, "the infringer would be in a 'heads-I-win, tails-you-lose' position."[69] This contradicts the purpose of the remedies provision in the Patent Act and the general function of remedies law to make the plaintiff whole—to place the plaintiff in its rightful position *but for* the wrong committed by the violation of its rights.[70]

Second, as a matter of the "reasonable and entire compensation" requirement in § 1498, it courts will construe this as an award of lost profits in the scheme of the price-control theory of § 1498. In the last 38 years, the Federal Circuit has decided only four cases interpreting the compensation requirement in § 1498.[71] None of these cases arose from a situation in which an infringing product was sold in the marketplace by a private company competing directly with the patented product sold by the patent owner. (This reinforces the point from the prior section that § 1498 is applicable only to the use or manufacture of a patented invention for or by the federal government, and not for or by private companies.) If the government were to adopt the unprecedented price-control theory of § 1498, which would entail authorizing competing

[65] Brennan, Kapczynski, et al., *supra* note 3, at 307-18.

[66] 35 U.S.C. § 284.

[67] Panduit Corp. v. Stahlin Bros. Fibre Works, 575 F.2d 1152, 1158 (6th Cir. 1978).

[68] *Id.*

[69] *Id.*

[70] *See* Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476, 507 (1964) ("The question to be asked in determining damages is 'how much had the Patent Holder and Licensee suffered by the infringement. And that question (is) primarily: had the Infringer not infringed, what would Patent Holder-Licensee have made?'") (quoting Livesay Window Co. v. Livesay Industries, Inc., 251 F.2d 469, 471 (5th Cir. 1958)); *Rite-Hite Corp.*, 56 F.3d at 1545 ("To recover lost profits damages, the patentee must show a reasonable probability that, 'but for' the infringement, it would have made the sales that were made by the infringer.").

[71] *See* FastShip LLC v. United States, 892 F.3d 1298, 1310 (Fed. Cir. 2018); Paymaster Techs., Inc. v. United States, 180 F. App'x 942, 944–45 (Fed. Cir. 2006); Gargoyles, Inc. v. United States, 113 F.3d 1572, 1572 (Fed. Cir. 1997); Hughes Aircraft Co. v. United States, 140 F.3d 1470 (Fed. Cir. 1998).

commercial products sold by private companies in the marketplace, then a court would likely apply the same remedies doctrines as those they have applied for all other cases of patent infringement arising from the same commercial competition—applying the default rule of lost profits in construing "reasonable *and entire* compensation."[72] In fact, the Court of Claims has already acknowledged that "awarding lost profits" is a proper method for determining a reasonable royalty rate when a court must "appraise a patent license taken by the Government."[73]

Third, since § 1498 is an eminent domain statute,[74] courts may apply the remedies doctrines they have developed under the Takings Clause to the novel scenario in which the federal government instructs a private company to make and sell a drug without authorization from the patent owner. Takings Clause jurisprudence reflects the same remedies principles discussed above: the Supreme Court has held that a property owner should "be put in as good [a] position pecuniarily as he would have been if his property had not been taken."[75] In sum, property owners are constitutionally entitled to receive the market value of their property when it is taken from them by the government.[76] In the context of a drug patent, its market value is the profits earned by the company in selling the drug in the healthcare market, because a patent owner would not license a competitor without accounting for its lost profits from a new market competitor. Thus, an award of lost profits represents the market value that serves as the legal standard by courts in awarding "just compensation" under the Takings Clause in the Fifth Amendment.[77] As an eminent domain statute, it is reasonable for a court to look to the remedy principles applied under the Takings Clause in determining how to award the "reasonable and entire compensation" under § 1498 in the novel scenario of the federal government directing a private company to infringe a drug patent for its own profit through sales to private consumers in the healthcare market.[78]

In sum, the "reasonable and entire compensation" requirement in § 1498 would likely require compensating a patent owner for its lost profits in the novel legislative or regulatory scheme proposed by advocates of the price-control theory of § 1498. This would be in accord with the remedies principles already adopted by courts in patent law, in their interpretation of § 1498, and in the interpretation of the "just compensation" requirement under the Takings Clause—all of

[72] 35 U.S.C. § 284 (emphasis added).

[73] Decca Ltd. v. United States, 640 F.2d 1156, 1167 (Ct. Cl. 1980) (citing Imperial Mach. & Foundry Corp. v. United States, 69 Ct. Cl. 667 (1930)).

[74] *See supra* notes 8 and 25-32, and accompanying text.

[75] Seaboard Air Line Ry. Co. v. United States, 261 U.S. 299, 304 (1923) (citations omitted); *see also* United States v. 564.54 Acres of Land, 441 U.S. 506, 510 (1979).

[76] *See, e.g.*, United States v. 50 Acres of Land, 469 U.S. 24, 25 n.1 (1984); United States v. 564.54 Acres of Land, More or Less, Situated in Monroe & Pike Counties, Pa., 441 U.S. 506, 511 (1979).

[77] *See supra* note 63, and accompanying text.

[78] *See* Jones v. United States, 529 U.S. 848, 857 (2000); Almendarez-Torres v. United States, 523 U.S. 224, 237–38 (1998).

which seek to place a property owner in the rightful position it would have been but for the violation of its rights by awarding the owner the market value of its property.[79]

As a result, the price-control theory of § 1498 would not lead to a reduction in total drug costs—unless the federal government chose to massively subsidize the competing sales of drugs by paying the difference to the patent owner the profits it lost due to the unauthorized sales of the drugs. But such massive public subsidies would defeat the very purpose of the price-control theory of § 1498 in lowering drug prices. The legislative or regulatory scheme would become merely another cross-subsidy in which third parties would pay, through taxes or other means, the same costs of development of innovative, life-saving medicines as they had before the adoption of the scheme. In fact, it would be even more costly and inefficient, because now litigation costs would be an added transaction cost that did not exist before the price-control scheme.

D. The Price-Control Theory of § 1498 Creates Uncertainties, Additional Costs, and is Rife with Unintended Consequences

The potential for significant, additional costs in the scheme proposed by the price-control theory of § 1498 is worth highlighting as further evidence of how this policy proposal is not based in the plain meaning of the statute. As observed in the Introduction, the U.S. healthcare system is extremely complex given a myriad of legislative and regulatory regimes in both the federal and state govermments. The scheme to lower drug prices through the price-control theory of § 1498 is seemingly straightforward and surprisingly simple, at least as it is presented in hypothetical scenarios in academic articles, letters to Congress, or in the petitions to the NIH. But real-world legislation necessarily creates transaction costs in the institutional implementation of any new regulatory regime. In this respect, the price-control theory of § 1498 represents the "nirvana fallacy"—the comparison of a real-world institution with all its costs (real-world drug prices) with an idealized institutional arrangement that fails to acknowledge its own inherent transaction costs (the price-control theory of § 1498).[80]

The purpose of this section is to identify some of these legal and institutional complexities that necessarily create uncertainties, additional costs, and unintended consequences. It is not possible in a single section to identify all of the relevant legal and economic issues, but this is not necessary. The purpose is to identify how the price-control theory of § 1498, assuming for the sake of argument it is a legally authorized agency power, is not as simple and easy as it is portrayed by its advocates. Thus, it is sufficient to identify some institutional conflicts and accompanying costs in the panacea-sounding proposal to lower drug prices through the price-control theory of § 1498.

Unintended consequences and unacknowledged costs are well known in the patent system, especially given institutional changes in the patent system over the past several decades. One example is the Patent Trial & Appeal Board (PTAB), the new administrative tribunal to cancel

[79] *See* State Industries, Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1577 (Fed. Cir. 1989) ("The measure of damages is an amount which will compensate the patent owner for the pecuniary loss sustained because of the infringement.").

[80] *See* Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J. L. & ECON. 1 (1969) (identifying and coining the "nirvana fallacy").

issued patents that was created in the America Invents Act of 2011.[81] Since the PTAB began operations in 2012, it has precipitated extensive legal and policy debate comprising regulatory disputes at the USPTO,[82] legislative bills proposed in Congress,[83] and six decisions by the Supreme Court in the PTAB's first decade of operation.[84] One would be hard pressed to identify a single administrative tribunal in the modern administrative state that has led to six separate Supreme Court decisions in a ten-year period. Another example is the institutional and legal regime for drug patents created by the Hatch-Waxman Act of 1984.[85] This law, which was enacted to lower drug prices, led to numerous, unforeseen legal disputes requiring resolution by the Supreme Court.[86] It also led to new regulatory actions by other agencies, such as the Federal Trade Commission.[87]

Given its direct function to promote faster generic drug entry into the healthcare market to lower drug prices, the Hatch-Waxman Act especially underscores the institutional and legal complexities that go unacknowledged in the price-control theory of § 1498. Congress enacted the Hatch-Waxman Act to reduce drug prices by creating a regulatory regime that results in faster entry into the healthcare market by generic drug companies competing with a drug innovator.[88] The Hatch-Waxman Act regime is a complex system of patent litigation, regulatory exclusivity, and approval of generic drugs by the Food and Drug Administration (FDA). It is too complex to describe succinctly, but a brief summary will suffice to establish its significance for this section.

Under the Hatch-Waxman Act, a generic company files an abbreviated new drug application (ANDA) with a "paragraph IV certification" at the FDA. An ANDA is filed while the

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[81] *See* Leahy-Smith America Invents Act of 2011, Pub. L. 112-29, 125 Stat. 284 (2011) (codified in 35 U.S.C. § 6) (creating patent trial and review board).

[82] *See, e.g.*, Eileen McDermott, *General Counsels Ask Raimondo to Immediately Repeal* NHK-Fintiv *Framework*, IPWATCHDOG (Feb. 14, 2022), https://www.ipwatchdog.com/2022/02/15/general-counsels-ask-raimondo-immediately-repeal-nhk-fintiv/id=145968/; Britain Eakin, *Tech Giants Urge Fed. Circ. To Abolish 'Unlawful' Fintiv Rule*, LAW360 (Feb. 9, 2022), https://www.law360.com/articles/1463601/tech-giants-urge-fed-circ-to-abolish-unlawful-fintiv-rule; Ryan Davis, *Tech Cos. Back Apple High Court Bid to Ax PTAB's Fintiv Rule*, LAW360 (Aug. 31, 2021), https://www.law360.com/articles/1417615/tech-cos-back-apple-high-court-bid-to-ax-ptab-s-fintiv-rule.

[83] *See, e.g.*, Patent Trial and Appeal Board Reform Act of 2022, S. 4417, 117th Cong. (2022) (creating changes to the procedures at the PTAB); Restoring American Leadership in Innovation Act of 2021, H.R. 5874, 117th Congress (2021) (eliminating the PTAB); STRONGER Patents Act of 2019, S. 2082 & H.R. 3666, 116th Cong. (2019) (adopting numerous procedural and substantive reforms in the PTAB).

[84] *See* United States v. Arthrex, 141 S. Ct. 1970 (2021); Thryv v. Click-To-Call Technologies, 140 S. Ct. 1367 (2020); Return Mail v. USPS, 139 S. Ct. 1853 (2019); Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 138 S. Ct. 1365 (2018); SAS Institute, Inc. v. Iancu, 138 S. Ct. 1348 (2018); Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131 (2016).

[85] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[86] *See, e.g.*, Federal Trade Commission v. Actavis, 570 U.S. 136 (2013); Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990).

[87] *See* Federal Trade Commission v. Actavis, 570 U.S. 136 (2013).

[88] *See* Erika Lietzan, *The History and Political Economy of the Hatch-Waxman Amendments*, 49 SETON HALL L. REV. 53 (2018) (describing the enactment of the Hatch-Waxman Act and critiquing the conventional wisdom that this legislation was the result of Congress carefully balancing the interests of patent owners, generics, and the public).

drug patent is still in force and thus a specific function of the ANDA is to trigger patent infringement litigation between the drug innovator and the generic company. The lawsuit results in the usual patent infringement claims by the drug innovator and the panoply of affirmative defenses asserted by the generic company that the drug patent is invalid.[89] If the patent owner prevails in this litigation—demonstrating infringement by the generic drug company and defending the validity of its patent—the FDA then stays final approval of the ANDA until the patent expires. But the generic company may prepare its manufacturing facilities and ready commercialization of its generic version of the drug.[90] The generic company must also meet the FDA's safety and efficacy standards for generic drug approval. If it meets the FDA's safety and efficacy standards, once the patent expires, the generic company may immediately leap into the market and start selling the drug to patients and it is awarded with a period of "exclusivity" in which it will be the only generic company to compete with the drug innovator. This market exclusivity for the generic drug company is the reward for filing the first ANDA and traversing the costly patent litigation gauntlet. This Hatch-Waxman regime has been in place for four decades.

If an agency implemented the price-control theory of § 1498 in directing a generic drug company to sell a drug covered by a patent, it is unclear how this would function within the existing regulatory and litigation regime for drug innovators and generic companies under the Hatch-Waxman Act. The generic company submits an ANDA for approval to manufacture and sell a drug in competition with the drug innovator at the moment the patent expires, which is done for the purpose of lowering drug prices. The express goal of the Hatch-Waxman Act is the same goal as the price-control theory of § 1498: authorize a generic drug company to make and sell drugs to lower drug prices. If the price-control theory of § 1498 reflected the actual text and function of this statute, then a generic drug company would add an affirmative defense in its Hatch-Waxman litigation that the drug innovator cannot sue the generic company, because it must instead sue the federal government for "reasonable and entire compensation" under § 1498 (just as Moderna tried to argue that this is what Arbutus was required to do).[91]

How this new § 1498 defense would work within the overall Hatch-Waxman regime is unclear, creating significant uncertainty and extensive new litigation to resovle. These additional litigation costs would necessarily add to the costs of drug development and commercialization for drug innovators and to the costs of doing business by generic drug companies. These added costs would result in higher prices for medical care, including drugs.

The failure to account for the well-known Hatch-Waxman regime is just one example of how the price-control theory of § 1498 is no more based on a proper institutional assessment of the reality of drug patents and generic competition today than it is based in the text of § 1498 itself. These institutional and regulatory complexities should be acknowledged and accounted for with proper empirical studies. Without this proper institutional assessment of how the price-control theory of § 1498 would in fact be implemented within the existing institutions and laws governing

[89] 21 U.S.C. § 355(j)(5)(B)(iii).

[90] 35 U.S.C. § 271(e)(4)(A) ("[T]he court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed . . . ."); *see also* 21 U.S.C. § 355(j)(5)(B)(iii)(II)(bb).

[91] *See supra* notes 52-59, and accompanying text (describing Moderna's argument and the court's rejection of it).

drug patents, it has not proven that it will be cost effective compared to the "excessive drug pricing" by patent owners.[92] This is only one example of many institutions and laws implicated by the price-control theory of § 1498, demonstrating the extent to which this is truly a *theory*, not an evidence-based legislative or policy proposal.[93]

The price-control theory of § 1498 is a policy proposal lacking a basis in either the text or function of this eminent domain statute. It contradicts the express text of § 1498, it conflicts with the function of § 1498 in only conferring jurisdiction on the Court of Federal Claims to hear complaints by patent owners for compensation when an invention is used by or for the federal government in an exercise of the eminent domain power. Courts and agencies have consistently interpreted and applied § 1498 according to this plain text. Even if one assumes for the sake of argument that the price-control theory of § 1498 is legally viable, its advocates have not addressed the inherent institutional and legal complexities of their price-control scheme, such as how it would interrelate with the Hatch-Waxman Act and other legislative and regulatory regimes in the modern U.S. healthcare system. In sum, the price-control theory of § 1498 offers a false promise of breaking patents to lower drug prices.

III. The Bayh-Dole Act Does Not Authorize the Federal Government to Control Drug Prices

The search for legal authority authorizing the federal government to break patents to lower drug prices has led to the creation of a second price-control theory—the price-control theory of the Bayh-Dole Act of 1980. Similar to § 1498, the text of the Bayh-Dole Act and its consistent interpretation by federal officials militates against this price-control theory. In fact, the price-control theory of the Bayh-Dole Act was "unrecognized" from 1980 until two professors claimed to have discovered it more than two decades later in a law journal article in 2001.[94] Unlike § 1498, though, the Bayh-Dole Act is a more complicated statutory regime and thus it requires a more detailed exposition of its statutory function, the text that allegedly supports the price-control

[92] Brennan, Kapczynski, et al., *supra* note 3, at 275.

[93] Another statute that may be possibly implicated in the scheme to lower drug prices under the price-control theory of § 1498 is the Federal Acquisition Streamlining Act of 1994 (FARA). *See* Federal Acquisition Streamlining Act of 1994, Pub. L. No. 103-355, 108 Stat. 3243 (1994). This statute established a strong preference for federal acquisition of "commercial items" by the federal government "to the maximum extent practicable." 10 U.S.C. § 3453(a); *see also* 10 U.S.C. § 3454(b) ("The head of an agency shall ensure that procurement officials in that agency, to the maximum extent practicable . . . acquire . . . commercial products . . . to meet the needs of the agency . . . ."). A patented drug that is already available to the public would appear to meet the definition of a "commercial item" under the FARA. *See* 10 U.S.C. § 2376 (A "commercial item" is "any item other than real property, that is of a type customarily used by the general public or by nongovernmental entities for purposes other than governmental purposes, and that – (i) has been sold, leased, or licensed to the general public; or (ii) has been offered for sale, lease, or license to the general public."). If the scheme proposed by the price-control theory of § 1498 was deemed to be a means to avoid direct government purchases of drugs that are readily available as commercial items, then this would conflict with Congress's express policy in the FARA. As with the Hatch-Waxman regime, the price-control theory of § 1498 produces many unanswered legal and institutional questions, sowing extensive uncertainty and creating new, additional costs in litigation or in other legal processes.

[94] *See* Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patients Deriving in Whole or in Part from Federally Funded Research*, 75 TULANE L. REV. 631 (2001).

theory, and the repeated agency interpretations of this statute that have consistently rejected the price-control theory.

A. The Function of the Bayh-Dole Act is to Promote Commercialization of Inventions

The Bayh-Dole Act was born of an unintended consequence of the federal government's decision to continue its funding programs for scientific research that it had first adopted during World War Two.[95] In fact, public funding of basic research by the government expanded in both breadth and scope in the post-war era.[96] As noted earlier, the creation of a new government policy can create unintended consequences both in commercial activities in the innovation economy and in the functioning of unrelated statutory or regulatory regimes.[97] The continuation and expansion of public funding of research in the second half of the twentieth century was no different in creating unintended consequences, whether positive or negative.[98]

One unintended consequence was the question of ownership of patented inventions derived from research funded—even if only in small part—by the government. This included funding of basic research in biochemistry and related fields that led to practical innovations, especially life-saving inventions in the modern pharmaceutical sector of the U.S. innovation economy. Beginning in the early to mid-twentieth century, the pharmaceutical sector arose from a business model of substantial investments in research and development to create new drugs that companies were able to commercialize through their property rights in these innovations—patents.[99] What happened

[95] *See* Daniel P. Gross & Bhaven N. Sampat, *America, Jump-Started: World War II R&D and the Takeoff of the U.S. Innovation System* (NBER Working Paper 27375, rev. Sep. 2022), https://www.nber.org/papers/w27375. Of course, the most famous research program was the Manhattan Project, which led to the invention of the first atomic bomb. *See* RICHARD RHODES, THE MAKING OF THE ATOMIC BOMB (1986). Another example is the research and development of radar, a ubiquitous technology today and the basis for consumer inventions like the microwave oven. *See* ROBERT BUDERI, THE INVENTION THAT CHANGED THE WORLD: HOW A SMALL GROUP OF RADAR PIONEERS WON THE SECOND WORLD WAR AND LAUNCHED A TECHNOLOGICAL REVOLUTION (1998).

[96] *See, e.g.*, BRUCE L. R. SMITH, AMERICAN SCIENCE POLICY SINCE WORLD WAR II (1990); Jeffrey K. Stine, *A History of Science Policy in the United States, 1940–1985*, Rep. for Task Force on Science Policy, Committee on Science & Technology, U.S. House of Representatives (1986) [copy on file with author].

[97] *See supra* Part I.D (identifying potential negative consequences of the price-control theory of § 1498 as a result of the "nirvana fallacy").

[98] *See* Gross & Sampat, *supra* note 95 (identifying positive aggregation externalities from federal funding of basic research in WWII).

[99] The modern biopharmaceutical sector and the drug patent were born twins in the nineteen thirties and forties. *See generally* BARRY WERTH, THE BILLION-DOLLAR MOLECULE 111-37 (1994) (discussing the early history of the pharmaceutical industry); THE COMPETITIVE STATUS OF THE U.S. PHARMACEUTICAL INDUSTRY 7-12 (1983) (same). The development and use of drugs existed prior to the nineteen thirties, but the rigorous research and development methods that are the hallmark of the biopharmaceutical sector did not begin until that time. *See* ALFRED D. CHANDLER, JR., SHAPING THE INDUSTRIAL CENTURY 177-211 (2005) (discussing the birth and evolution of many pharmaceutical companies, such as Merck and SmithKline, from the "therapeutic revolution" in the nineteen forties); JONATHAN LEIBENAU, MEDICAL SCIENCE AND MEDICAL INDUSTRY (1987) (surveying the pharmaceutical industry from the nineteenth century up through World War One). Werth writes:

> The birth of drug research in the 1930s had introduced a bristling new competitiveness as companies sought to protect their investments. Where patents were once reviled, they were now

(continued…)

when these drugs and other inventions were produced by research that was now funded several decades later by the federal government through the many post-WWII research programs? The federal government's initial answer to this question was that it owned the inventions no matter how small the contribution from the federal funding program.[100]

Government ownership of patents proved to stifle, rather than to promote distribution of new innovations. The Senate Judiciary Committee Report for the Bayh-Dole Act quoted approvingly an earlier policy report by the Carter Administration that "[e]xperience has shown that the Government . . . is not in a position to take advantage of its ownership of patents to promote enterprise."[101] Congress received evidence about extensive numbers of inventions that were lying fallow due to the government's inability to commercialize the patents it owned or due to costs associated with regulatory restrictions on commercialization created by government ownership of patents.[102] Drugs in particular went undeveloped as medical treatments for patients—not a single new drug had been commercialized from billions distributed by the National Institutes of Health (NIH) for biomedical research.[103]

In response to this problem, Congress enacted the Bayh-Dole Act in 1980.[104] The express function of the Bayh-Dole Act is to make clear that inventors making discoveries or creating inventions produced from research that was funded even in part by the public fisc may receive property rights in the fruits of their labors—patents. The statute expressly states that "[i]t is the policy and objective of the Congress to use the patent system to promote the utilization of

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> pursued ruthlessly. Squibb, which had one patent in 1920, had more than 200 by 1940. In 1937 alone, Merck had filed forty-six domestic and foreign patent applications.
>
> WERTH, *supra*, at 122.

[100] *See* S. Rep. No. 480, 96th Cong., 1st Sess., at 21 (1979) (stating that "agencies can retain title to inventions arising from research which only received a small percentage of its funding from the Government").

[101] S. Rep. No. 480, 96th Cong., 1st Sess., at 18 (1979) (quoting Advisory Subcommittee on Patent and Information Policy of the Advisory Committee on Industrial Innovation (Dec. 20, 1978)).

[102] *See* S. Rep. No. 480, 96th Cong., 1st Sess., at 20 (1979) ("A GAO study conducted in 1968 found that [the NIH's] policy of retaining patent rights to inventions arising from its supported research programs resulted in an inability to obtain the cooperation of industry in developing potential new drugs."); S. Rep. No. 480, 96th Cong., 1st Sess., at 28 (1979) ("It is essentially a waste of public money to have good inventions gathering dust on agencies' shelves because of unattractiveness of nonexclusive licenses."); Jay Kesan, *Transferring Innovation*, 77 FORDHAM L. REV. 2169, 2175 (2009) ("Prior to the passage of the Bayh-Dole Act, the government agencies responsible for funding research did not have a uniform policy concerning the fate of the potential intellectual property rights in the fruits of government-funded research."); *see also* Dr. Wolfgang Klietmann, *Ivy League profs taking potshots at patents imperil innovation*, BOSTON HERALD (Dec. 5, 2022), https://www.bostonherald.com/2022/06/27/klietmann-ivy-league-profs-taking-potshots-at-patents-imperil-innovation/ ("Nearly 30,000 government-patented discoveries were sitting idle before Bayh-Dole. This meant that taxpayer money put towards scientific research wasn't actually benefiting taxpayers."); Joseph Allen, *Bayh-Dole Rocks While the Critics Play the Same False Note*, IPWatchdog (June 11, 2019), https://www.ipwatchdog.com/2019/06/11/bayh-dole-rocks-critics-play-false-note/id=110254/ (explaining that in "the pre-Bayh-Dole era . . . . federally funded inventions were micromanaged from Washington . . . . The result: less than 5% of 28,000 inventions were licensed" in the marketplace).

[103] *See* Allen, *supra* note 102 (explaining that in "the pre-Bayh-Dole era . . . . the Comptroller General found that not a single new drug had been developed . . . despite billions of taxpayer dollars invested in the National Institutes of Health (NIH)").

[104] Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified at 35 U.S.C. §§ 200–212).

inventions arising from federally supported research or development."[105] Accordingly, owners of patented inventions derived from federally funded research have the same basic rights as all other patent owners to commercialize their innovations, barring any limitations accepted by the inventor in the funding contract.[106] This includes obtaining venture capital financing to create startups,[107] licensing or engaging in other commercial transactions to create new innovation markets,[108] or transferring the patents to third parties who can more efficiently commercialize the innovation asset in the marketplace.[109]

The Bayh-Dole Act has been identified as one of the most significant acts of innovation policy adopted by Congress in the modern era,[110] but some scholars have critiqued the law on both empirical and policy grounds. Some academics have argued that it has not been successful given lack of evidence that university researchers are actually incentivized by patents to invent.[111] Others have argued that most universities do not on net benefit from patent licensing insofar as licensing revenue exceeds the operational expenses in running licensing programs, except for highly publicized albeit relatively rare "blockbuster" inventions.[112] Moreover, some academics critique

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[105] 35 U.S.C. § 200.

[106] *See* 35 U.S.C. § 202(c) (specifying additional conditions agencies may adopt in research funding agreement).

[107] *See* Joan Farre-Mensa, Deepak Hegde & Alexander Ljungqvist, *What Is a Patent Worth? Evidence from the U.S. Patent "Lottery,"* 75 J. FINANCE 639 (2020) (identifying a causal link between a startup owning a patent and its increased chances of securing venture capital financing, and further demonstrating a causal link of these patent-based startups with higher rates of success as commercial enterprises in the marketplace).

[108] *See, e.g.*, JONATHAN M. BARNETT, INNOVATORS, FIRMS, AND MARKETS: THE ORGANIZATIONAL LOGIC OF INTELLECTUAL PROPERTY (2020) (detailing the historical and economic evidence of the commercialization function of patents as representing property rights in inventions); B. ZORINA KHAN, INVENTING IDEAS: PATENTS, PRIZES, AND THE KNOWLEDGE ECONOMY (2020) (detailing the historical and economic evidence of the comparative advantage of property rights (patents) over prizes as drivers of economic activity and economic growth); B. ZORINA KHAN, THE DEMOCRATIZATION OF INVENTION: PATENTS AND COPYRIGHTS IN AMERICAN ECONOMIC DEVELOPMENT, 1790–1920, at 9-10 (2005) ("[P]atents and . . . intellectual property rights facilitated market exchange, a process that assigned value, helped to mobilize capital, and improved the allocation of resources. . . . Extensive markets in patent rights allowed inventors to extract returns from their activities through licensing and assigning or selling their rights.").

[109] *See generally supra* note 108; *see also* Stephen Haber & Seth H. Werfel, *Patent Trolls as Financial Intermediaries? Experimental Evidence*, 149 ECON. LETTERS 64 (2016).

[110] *See Innovation's Golden Goose*, 365 ECONOMIST 3, 3 (2002) (calling the Bayh-Dole Act "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century"); *see also* Jay P. Kesan, *Transferring Innovation*, 77 FORDHAM L. REV. 2169, 2174 (2009) ("From a patent standpoint, the Bayh-Dole Act was a very significant piece of legislation during the 1980s, because it led to an increase in nonprofit organizations' involvement in the patent system.").

[111] *See, e.g.*, Lisa Larrimore Oullette & Andrew Tutt, *How Do Patent Incentives Affect University Researchers?*, 61 INT'L REV. L. & ECON. (2020), https://doi.org/10.1016/j.irle.2019.105883.

[112] *See, e.g.*, David Orozco, *Assessing the Efficacy of the Bayh-Dole Act Through the Lens of University Technology Transfer Offices (TTOS)*, 21 N.C. J.L. & TECH. 115, 142 (2019) (observing that it is estimated that universities make annual aggregate royalties of $2.7 billion from approximately 8,000 patent licenses but that a "large portion of those royalties, however, are derived from a few sizeable inventions at a handful of academic institutions"); Jay P. Kesan, *Transferring Innovation*, 77 FORDHAM L. REV. 2169, 2179-81 (2009) (describing university licensing programs and the transaction costs and inefficiencies in these programs).

university patent licensing as conflicting with norms of open research or undermining incentives by university professors to engage in basic research.[113]

If these critiques are true, they are still too constricted in their accounting of the relevant variables, focusing solely on what occurs *inside* a university, such as on researcher incentives. There is no doubt that university researchers, especially full-time tenured professors, engage in research without the promise of patent protection. But the function of patents is not merely to incentivize invention; as property rights, patents function as all other property rights as a platform for commercialization of new products and services in the marketplace.[114] As stated by Congress, the purpose of the Bayh-Dole is to promote commercialization of new inventions just as all other innovations have been commercialized in the United States—through the longstanding mechanisms of property rights and contracts.[115]

Researchers have demonstrated that the Bayh-Dole Act has achieved its purpose in promoting commercialization in the marketplace by establishing a reliable legal platform on which to license and otherwise commercially deploy new products and services in the marketplace.[116] One recent study found that patent licensing facilitated by the Bayh-Dole Act contributed between $631 billion to $1.9 trillion to industry gross output between 1996-2020.[117] Walter Copan, the former Director of the National Institute for Standards and Technology, has stated that the Bayh-Dole Act has contributed to "more than 4.2 million jobs, and over 11,000 startup companies from the nation's universities."[118] It may be possible that these commercial and economic benefits are

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[113] *See, e.g.*, Margo A. Bagley, *Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place*, 47 B.C. L. REV. 217, 251 (2006) (noting that a focus on patenting of university research can "be detrimental, leading in some cases to rancor, turf disputes, loss of collegiality, and more," and that "it may lead some academics to shift the focus of their research into areas more likely to generate proprietary, commercializable results"); Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government – Sponsored Research*, 82 VA. L. REV. 1663, 1667 (1996) (arguing that the Bayh-Dole's incentives to patent "threatens to impoverish the public domain of research science that has long been an important resource for researchers in both the public and private sectors")

[114] *See supra* notes 107-109, and accompanying text (describing briefly some of the commercial functions of patents as property rights).

[115] 35 U.S.C. § 200 ("It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development . . . ."); *see also* Ian Ayres & Lisa Larrimore Ouellette, *A Market Test for Bayh-Dole Patents*, 102 CORNELL L. REV. 271 (2017) ("The commercialization argument takes on even more significance in the university context (where ex ante incentives are less important), and this focus is expressly stated in the text of the Bayh--Dole Act.").

[116] *See* Chester G. Moore, *Killing the Bayh-Dole Act's Golden Goose*, 8 TUL. J. TECH. & INTELL. PROP. 151, 155-57 (2006) (surveying evidence of economic success of Bayh-Dole Act in driving economic activity, spurring job growth, and growing the innovation economy).

[117] LORI PRESSMAN, MARK PLANTING, CAROL MOYLAN, & JENNIFER BOND, ECONOMIC CONTRIBUTIONS OF UNIVERSITY/NONPROFIT INVENTIONS IN THE UNITED STATES: 1996-2020, at 3 (2022), https://autm.net/AUTM/media/About-Tech-Transfer/Documents/BIO-AUTM-Economic-Contributions-of-University-Nonprofit-Inventions_14JUN2022.pdf.

[118] Walter Copan, *Reflections on the Impacts of the Bayh-Dole Act for U.S. Innovation, on the Occasion of the 40th Anniversary of this Landmark Legislation*, IPWATCHDOG (Nov. 2, 2020), https://ipwatchdog.com/2020/11/02/reflections-on-the-impacts-of-the-bayh-dole-act-for-u-s-innovation-on-the-occasion-of-the-40th-anniversary-of-this-landmark-legislation/id=126980/.

outweighed by the costs, but these trade-offs must be fully assessed in evaluating any legal institution, comparing all the benefits and the costs.[119] Thus far, critics of the Bayh-Dole Act have not fully compared and balanced both benefits and costs.[120]

B. The Price-Control Theory of the Bayh-Dole Act: The "March In" Power

Another indicator of the success of the Bayh-Dole Act is the price-control theory itself. Instead of critiquing the statute, advocates for the price-control theory now co-opt it for purposes other than to promote the licensing or other commercial uses of reliable and effective patents. Advocates for the price-control theory of the Bayh-Dole Act now argue that the statute authorizes the federal government (or, more specifically, a federal agency like the NIH) to license patents covered by the statute for the sole purpose of imposing price controls on drug patents. This is known as the "march-in power" or "march-in right," but neither the statutory text nor extra-statutory sources of legislative meaning state that *price controls* are authorized legal action under the prescribed march-in power. Before assessing the price-control theory of the Bayh-Dole Act, it is first necessary to describe the march-in power and the argument that this is an existing legal tool to lower drug prices in the healthcare market through the imposition of price controls.

1. The March-In Power in § 203 of the Bayh-Dole Act

Section 203 in the Patent Act, as enacted in the Bayh-Dole Act, creates the "march in right."[121] The provision authorizes a federal agency like the NIH that has funded research that resulted in a patented invention "to grant a nonexclusive, partially exclusive, or exclusive license" under four specified conditions.[122] Section 203 permits a federal agency to grant licenses "to a responsible applicant" without authorization from the patent owner in four specific, delimited circumstances: (1) if an assignee or licensee "has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use," (2) "to alleviate health or safety needs which are not reasonably satisfied," (3) "requirements for public use specified by Federal regulations . . . are not reasonably satisfied," or (4) "a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement."[123]

All four conditions in § 203 authorize a federal agency to "march in" and license other companies to make and sell a patented product or service in specific circumstances in which a

[119] *Cf.* Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S Science and Technology Policy*, 24 VT. L. REV. 347 (2000) ("Weighing the costs and benefits of Bayh-Dole is a tremendous task that depends significantly on empirical research of, inter alia, the actual rates of foreign misappropriation of federally-funded research (not simply foreign competition) and a counterfactual measure of deadweight costs from under-utilization.").

[120] *See* Dov Greenbaum, *Academia to Industry Technology Transfer: An Alternative to the Bayh-Dole System for Both Developed and Developing Nations*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 311, 376 (2009) ("There is a dearth of hard data on the effect of Bayh-Dole on basic research, and much of what is available is contradictory.").

[121] *See* 35 U.S.C. § 203 (2011).

[122] § 203(a).

[123] § 203(a)(1)-(4).

patent owner or licensee is not commercializing the patented invention in the marketplace.[124] The first condition, for example, addresses circumstances in which a patent owner or licensee is figuratively sitting on its hands and not achieving the commercialization function that is the purpose of the Bayh-Dole Act. The second condition addresses a situation in which a patent owner or licensee lacks manufacturing capacity to fully respond to demand for health or safety needs. The third condition addresses the situation when regulatory mandates for public use are not met by a patent owner or licensee, such as a licensee being unable to produce enough water filters required for public drinking safety requirements set by the Environmental Protection Agency.[125] The fourth condition identifies the circumstances when a licensee is in breach of its agreement and thus is not commercializing the patented invention.

These are the four prerequisites, provided in the disjunctive, for a federal agency to exercise the march-in power in § 203(a)(1)-(4). Each sub-section in § 203(a) specifies necessary preconditions for the march-in power to be used by a federal agency or other official in the federal government. Notably, there is no mention of "price" in the four authorizing conditions for a federal official to invoke the march-in power to issue licenses without approval without approval from a patent owner.

Moreover, there is no catch-all march-in clause in § 203. This is significant for two reasons. First, Congress knows how to create broadly framed and explicitly expansive authorizations for agency action, if this is its purpose. For example, Congress has expressly created broadly-framed authorizations in other statutes, such as the well-known language in the Federal Communications Act of 1934 authorizing the Federal Communications Commission to grant radio transmission licenses according to whether the "public convenience, interest, or necessity will be served thereby."[126] Second, the canon of statutory construction of *expressio unius est exclusio alterius* establishes that, without a catch-all clause, the march-in power is delimited to only these four express "exemptions" from the longstanding rights of patent owners covered by the Bayh-Dole Act to freely assign or license their property in the marketplace.[127] In sum, Congress chose not to create an open-ended grant of authority in § 203 in listing only four specific march-in conditions

[124] *See* § 203(a)(1)-(4).

[125] Admittedly, § 203(a)(3) is not clear on its face, but this is the meaning attributed to this statutory language. *See* Joseph P. Allen, *Taking the Mystery Out of March-in Rights*, RealClearPolicy (Sep. 16, 2022), https://www.realclearpolicy.com/articles/2022/09/16/taking_the_mystery_out_of_march-in_rights_853859.html. Joseph Allen was a congressional staff member who worked for Senator Birch Bayh in the legislative process that led to the enactment of the Bayh-Dole Act and he was later appointed as the first Director of the new Office of Technology Commercialization in the U.S. Department of Commerce to develop the implementing regulations for the Bayh-Dole Act. More important, since § 203(a)(3) is not invoked as a relevant statutory provision in the price-control theory, whether this particular condition is clear is merely academic for the purpose of this Article.

[126] 47 U.S.C. § 307(a) ("The Commission, if public convenience, interest, or necessity will be served thereby, subject to the limitations of this Act, shall grant to any applicant therefor a station license provided for by this Act.").

[127] *See* Tennessee Valley Authority v. Hill, 437 U.S. 153, 188 (1976) ("In passing the Endangered Species Act of 1973, Congress was also aware of certain instances in which exceptions to the statute's broad sweep would be necessary. Thus, § 10, 16 U.S.C. § 1539 (1976 ed.), creates a number of limited 'hardship exemptions,' . . . . meaning that under the maxim *expressio unius est exclusio alterius*, we must presume that these were the only 'hardship cases' Congress intended to exempt."); *see also* 73 Am. Jur. 2d Statutes § 129 (2002) (describing the statutory canon of interpretation, *expressio unius est exclusio alterius*).

that strictly specify the narrow scope and application of the march-in power exemption in the Bayh-Dole Act.

2. The Price-Control Theory of § 203

As previously noted, the price-control theory of the Bayh-Dole Act was born of a law journal article published more than twenty years after the Bayh-Dole Act was enacted into law in 1980. In 2001, Professors Peter Arno and Michael Davis published their article, *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*.[128] As the title makes clear, they argued that the (previously unrealized) purpose of the march-in power in the Bayh-Dole Act is to impose price controls on the marketplace.

Professors Arno and Davis claim that, in enacting the Bayh-Dole Act, "Congress's concern with march-in rights focused exclusively on maintaining competitive conditions, controlling profits, and doing so through price control."[129] They specifically maintain that the legislative record confirms that Congress intended to the march-in power to be "focused exclusively on . . . price control." This is a surprising claim for a couple reasons.

First, there is a significant dearth of evidence for their claim that price controls was one of the expressly stated purposes of the Bayh-Dole Act. Professors Arno and Davis identify approximately seven references in the legislative record in which a few congresspersons and witnesses raised concerns about "prices," if one excludes their explicit decision to conflate references to the "public interest" in the legislative record as identical to "price control" references.[130] These few, scattered references to "prices" in the legislative record calls to mind the famous statement by Judge Harold Leventhal that the use of legislative history can be "the equivalent of entering a crowded cocktail party and looking over the heads of the guests for one's friends."[131] For example, other scholars have found statements in the legislative history emphasizing the commercialization function of patents as the primary goal of the Bayh-Dole Act—the "first-listed goal in the statute" according to two scholars.[132] In a 2004 statement to the NIH, former Senator Bayh further critiqued the price-control theory of the Bayh-Dole Act given the selective misreading of the legislative record by a march-in petition advancing "the same arguments" by Professors Arno and Davis.[133] In sum, in a lengthy legislative record pages

[128] *See* Arno & Davis, *supra* note 94.

[129] *Id.*, at 659.

[130] *See id*., at 656-67 (identifying a total of about seven statements in the entire legislative record to "price" or "pricing" of patented products as something that should be restricted or controlled).

[131] Conroy v. Aniskoff, 113 S. Ct. 1562, 1567 (1993) (Scalia, J., concurring).

[132] *See* Ayres & Oulette, *supra* note 145 (observing that commercialization is the "first-listed goal in the statute" and supporting this point about the function of Bayh-Dole from quotes from the legislative history).

[133] *See Statement of Senator Birch Bayh to the National Institutes of Health* 3-5 (May 25, 2004), https://bayhdolecoalition.org/wp-content/uploads/2023/05/2004-Bayh-Statement-to-NIH.pdf.

underlying the Bayh-Dole Act that is more than 1,000 pages in length,[134] Professors Arno and Davis found a few price-control friends to justify their conclusion that Congress "focused exclusively on . . . price control" in enacting § 203 as part of the Bayh-Dole Act.[135]

Second, as noted above, Professors Arno and Davis conflate "public interest" with "price control," which confirms that they are engaging in the scholarly equivalent of artistic license in reconstructing the legislative history of the Bayh-Dole Act. References to the public interest are not by themselves a confirmation of an "exclusive focus" on "price control." The commercialization of new innovations through patents is in the public interest; the inventions figuratively sitting on shelves unused by the public was the problem spurring the enactment of the Bayh-Dole Act to prompt commercialization of these inventions through patent rights. The Bayh-Dole Act reflects the longstanding policy that reliable and effective patents secured to innovators serve the public interest.[136] In the *Federalist No. 43*, James Madison justified the Patent and Copyright Clause on the basis that the "public good fully coincides in both [patents and copyrights] with the claims of individuals."[137]

Professors Arno and Davis' price-control theory of the Bayh-Dole Act was not based solely in their expansive reading of the legislative record. They did attempt to ground their price-control theory in the statute in a perfunctory section in their article,[138] but most of their article is devoted to critiquing the Bayh-Dole Act and to critiquing agencies and other stakeholders for failing to implement their price-control theory.[139] Nonetheless, their general interpretative approach is the statutory argument restated by advocates for the price-control theory of the Bayh-Dole Act to this day; in fact, perhaps sensing the weakness of their reliance on the legislative record, the statutory argument largely dominates the price-control arguments today.[140]

The statutory interpretation of the Bayh-Dole Act as a price-control statute proceeds in two steps. First, price-control theorists focus on the first march-in condition in § 203(a)(1), which

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[134] *See* Act of December 12, 1980, 94 Stat. 3015, https://1.next.westlaw.com/Document/I71880d30a97e11e0b16e010000000000/View/FullText.html?VR=3.0&RS=cblt1.0&__lrTS=20230211221450846&transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1 (listing entire legislative record and identifying lengthy as approximately 1,073 pages).

[135] Arno & Davis, *supra* note 94, at 121.

[136] *See, e.g.*, Douglas Dynamics v. Buyers Products Co., 717 F.3d 1336, 1346 (Fed. Cir. 2013) (recognizing that "the public has a great[ ] interest in acquiring new technologies through the protection provided by the Patent Act"); Blanchard v. Sprague, 3 F. Cas. 648, 650 (C.C.D. Mass. 1839) (No. 1,518) (Story, Circuit Justice) ("Patents for inventions are now treated as a just reward to ingenious men, and as highly beneficial to the public."); Pilot Inc. v. Coolman Outdoor Corp., No. 18-CV-02286 (JAK) (SPX), 2019 WL 2620723, at *5 (C.D. Cal. Apr. 10, 2019) (observing that that "[u]nfair competition through patent infringement is contrary to the interests of the public"); Amazon.com Inc. v. Barnesandnoble.com Inc., 73 F.Supp.2d 1228, 1248-49 (W.D. Wash. 1999), *vacated on other grounds and remanded*, 239 F.3d 1343 (Fed. Cir. 2001) ("The public has a strong interest in the enforcement of intellectual property rights.").

[137] Federalist No. 43 (James Madison), in THE FEDERALIST PAPERS 272 (Clinton Rossiter ed., 1961).

[138] *See* Arno & Davis, *supra* note 94, at 649-53.

[139] *See id*., at 667-91.

[140] *See supra* notes 5-7 (citing sources).

covers a patent owner or licensee who "has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use."[141] Second, they look to the statutory definition in § 201(f) of the phrase "practical application," as this term is used in § 203(a)(1); there, "practical application" is defined to "mean 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."[142] In this lengthy definition § 201(f), they focus on the phrase, "available to the public on reasonable terms."

The price-control theory is thus based a two-step interpretative process of combining § 203(a)(1) and § 201(f) in the Bayh-Dole Act. The phrase "available to the public on reasonable terms" in the final clause of the definition in § 201(f) is applied to the phrase "practical application" in § 203(a)(1) as a specific condition for authorizing the march-in power.[143] Advocates for the price-control theory argue that high prices prevent drugs from being made "available to the public on reasonable terms," and thus this means that high prices for drugs are not achieving "practical application of the subject invention in the field of use."[144] They conclude that high drug prices

[141] 35 U.S.C. § 203(a)(1). Some advocates for the price-control theory of the Bayh-Dole Act also invoke § 202, which specifies agency powers in imposing conditions in research funding agreements, including that the government may claim a royalty-free license for its own use of patents. *See* § 35 U.S.C. § 202(c)(4); Kapczynski, Kesselheim et al. *supra* note 7, at 5 ("In the Bayh-Dole Act, § 202 grants the government irrevocable, non-transferrable, royalty-free licenses to covered patents. . . . [T]he only requirement under § 202 is that the patent be used by, for, or on behalf of the government."). But whether one looks to § 202 or § 203 is a distinction without a difference. First, § 202 does not specify "price," "reasonable price," or "price controls" as conditions or limitations agencies may impose on inventors in research funding agreements. *See infra* Part III.C. Second, the royalty-free license authorized in § 202(c)(4) is expressly limited to use of a patent "for or on behalf of the United States." This is almost identical to § 1498, the eminent domain statute, which does not authorize agencies to impose price controls on private transactions in the marketplace. *See supra* Part II.B. Courts give similar statutory language similar effects, and thus the eminent domain provision in § 202(c)(4) does not authorize price controls. Third, § 202(c)(8) authorizes agencies to impose conditions in funding research agreements expressly incorporating the march-in conditions in § 203, and thus it incorporates by reference the same phrase "available to the public on reasonable terms" in § 203(a)(1) already invoked by price-control theorists. As explained, this phrase is not an authorization to impose price controls on private transactions in the marketplace. *See infra* Part III.C-F.

[142] 35 U.S.C. § 201(f).

[143] *See, e.g.*, Peter Arno, Robert Sachs & Kathryn Ardizzone, *Will the Biden administration use 'march-in' to protect prostate cancer patients from excessive drug prices?*, STATNEWS (Jan. 3, 2022), https://www.statnews.com/2022/01/03/march-in-rights-protect-prostate-cancer-patients-from-excessive-drug-prices/ (identifying "available to the public on reasonable terms" in § 203(a)(1) as "strong legal underpinnings" for using the march-in power to impose price controls to lower the price of Xtandi); Letter from Eric Sawyer to Xavier Becerra, Secretary of the Department of Health and Human Services (Dec. 13, 2021), at 1, https://www.keionline.org/wp-content/uploads/Eric-Sawyer-HHS-Xtandi-Request-13Dec2021.pdf (proposing march-in power be exercised on Xtandi given "price gouging" by the drug innovator (Astellas) and thus it "is not "making the benefits of the patented inventions 'available to the public on reasonable terms,' which is a requirement of bringing a product to 'practical application,' as defined in 35 USC 201(f)").

[144] *Id.*; *see also* Jeannie Baumann, *New Biomed Unit Under Pressure to Use Untried Drug Patent Grabs*, BLOOMBERG LAW (May 2, 2022), https://www.bloomberglaw.com/bloomberglawnews/pharma-and-life-sciences/XCKMFCBG000000?bna_news_filter=pharma-and-life-sciences#jcite (quoting Emory University law professor Liza Vertinsky that "If no one can afford it, that's not reasonably available"); Steven Seidenberg, *March-*
(continued…)

triggers an authorizing condition under § 203(a)(1) for a federal agency to march in and grant a license to another drug company to sell the patented drug at a lower price in the U.S. healthcare market. Thus, the price-control theory of the Bayh-Dole Act claims this statute empowers the federal government to impose price controls on drug patents by authorizing it to license these patents to generic drug companies directed by the federal government to charge lower prices.

C. The March-In Section in the Bayh-Dole Act is Not a Price-Control Provision

The price-control theory is based on an unduly narrow, out-of-context interpretation of two phrases within two sections of the Bayh-Dole Act. Although the price-control theory appears to be merely interpreting the text in these two statutory phrases, it does so at the expense of ignoring the plain text of both provisions in which these phrases are contained and ignoring the statute as a whole in which these provisions are contained as well. By myopically focusing on these two phrases, which are taken out of their grammatical and statutory context, the price-control theory violates longstanding canons of statutory construction and additional sources of statutory meaning that militate against this interpretation of § 203. This includes the consistent interpretation of § 203 by agencies over several decades that this section does not authorize price controls, among other extra-textual sources of meaning. This Section details this statutory analysis.

1. Section § 203 Does Not Authorize Price Controls in Its Express Text

The Supreme Court has stated that the "first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning."[145] The first place all courts begin is the text of the statute, but the text is not read out of context as individual words. "The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole."[146]

In considering the meaning of the text in § 203(a)(1), and the definitional text in § 201(f), one fact stands out: none of these statutory provisions state that "price" or "reasonable price" is a trigger for the federal government to exercise the march-in power. As the United States Supreme Court has explained: "We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there. When the words of a

in Rights: A Lost Opportunity To Lower US Drug Prices, IPWATCH (May 18, 2017), https://www.ip-watch.org/2017/05/18/march-rights-lost-opportunity-lower-us-drug-prices/ ("When inventions are priced exorbitantly – particularly in comparison to prices in other high-income industrialized countries – those inventions are not available to the public on reasonable terms. So march-in rights can, and should, be used to allow third parties to make and sell the invention at lower prices."); Jennifer Penman & Fran Quigley, *Better Late Than Never: How the U.S. Government Can and Should Use Bayh-Dole March-In Rights to Respond to the Medicines Access Crisis*, 53 WILLIAMETTE L. REV. 1, 2 (2017) (stating that "the current medicines pricing and access crisis . . . calls for the U.S. agencies to finally fulfill the terms of the [Bayh-Dole] Act").

[145] Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997) (citations omitted); *see also* Caminetti v. United States, 242 U.S. 470, 485 (1917) ("It is elementary that the meaning of a statute must, in the first instance, be sought in the language in which the act is framed, and if that is plain, . . . the sole function of the courts is to enforce it according to its terms.") (citations omitted).

[146] *Robinson*, 519 U.S. at 341 (1997) (citations omitted).

statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete.'"[147] This is the "cardinal canon" that all courts apply "in interpreting a statute."[148]

This cardinal canon of statutory interpretation confirms that § 203 does not authorize a federal agency to "march in" to grant a license to a private company directed to charge lower prices to consumers through commercial transactions in the marketplace. If Congress intended to create a price-control power in § 203, it would have specified this as one of the statutory conditions, or at least specified this power in express language in one of the existing statutory conditions.

Congress would have expressly enacted text conferring a price-control power in § 203 if it intended this to be a price-control statute because it has enacted such text many times in past statutes.[149] The Emergency Price Control Act of 1942 is one such example.[150] Similarly, rate-regulation statutes enacted by the states according to their police powers expressly authorize legislators or regulators to set "prices" or determine "rates."[151] Contrary to these price-control or rate-regulation statutes, § 203(a) and § 201(f) are devoid of any archetypical pricing terms, such as "price," "prices charged by an assignee or licensee," "market price," or "reasonable price." According to the "the ordinary meaning of the words used" in § 203 and § 201(f) in the Bayh-Dole Act, the march-in power does not authorize licenses for the purpose of imposing price controls.[152]

Proponents for the price-control theory might still argue that the relevant statutory text is not plain and unambiguous in its meaning, leaving the door open for a federal agency to engage in a reasonable construction of its terms.[153] Accordingly, they would claim that § 203(a)(1) speaks of the lack of "practical application" and "use" of a patented invention as a triggering condition for the exercise of the march-in power by a federal agency, and § 201(f) speaks of the lack of

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[147] Connecticut Nat'l Bank v. Germain, 503 U.S. 249, 253-54 (1992) (quoting Rubin v. United States, 449 U.S. 424, 430 (1981)) (internal citations omitted).

[148] *Connecticut Nat'l Bank*, 503 U.S. at 253.

[149] *See, e.g.*, Economic Stabilization Act of 1970, Pub. L. No. 91-379, § 202, 84 Stat. 799, 799-800 ("The President is authorized to issue such orders and regulations as he may deem appropriate to stabilize prices, rents, wages, and salaries at levels not less than those prevailing on May 25, 1970."); Housing and Rent Act of 1947, Pub. L. No. 129, 61 Stat. 193, 198 (imposing rent controls on existing structures set at levels permitted to be charged under the Economic Price Control Act of 1942).

[150] *See* Pub. L. No. 77-421, 56 Stat. 23 (1942).

[151] *See, e.g.*, Nebbia v. People of New York, 291 U.S. 502, 515 (1934) ("The Legislature of New York established by chapter 158 of the Laws of 1933, a Milk Control Board with power, among other things to 'fix minimum and maximum ... retail prices to be charged by ... stores to consumers for consumption off the premises where sold.'"); Stone v. Farmers' Loan & Trust Co., 116 U.S. 307, 308 (1886) (reviewing "the statute of Mississippi passed March 11, 1884, entitled 'An act to provide for the regulation of freight and passenger rates on railroads in this state, and to create a commission to supervise the same, and for other purposes'").

[152] INS v. Phinpathya, 464 U.S. 183, 189 (1984) (stating that "in all cases involving statutory construction, our starting point must be the language employed by Congress, . . . and we assume that the legislative purpose is expressed by the ordinary meaning of the words used") (quotations and citations omitted).

[153] *See* Chevron, U.S.A., Inc. v. Natural Resource Defense Council, Inc., 467 U.S. 837, 844 (1984) ("Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.").

"reasonable terms" in licenses as one example of a failure of this "practical application." Rate-regulation regimes are often adopted for the purpose of ensuring *reasonable* prices or *reasonable* pricing terms.[154] Thus, the absence of "reasonable terms" in patent licenses, as a definitional element in § 201(f) for the march-in condition in § 203(a)(1) of a lack of "practical application" of a patented invention, could conceivably encompass high drug prices.

But this argument does not carry the day for the price-control theory. As noted above, statutory authorizations for imposing price controls or other forms of rate regulation expressly refer to reasonable *prices*, and not merely broadly framed "reasonable terms" of licenses or contracts.[155] In fact, statutes distinguish between "price" and "terms" by listing them separately.[156] This distinction is also consistent with past official usage of "practical application," which referred to the "successful development and terms of the license, not with a product's price."[157] For example, President John F. Kennedy issued a statement on patent policy in 1963 in which he expressly stated that government licensing may be required to achieve "practical application" of an invention to "guard against failure to practice the invention" by a government "contractor."[158] In enacting the Bayh-Dole Act in 1980, Congress could have included language referring to unreasonably high prices as a triggering condition for a march-in provision; this is the standard, undisputed "price" or price-related text that legislatures has long used in price-control or rate-regulation statutes. Congress chose not to include this language in the Bayh-Dole Act.

2. A Power to Impose Price Controls Conflicts with the Bayh-Dole Act as a Whole

It is not an accident that Congress did not include express text specifying high prices or unreasonable prices as a triggering condition for an agency to use its march-in power in § 203. In interpreting a statutory provision, courts inquire into "the specific context in which that language

[154] *See, e.g.*, 47 U.S.C. § 335(b)(3) ("A provider of direct broadcast satellite service shall meet the requirements of this subsection by making channel capacity available to national educational programming suppliers, upon *reasonable prices, terms, and conditions*, as determined by the Commission . . . .") (emphasis added).

[155] *Id.*

[156] *See id.*

[157] Joseph Allen, *New Study Shows Bayh-Dole is Working as Intended—and the Critics Howl*, IPWATCHDOG (March 12, 2019), https://www.ipwatchdog.com/2019/03/12/new-study-shows-bayh-dole-working-intended/id=107225/.

[158] Government Patent Policy, Memorandum of Oct. 10, 1963, Fed. Reg. 10943 (Oct. 12, 1963).

is used, and the broader context of the statute as a whole."[159] The Supreme Court has bluntly stated: "We do not . . . construe statutory phrases in isolation; we read statutes as a whole."[160]

As Justice Antonin Scalia put the point, "we do not really look for subjective legislative intent. We look for a sort of 'objectified' intent—the intent that a reasonable person would gather from the *text* of the law . . . ."[161] Unlike in some statutes, Congress expressly stated its "objectified intent" in the text of the Bayh-Dole Act: "It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development." The march-in power is an *exemption* from the purpose of the Bayh-Dole Act to stimulate universities and other researchers receiving federal research funds to receive patents to license or otherwise commercialize their inventions into the marketplace. In fact, this exemption was included in the Bayh-Dole Act because it advanced its primary commercialization function: if a patented invention is not licensed or made available in the marketplace by its owner or licensees, then an agency is authorized to act to achieve this goal. Thus, § 203(a)(1)-(4) specifies four conditions in which the march-in power is justified, and, as explained above, these conditions identify situations in which inventions are not sold or commercialized in the marketplace.[162]

In construing § 203 within the Bayh-Dole Act as a whole, it becomes apparent that the price-control theory commits the interpretative vice of "wooden textualism." This is the interpretive vice in statutory analysis in which a court or agency focuses solely on the meaning of a word or phrase taken out of its context within the statute as a whole.[163] The price-control theory commits wooden textualism by deriving its statutory argument through a myopic focus on phrases in "isolated provisions" in the Bayh-Dole Act.[164] It invokes "reasonable terms" as a definitional element in § 201(f) without regard to the complete statutory condition set forth in § 203(a)(1) in which the defined phrase "practical application" appears. If "reasonable terms" as a definitional element for "practical application" is considered within the *full context* of the march-in condition

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[159] *Robinson*, 519 U.S. at 340; *see also* Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280, 290 (2010) ("Courts have a 'duty to construe statutes, not isolated provisions.'") (quoting Gustafson v. Alloyd Co., 513 U.S. 561, 568 (1995)); Gonzales v. Oregon, 546 U.S. 243, 273 (2006) (stating that "statutes 'should not be read as a series of unrelated and isolated provisions.'") (quoting Gustafson v. Alloyd Co., 513 U.S. 561, 570, (1995)); Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) ("It is a 'fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'") (quoting Davis v. Michigan Dept. of Treasury, 489 U.S. 803, 809 (1989)); Louisville & N.R. Co. v. Gaines, 3 F. 266, 276 (C.C.M.D. Tenn. 1880) ("Where the language [of a statute] is clear and explicit the court is bound . . . . It must be construed as a whole. The office of a good expositor, says My Lord Coke, 'is to make construction on all its parts together.'").

[160] Samantar v. Yousuf, 560 U.S. 305, 319 (2010) (quoting United States v. Morton, 467 U.S. 822, 828, (1984)).

[161] Antonin Scalia, *Common-Law Courts in a Civil Law System: The Role of the United States Federal Courts in Interpreting the Constitution and Law*, *in* A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW 17 (Amy Gutmann, ed., 1997) (emphasis added).

[162] *See supra* notes 121-127, and accompanying text.

[163] *Cf.* Scalia, *supra* note 161, at 23-24 (critiquing out-of-context linguistic construction of statutory terms because a "good textualist is not a literalist").

[164] Gonzales v. Oregon, 546 U.S. 243, 273 (2006) (stating that "statutes 'should not be read as a series of unrelated and isolated provisions.'") (quoting Gustafson v. Alloyd Co., 513 U.S. 561, 570, (1995)).

in § 203(a)(1) and of the Bayh-Dole Act broadly, then the conclusion seems ineluctable that § 203(a)(1) does not authorize a federal agency to impose price controls on drug patents.

The Bay-Dole Act addressed the policy and economic dilemma that innovations were not being commercialized in the marketplace given the government's inability to commercialize the patented inventions it owned as a result of even a modicum of federal funding of upstream research.[165] The Bayh-Dole Act has achieved its goal through a simple declaratory provision: any invention derived from research funded even in part by the federal government may be patented and the owner of this patent has the same rights as all other patent owners to commercialize its property in the marketplace.[166] The Bayh-Dole Act was enacted on the basis of the commercialization function of the U.S. patent system, and these new patent owners, such as universities, have since conveyed their property rights via assignments or licenses in the marketplace.[167]

Given this "broader context of the statute as a whole" of the Bayh-Dole Act,[168] § 203 lists four narrow, delimited circumstances in which federal officials or agencies can "march in" and license other companies when a patented invention is not being deployed in the marketplace pursuant to the commercialization function of this statute. The commercialization function of the Bayh-Dole Act animates all four march-in conditions in § 203, as each sub-section addresses a distinct set of circumstances in which a patented product or service is not available in the marketplace. For example, § 203(a)(4) would authorize a federal agency to march in and license another company if an exclusive licensee is in breach of its license agreement with the patent owner, the patent owner has not licensed another company, and thus the product or service is languishing commercially and not being sold in the marketplace to the benefit of consumers.

The march-in condition set forth in § 203(a)(1) provides that "effective steps" must be taken by a patent owner or licensee "to achieve practical application of the invention in its field of us." This march-in condition must be read in the same "context and with a view to [its] place in the overall statutory scheme" of the Bayh-Dole Act as the other three march-in conditions set forth in § 203.[169] To focus exclusively on a portion of the definition in § 201(f) of "practical application" as ensuring the invention is available on "reasonable terms" without regard to this statutory context

[165] *See supra* notes 99-110, and accompanying text. *See also* Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System* 24-27 (ITIF, March 2019), https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system?mc_cid=f1a53e317f&mc_eid=5c5d018a35 (detailing inability or lack of licensing of government of inventions developed from federally funded research).

[166] These rights are expressly secured in 35 U.S.C. § 261. *See also* Adam Mossoff, *Exclusion and Exclusive Use in Patent Law*, 22 Harv. J. L. & Tech. 321, 343-45 (2009) (discussing legislative history of § 261 and its function in codifying case law reaching back to 1790s securing rights of patent owners to convey their property).

[167] *See supra* notes 108-109, and accompanying text.

[168] *Robinson*, 519 U.S. at 340.

[169] *Davis*, 489 U.S. at 809.

violates the basic interpretative maxim not to engage in wooden textualism in construing the reasonable meaning of a statutory provision within the context of the statute as a whole.[170]

What is the reasonable meaning of a failure of "practical application" as a trigger for the march-in power in § 203(a)(1), especially as a distinct condition from the other three march-in provisions in § 203(a)(2)-(4)? This is the general provision in the march-in power section specifying a situation in which a patent owner or licensee fails to deploy through regular commercial means a product or process in the marketplace, what those commercial means may be. In the healthcare market, for example, § 203(a)(1) would apply when a drug is not manufactured or sold to patients, as distinguished from a licensee failing to make or sell drugs given its breach of a license agreement under § 203(a)(4) or the patent owner or licensee is unable to manufacture sufficient numbers of drugs to respond to a "health or safety" crisis under § 203(a)(2).[171] In sum, the phrase "reasonable terms" in § 201(f), as comprising part of the definition of "practical application" in § 203(a)(1), is not an open-ended authorization for a federal official or agency to impose price controls—it is part of a statutory regime whose function is to ensure that patented products or services are commercialized in the relevant marketplace.[172]

In construing § 203 within the context of the Bayh-Dole Act as a whole, it is evident why the price-control theory insists that agencies focus only on the isolated phrases "reasonable terms" in § 201(f) and "effective steps to achieve practical application" in § 203(a)(1). If the function of the Bayh-Dole Act is to promote commercialization of new inventions through patent licensing and other commercial activities in the marketplace, then the exemptions would authorize actions that would conflict with this only if the invention is not being commercialized as the statute intended. The exemptions would certainly not promote government actions that would undermine incentives to commercialize, such as an open-ended authorization to impose price controls whenever a federal official may deem a price to be too high or unreasonable.

D. Agency Interpretations of the March-In Power in § 203 Have Consistently Rejected the Price-Control Theory of the Bayh-Dole Act

The plain text of § 203 and its function within the Bayh-Dole Act as a whole explains why federal agencies—spanning bipartisan administrations over several decades—have repeatedly rejected numerous petitions to use the march-in power to impose price controls on drug patents.

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[170] The same rule of construction applies to the use of the phrase "upon terms that reasonable for the circumstances" in the preamble of § 203 that sets forth what a federal agency may do in licensing the patented product or process through its march-in power. In sum, this is not an open-ended reference to or authorization for price controls, but rather it ensures the context-specific commercial conditions for differing innovations are recognized and respected by the agency in its licensing agreements.

[171] This provision could not have been invoked during the COVID-19 pandemic, because there was massive production of the COVID-19 vaccine doses. Approximately 12 billion doses had been manufactured by the end of 2021, almost double the global population. *See* Adam Mossoff & Amesh Adalja, *Patents as a Driver of the Unprecedented Biomedical Response to COVID-19*, 59 INQUIRY: THE JOURNAL OF HEALTH CARE ORGANIZATION, PROVISION, AND FINANCING (2022), https://journals.sagepub.com/doi/10.1177/00469580221124819. It is estimated that approximately 24 billion vaccine doses were produced in 2022. *Id.*

[172] Section 203(a)(3) also authorizes the march-in power when a patent owner or licensee fails to meet the statutory conditions of § 204 (a mandate of manufacturing the product in the U.S.).

In 2016, the Congressional Research Service identified six petitions submitted to the NIH requesting it to exercise its march-in power solely for the purpose of lowering prices of patented drugs sold in the healthcare market.[173] The NIH denied all six petitions on the grounds that § 203, as confirmed by the NIH's prior interpretation of this statutory, did not permit the march-in power to be used for the purpose of lowering drug prices.[174] By 2019, four more petitions had been filed with the NIH by policy organizations and activists, each requesting again that the NIH invoke the march-in power for the sole purpose of lowering drug prices.[175] As with the prior six petitions reaching back to the 1990s, the NIH rejected these petitions on the statutory ground that "the use of march-in to control drug prices was not within the scope and intent of its authority."[176]

In 1997, for example, the NIH was petitioned to invoke the march-in power for the Isolex 300, a patented medical device used in organ transplant procedures.[177] The NIH rejected the petition for failing to meet the burden of proof that any of the four distinction march-in conditions specified in § 203 had been triggered, authorizing the NIH to march in and license other companies to make and sell this medical device in the healthcare market. The NIH found that the Isolex 300 was being commercialized in the marketplace: the patent owner was actively licensing the patented device, seeking regulatory approval, and meeting research demands.[178] These facts precluded the triggering of the march-in power under the four authorizing conditions in § 203.

The NIH went further and explained why the price-control theory of the Bayh-Dole Act was not justified by the plain text of § 203 and the function of the Bayh-Dole Act in promoting the commercialization of patented inventions. The NIH stated that, even if the petitioner proved that there would be greater accessibility and *lower prices* given additional licenses from the NIH invoking the march-in power, this was by itself insufficient authorization under § 203.[179] The NIH stated emphatically that the march-in power in § 203 did not exist for the purpose of "forced attempts to influence the marketplace."[180] It acknowledged the inherent conflict between the function of the Bayh-Dole Act in promoting and commercializing new innovations and the adoption of the march-in power for the purpose of imposing price controls, observing that "such actions may have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies."[181] This was not merely a freestanding policy assessment by the NIH of this petition; it derived this conclusion from the plain meaning of § 203 within the context of the Bayh-Dole Act and its commercialization function.

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[173] *See* John R. Thomas, *March-In Rights Under the Bayh-Dole Act* 8-10 (Congressional Research Service, Aug. 22, 2016).

[174] *Id*.

[175] *See Return on Investment Initiative for Unleashing American Innovation*, *supra* note 4, at 29.

[176] *Id*.

[177] *See, e.g.*, NIH Office of the Director, *Determination in the Case of Petition of CellPro, Inc.* (Aug. 1, 1997), https://www.ott.nih.gov/sites/default/files/documents/policy/cellpro-marchin.pdf (rejecting petition in part to invoke march-in power given argument that company was too slow in bringing a medical device to market).

[178] *Id.*

[179] *Id.*

[180] *Id.* at 7.

[181] *Id.* at 7.

Another petition in 2004 again requested that the NIH invoke the march-in power in § 203 to license a patent specifically to lower the price for Norvir, a drug used to treat AIDS. Again, the NIH rejected the petition.[182] The NIH explained that "the extraordinary remedy of march-in is not an appropriate means of controlling prices," and that "[t]he issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively."[183]

Applying the classic rule, "if at first one does not succeed, try, try again," another petition was submitted to the NIH in 2013 asking it again to invoke the march-in power in § 203 for the purpose of lowering the price of Norvir sold by AbbVie to consumers in the healthcare market. The NIH again rejected the petition, stating that the imposition of price controls on drug patents was not a statutorily authorized march-in power in § 203 of the Bayh-Dole Act.[184] The NIH bluntly concluded: "As stated in previous march-in considerations the general issue of drug pricing is appropriately addressed through legislative and other remedies, not through the use of the NIH's march-in authorities."[185] The frustration by NIH officials with the serial petitions seeking to impose price controls on drug patents via the march-in provision in the Bayh-Dole Act is palpable.

Lastly, on March 21, 2023, the NIH rejected the latest petition (filed again) for this agency to invoke the march-in power solely to lower the price of Xtandi, a cancer drug covered by patent.[186] In its latest rejection of the price-control theory of the Bayh-Dole Act, the NIH reiterated that the "purpose of the Bayh-Dole Act is to promote commercialization and public availability of government-funded inventions."[187] With this statutory framework and purpose in mind, the NIH expressly "found Xtandi to be widely available to the public on the market" and "[t]herefore, the patent owner, the University of California, does not fail the requirement of bringing Xtandi to practical application."[188] The NIH further pointed out that this decision about Xtandi is consistent with its prior multiple rejections of march-in petitions also seeking to lower drug prices.[189] It also recognized that the administrative processes and delays, especially in light of Xtandi's remaining patent term, led it to conclude that "NIH does not believe that use of the march-in authority would be an effective means of lowering the price of the drug."[190]

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[182] *See* NIH Office of the Director, *In the Case of Norvir Manufactured by Abbott Laboratories, Inc.* (July 29, 2004), http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

[183] Dr. Elias A. Zerhouni, Nat'l Institute of Health, *Determination in the Case of Norvir I*, at 5-6 (July 2, 2004).

[184] NIH Office of the Director, *In the Case of Norvir Manufactured by AbbVie* (Nov. 1, 2013), https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf.

[185] *Id.*

[186] *See* Letter from Lawrence A. Tabak, Performing the Duties of the NIH Director, to Robert Sachs and Clare Love, *supra* note 5.

[187] *Id.* at 2.

[188] *Id.*

[189] *Id.*

[190] *Id.*

The NIH's multiple decisions over several decades in interpreting the scope of the march-in power granted to it under § 203 is significant evidence that the price-control theory of the Bayh-Dole Act is without basis in the statute. The eleven or more decisions ranging from the 1990s through 2023 in which the NIH has consistently rejected march-in petitions requesting it impose price controls on drug patents under § 203 constitute "the well-reasoned views of the agenc[y] implementing a statute [that] 'constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.'"[191] The Supreme Court has "long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer."[192]

E. The Supreme Court Has Rejected Agencies' Claims to Unprecedented Powers Similar to the Price-Control Theory of the Bayh-Dole Act

The Supreme Court's 2022 decision in *West Virginia v. Environmental Protection Agency* confirms the significance of the NIH's repeated interpretation of § 203 over several decades.[193] As the NIH has repeatedly stated, the march-in power is an "extraordinary" act that is "not an appropriate means of controlling prices" and that proponents of price controls on drug patents must look to "Congress to address legislatively" the power to achieve this goal.[194] The power to impose price controls on drug patents is simply the delimited conditions set forth in § 203 of the Bayh-Dole Act. The price-control theory of the Bayh-Dole Act argues that federal agencies can take the extraordinary and unprecedented administration action in imposing price controls on drug patents solely on the basis of an inference of implied authority from generalized language in two distinct clauses construed in isolation within the entire statute. It would be unprecedented for a federal agency to impose price controls on drugs produced and sold by private companies to consumers and patients in the healthcare market solely on the basis of statutory text stating only that a lack of "reasonable terms" represents a failure of "practical application" of a drug patent.[195]

West Virginia closes the door on this broad-based argument for unprecedented agency power to impose price controls on drug patents absent explicit authorization in § 203.[196] This was not the first time the Supreme Court rejected an argument for discretionary administrative power based in generalized, out-of-context statutory phrases in the governing statute. In *Food & Drug Administration v. Brown & Williamson Tobacco Corporation,*[197] the Court assessed the FDA's broad-based construction of generalized, out-of-context phrases in its governing statute to justify its unprecedented assertion of power to regulate cigarettes. The *Brown & Williamson* Court rejected the FDA's "'expansive construction of the statute,' concluding that 'Congress could not

[191] *See* United States v. Mead Corp., 533 U.S. 218, 227 (2001) (quoting Bragdon v. Abbott, 524 U.S. 624, 642 (1998) (quoting Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)))

[192] *Chevron*, 467 U.S. at 844.

[193] *See* West Virginia v. Environmental Protection Agency, 142 S. Ct. 2587 (2022).

[194] *See supra* notes 183-185, and accompanying text.

[195] *See supra* note 138-141, and accompanying text (explaining the statutory interpretation set forth by the price-control theory of the Bayh-Dole Act).

[196] *See West Virginia*, 142 S. Ct. at 2609.

[197] Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

have intended to delegate' such a sweeping and consequential authority 'in so cryptic a fashion.'"[198] This conclusion applies with equal force to the price-control theory of the Bayh-Dole Act, which engages in an "expansive construction of the statute" to justify a "sweeping and consequential authority" based entirely in generalized "cryptic" statutory language.[199]

F. The Price-Control Theory was Rejected by the Namesakes of the Bayh-Dole Act

The price-control theory of the Bayh-Doel Act was allegedly "discovered" by two professors more than two decades after the enactment of the Bayh-Dole Act,[200] which reconfirms the applicability of the fundamental principles of statutory interpretation and constitutional law that limit agency powers, as stated in *Brown & Williamson*, *West Virginia*, and in other cases.[201] The eponymous sponsors of the Bayh-Dole Act agree. Senator Birch Bayh and Senator Robert Dole expressly rejected the price-control theory of the Bayh-Dole Act.

Similar to the *New York Times* editorial in 2021 advocating for the price-control theory of § 1498, which was prompted by a 2016 law journal article,[202] Professors Arno and Davis published an op-ed in the *Washington Post* in 2002 restating their argument from their law journal article the year before that the Bayh-Dole Act mandates that patented inventions resulting from "federal funds will be made available to the public at a *reasonable price*."[203] Professors Arno and Davis' op-ed prompted a response from Senators Bayh and Dole, published as a letter to the editor in the *Washington Post* two weeks later:

> 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. . . . The [Arno and Davis] article also mischaracterizes 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 the 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.[204]

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[198] *See West Virginia* 142 S. Ct. at 2608 (quoting Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 159 (2000)).

[199] *Brown & Williamson*, 529 U.S. at 159.

[200] *See supra* note 128, and accompanying text.

[201] *See* Alabama Ass'n of Realtors v. Dep't of Health and Human Services, 141 S. Ct. 2485, 2487 (2021) (rejecting the Center for Disease Control's moratorium on rental evictions given the "wafer-thin reed" of support in its organic statute's text and the "unprecedented" nature of the asserted regulatory power).

[202] *See supra* notes 37-40, and accompanying text.

[203] *See* Peter Arno & Michael Davis, *Paying Twice for the Same Drugs*, 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/ (emphasis added).

[204] Birch Bayh and Robert Dole, *Our Law Helps Patients Get New Drugs Sooner*, Wash. Post (Apr. 11, 2002), https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/.

In sum, there is no "clear congressional authorization" in § 203 that grants federal agencies power to impose price controls on patented products or services that are commercialized in the marketplace.[205] Beyond the plain text of § 203, the price-control theory of the Bayh-Dole Act contradicts the function of this statute in promoting the commercialization of inventions by patent owners in the marketplace.[206] The NIH has confirmed this lack of express statutory authorization in § 203 to impose price controls in its consistent, repeated rejections of numerous march-in petitions over several decades that have sought use of this power solely to lower drug prices. Although it does not have the same legal status as the canons of statutory interpretation and official interpretation and application of a statute, Senators Bayh and Dole make clear that the price-control theory of the Bayh-Dole Act proposes an unprecedented assertion of agency power to control prices in private market transactions between private parties given only generalized, out-of-context statutory phrases like "practical application" and "reasonable terms."

IV. Conclusion

For at least five decades, a significant policy debate over drug prices has waxed and waned in the U.S. Initially, this was principally a debate only in healthcare policy. In recent decades, the patent system has been drawn into this sometimes heated debate with scholars and activists arguing that drug patents are a primary cause of what they contend are unacceptably high drug prices.[207] They argue that the federal government can break patents and impose price controls on drug patents. They assert that two federal laws—§ 1498 and the Bayh-Dole Act—are an "important tool" authorizing federal agencies to achieve their policy goal of imposing price controls on drug patents.[208]

This is a false promise. The price-control theories of § 1498 and the Bayh-Dole Act represent policy arguments superimposed on two statutes by advocates seeking a quick-and-easy path to justifying an unprecedented regulatory policy—the imposition of price controls on drug patents. Since 1790, Congress has considered proposals for various forms of compulsory licensing of patents, and Congress has consistently rejected these proposals.[209] Perhaps recognizing this significant hurdle in proposing an unprecedented—and expressly rejected—policy proposal for

[205] *See supra* notes 145-157, and accompanying text (describing the text in § 203 and the lack of any express authorization to control or delimit prices).

[206] *See supra* notes 159-172, and accompanying text (applying the canon of statutory interpretation that § 203 must be construed within the entire context of the Bayh-Dole Act).

[207] *See supra* note 3, and accompanying text (detailing this policy argument).

[208] *See supra* note 18, and accompanying text.

[209] *See, e.g.*, BRUCE W. BUGBEE, GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW 143-44 (1967) (discussing the rejection of a Senate proposal for a compulsory licensing requirement in the bill that eventually became the Patent Act of 1790); Kali Murray, *Constitutional Patent Law: Principles and Institutions*, 93 NEB. L. REV. 901, 935-37 (2015) (discussing a congressional bill in 1912 requiring compulsory licensing for patent owners not manufacturing a patented invention, which received twenty-seven days of hearings, but was not enacted into law).

price controls on drug patents, advocates attempt to bootstrap their policy arguments by arguing that Congress has already approved of a price-control policy in two existing federal statutes.

The price-control theories of § 1498 and the Bayh-Dole Act are profoundly mistaken. Neither § 1498 nor the Bayh-Dole Act authorize agencies to impose price controls on drug patents for the purpose of lowering drug prices. This is confirmed by their plain text, their consistent interpretation by courts and agencies, by principles of constitutional law, and by extra-textual sources of statutory meaning. Ultimately, the price control theories of § 1498 and the Bayh-Dole Act engage in interpretative acts of legerdemain that essentially pull a price-control rabbit out of statutory hat to proclaim, "Voila, lower drug prices through price controls on patents!"

This article has not addressed the policy arguments for or against price controls on drug patents, but only because advocates for price controls have chosen to advance as their primary argument a seemingly straightforward claim about statutory authorization—the price-control theories of § 1498 and the Bayh-Dole Act. This requires engaging in rigorous analysis of the meaning of these respective statutes as a necessary first step before engaging with the normative arguments based on the price-control theories of § 1498 and the Bayh-Dole Act. Ultimately, policy advocates should be careful not to replace rigorous normative justifications with statutory claims that are the equivalent of "law office history"—the practice by legal actors of using isolated, out-of-context historical facts in the service of modern policy arguments.[210] The price-control theories of the Bayh-Dole Act and § 1498 are policy arguments masquerading as statutory construction. It is time to lay these legal myths to rest and to have a forthright policy debate.

[210] Larry D. Kramer, *When Lawyers Do History*, 72 GEO. WASH. L. REV. 387, 389-94 (2003) (criticizing bad historiography of lawyers, who produce "law office history" intended only "to generate data and interpretations that are of use in resolving modern legal controversies" (citations omitted)).

Submission Date: 7/27/2023

Name: Brian O'Shaughnessy

Name of Organization: Licensing Executives Society (USA & Canada), Inc.

Comment:

Dear Colleagues:

The Licensing Executives Society (USA & Canada), Inc. appreciates the opportunity to submit comments for NIH consideration in relation to its "Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer." Our comments are attached.

Please feel free to contact me with any questions.

Respectfully submitted,

--Brian

Dinsmore

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July 27, 2023

Lyric Jorgenson, Ph.D.
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Dear Director Jorgenson:

On behalf of the Licensing Executives Society (USA & Canada), Inc., we appreciate the opportunity to provide comments in advance of the National Institutes of Health's upcoming workshop, *Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer*.

LES is an independent, non-profit, non-partisan, professional association devoted to the commercialization of inventions and intellectual property through education, networking, standards development, and certification. We are the leading professional organization devoted to the industry of technology licensing -- that is, technology-related commercial transactions involving patents, trade secrets, know-how, trademarks, and copyrights. Our members come from across the innovation economy and include business executives, technology transfer professionals, IP experts, and entrepreneurs representing diverse industries, including life sciences.

We commend NIH for convening this workshop and engaging in an important discussion on efficient and effective development of federally funded discoveries. A fully functional innovation ecosystem requires an array of funding and market-based incentives to transform experiments into commercial products. Our members rely on the market-based incentives to justify the assumption of risk and investment inherent in commercially developing the basic research done at research centers like NIH. Absent those incentives, government funded discoveries will not be licensed by private enterprise for commercial development, and the public will derive no benefit from the federal funding of such basic research.

Such was the case less than a half-century ago. At that time, the federal government retained the patent rights in any invention made with the assistance of any federal funds, and often provided only non-exclusive licenses. As a result, private enterprise

was reluctant to invest in the transformation of such basic research into viable commercial products. Economists refer to it as the free-rider phenomenon. Innovators know that without some form of protection, imitators will enter the market, and, without the same costs of development, depress prices to the point only the imitator can bear, and drive the innovator out of the very market the innovator created.

As a result of such concerns, promising scientific discoveries from research centers like NIH were passed over and left undeveloped, wasting taxpayer dollars, and depriving us all of the benefits of products derived of those discoveries.

The Bayh-Dole Act and the Federal Technology Transfer Act (Stevenson-Wydler Act) addressed that problem, and opened up a new era of vibrant, productive public-private partnerships. These laws granted universities, small businesses, and federal labs proprietary rights to inventions made with any amount of federal funding, enabling them to exclusively license those discoveries to private enterprise for development, and ultimately commercialization. As a result of those licenses, universities, small companies, and federal labs earn royalties, providing the resources needed to fund additional research, reward inventors, and enter into cooperative research and development agreements (CRADAs).

These laws fostered fruitful collaboration combining the extensive theoretical knowledge of the country's leading academics and government scientists with the business acumen and resources of the private sector. In the years since, countless licensing deals and associated sponsored research has given the public the benefit of products developed from those discoveries. Technology transfer to the private sector from our universities alone led to nearly 800 new commercial products in 2021.[1] These products, and many more, have had profoundly beneficial effects on our quality of life.

As the NIH contemplates ways to further improve technology transfer, we urge the agency to uphold the original intent and structure of Bayh-Dole and the Federal Technology Transfer Act. Specifically, we urge NIH to reject initiatives that would seek to exploit these valuable relationships with industry to impose price controls.

Some of those initiatives would condition the development of those technologies on a commitment to make resulting products available at a "reasonable price." But since no one knows at such an early stage what the resulting products will be, how much time and effort is required to get to a commercial product, or who will decide what constitutes a reasonable price,

[1] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-2021_1.pdf pg. 2

industry will not take the deal. As a result, groundbreaking technologies will be left undeveloped, doing no one any good.

Instead, NIH should do what it did most recently in March 2023 on the drug Xtandi. There the NIH rejected efforts to impute to NIH the role of a super-regulator of the pharmaceutical market. NIH had been petitioned, as it had in the past, to use the carefully defined, narrowly constructed "march-in" power to revoke carefully crafted agreements with private enterprise relating to Xtandi. The petitioner had argued that because the petitioner deemed the price of Xtandi to be excessive, NIH should distort the purpose of march-in to permit others to make and sell the drug at a lower price. But the march-in power was never meant to be a mechanism for price controls, and NIH lacks the expertise to second guess the pharmaceutical market. Thus, NIH again refused to invoke the march-in power for purposes of price controls.[2] Among other things, NIH seems to have recognized that federal labs should do what they do best - research, and let markets control prices. Indeed, the authors of the Bayh Dole Act themselves expressly rejected the proposition that the march-in power could be used for purposes of price controls.[3]

If NIH were to adopt the role of price regulator after the fact, whether through reasonable price provisions or march-in, private enterprise would be ever more reluctant to license federally funded discoveries for commercial development – undermining decades of successful collaboration between government, university, and private sector partners.

This is not mere speculation. We've run this experiment before, and the results are clear. In response to political pressure, in 1989 NIH began imposing reasonable pricing clauses in its CRADAs, licenses, and extramural research grants and contracts. This contractually bound licensees to set a reasonable price for any product that was developed under the license. However, after running this reasonable pricing experiment for six years, and after conducting an extensive study on its effect on potential licensees, the NIH Director eliminated the practice, stating that it had "driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public."[4]

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[2] https://www.aamc.org/advocacy-policy/washington-highlights/nih-declines-march-cancer-drug-nist-releases-new-bayh-dole-regulations

[3] https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=lk_inline_manual_11

[4] https://bayhdolecoalition.org/wp-content/uploads/2023/06/CRADA-QA-Nov-2021-FINAL.pdf pg. 2

NIH should make every effort to avoid resurrecting failed price control policies and practices. The greatest potential for public benefit derived of federally funded discoveries resides in our patent system, and in reliable and durable license agreements under the Bayh-Dole Act and the Federal Technology Transfer Act. The prospect that those agreements will be unilaterally altered or revoked after the fact will only drive industry away and deprive the public of the benefits of that research. The choice is simple: either protect patent rights and associated licenses that promote technology transfer and product development, or resurrect failed practices that will stunt U.S. biomedical innovation for years to come.

Thank you for this opportunity to comment. LES looks forward to further engaging with NIH on this important matter both now and in the future.

Respectfully submitted,

Brian P. O'Shaughnessy

Sr. V.P., Public Policy
Licensing Executives Society (USA and Canada), Inc.

Submission Date: 7/27/2023

Name: Lizbet Boroughs

Name of Organization: Association for American Universities & COGR

Comment:

Dear Dr. Jorgenson,

On behalf of AAU and COGR, I am pleased to submit our joint comments for consideration during the NIH's upcoming workshop, "Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer. "

My best,

Lizbet Boroughs, MSPH
Associate Vice President for Federal Relations
Association for American Universities (AAU)

Additional Comment (attachment):

To: Lyric Jorgenson, PhD
Acting Director, Office of Science Policy, and Acting Associate Director for Science Policy
National Institutes of Health

From: Kate Hudson, JD, Associate Vice President and Counsel, AAU
Lizbet Boroughs, MSPH, Associate Vice President of Federal Relations, AAU
Robert Hardy, Director of Research Security & Intellectual Property Management, COGR

Date: July 27, 2023

Re: Comments on NIH's Workshop: Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer, July 31, 2023

The Association of American Universities (AAU) and COGR appreciate the opportunity to share input on the ongoing discussion regarding NIH's levers to catalyze technology transfer. AAU is an organization of 71 leading U.S. and Canadian research universities that transform lives through education, research, and innovation. COGR is an association of over 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR focuses on the impact of federal regulations, policies, and practices on the performance of research conducted at our member institutions, and we advocate for sound, efficient, and effective regulation that safeguards research and minimizes administrative and cost burdens.

Our combined member universities comprise the majority of competitively awarded federal funding for research that improves public health, seeks to address national challenges, and contributes significantly to our economic strength, while educating and training tomorrow's visionary leaders and innovators. Additionally, many of our member institutions operate hospitals and affiliated health systems throughout the U.S. and are themselves large-scale purchasers of drugs and therapies developed for patients by the commercial market. AAU and COGR member institutions represent multiple stakeholder positions in the NIH research and commercialization lifecycle.

As in all ecosystems, changes to one part of the ecosystem affect other parts as well. Disruptions to the current innovation ecosystem that are hastily designed and implemented will have ripple effects which will discourage research partnerships between federally funded researchers, industry, and other important players in the technology transfer pipeline. Such changes in policy and practice must be done in a deliberate manner to ensure the effectiveness and longevity of the technology transfer and U.S. innovation system. To do otherwise would jeopardize U.S. leadership in biomedical research and innovation, to the detriment of the American people and the world.

In addition to providing these written comments today, our associations echo the sentiments submitted to this solicitation by AUTM, the non-profit leader in efforts to educate, promote and inspire professionals to support the development of academic research that changes the world and drives innovation forward.

The American Innovation Ecosystem & the Role of the NIH

The United States leads the world in novel biomedical innovation, thanks in large part to strong and sustained government support for research, strong research universities, talented researchers, efficient drug approval processes, and a pricing system that enables companies to earn sufficient revenues to reinvest in future generations of innovation. [1] Indeed, the Bayh-Dole Act, combined with sustained government support for research at NIH, has helped to ensure U.S. competitiveness in biomedical research and technology. It remains critical that this existing policy apparatus and federal support be maintained and strengthened.

The pathway from discovery to commercialization is a years, often decades-long process. The average length of development is 10-15 years from identification of a biomarker to development of a medication through regulatory approval process to market distribution. The expected cost to develop a new drug—including capital costs and expenditures on drugs that fail to reach the market—has been estimated to range from slightly less than $1 billion to more than $3 billion, with many different factors that determine the necessary levels of investment. Detailed case studies reveal that public support has played at least some role in virtually all of the 26 most clinically and commercially significant drugs and drug classes approved over the past several decades.[2, 3]

NIH's investments in university-based basic research are a part of the innovation ecosystem, setting the stage for the industry-led applied research and development activity that leads to the commercialization of new medicines and treatments. Broad scientific endeavors such as the Framingham study, the Human Genome Project, and research on vaccine development have helped catalyze the identification of novel approaches to improve diagnostics and treatments.[4] The Framingham study led to the identification of cholesterol as a factor for cardiac disease and the development of medications to mitigate risks for strokes and heart attacks.[5] The Human Genome Project, among many other things, facilitated

[1] Ezell, S, The Bayh Dole Act's Vital Importance to U.S. Life-Sciences Innovation System, Information Technology & Innovation Foundation, 2019.
[2] Wouters, OJ, McKee, M, Luyten, J: Estimated Research and Development Investment Needed to Bring New Medicines to Market, 2009-2018. *JAMA*. 2020; 323 (9): 844-853.
[3] NASEM 2020 Workshop "The Role of NIH in Drug Development Innovation and its Impact on Patient Access" National Academies of Sciences, Engineering, and Medicine. 2020. The Role of NIH in Drug Development Innovation and Its Impact on Patient Access: Proceedings of a Workshop. Washington, DC: The National Academies Press. https://doi.org/10.17226/25591.
[4] Collins, Francis S., Opportunities for Research and NIH. *Science* 327,36-37(2010). DOI:10.1126/science.1185055
[5] Franklin, S. S., and Wong, N. D. (2013). Hypertension and cardiovascular disease: contributions of the Framingham heart study. *Global heart*, *8*(1), 49–57. https://doi.org/10.1016/j.gheart.2012.12.004

improvements in cancer diagnoses through the identification of genetic variants[6]. Decades-long research on vaccine efficacy helped catalyze mRNA approaches to vaccine development[7], which allowed Operation Warp Speed to develop, test, and bring to market revolutionary vaccines in response to COVID-19.

NIH's support for basic research related to the biological target, rather than the development of a specific drug, is consistent with its national service and public health mission to promote and facilitate pre-competitive research aimed at advancing the health and well-being of the American people. NIH has historically remained removed from the drug development and marketing process, which should be rightfully left up to private industry. This is why, of the 356 drugs approved and brought to market from 2010 to 2019, all were brought to market in the United States by a biopharmaceutical company, rather than by an academic, governmental, or non-governmental organization.[8]

Role of University-Industry Collaboration

Universities are hubs for research, discovery, and innovation. Very often, academic researchers identify a new idea or concept that has potential for development into a commercial product. University-industry collaborations and partnerships are critical for realizing the public benefits of federally funded research. Initial discovery is critical, but potential impact for the public requires proof that concepts work in humans and years of further investment and development by industry. The expertise, infrastructure, and capital required to bring a medication or technology to commercial market is most often a function of industry investment, which neither the federal government nor research universities are able to bear.

Technology transfer of NIH-funded research between universities and industry allows research to catalyze into the development of potential biomedical innovations. Technology transfer can be operationalized through a variety of mechanisms, such as licensing agreements, assignment of intellectual property rights, material transfer agreements, and collaborative research agreements. The most utilized technology transfer vehicle is licensing.

Examples of technology transfer success stories from universities to industry partnerships leading to biomedical innovation include:

- Emory's development of an HIV medication that disrupts viral DNA from replicating. Emory licensed its discovery in 1996 to a biotech company for further development. Emtriva™ was eventually brought to market in 2003 by Gilead pharmaceuticals.[9]

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[6] Hood, L., Rowen, L. The Human Genome Project: big science transforms biology and medicine. *Genome Med* 5, 79 (2013). https://doi.org/10.1186/gm483

[7] Clin, J., Invest. 2021;131(19):e153721. https://doi.org/10.1172/JCI153721.

[8] Cleary, Ekaterina, Jackson, Matthew J. and Ledley, Fred, Government as the First Investor in Biopharmaceutical Innovation: Evidence From New Drug Approvals 2010–2019 (August 5, 2020). Institute for New Economic Thinking Working Paper Series No. 133 https://doi.org/10.36687/inetwp133

[9] Schinazi, R., & Liotta, D. (n.d.). *HIV Antiretrovirals*. Emory University Office of Technology Transfer. http://www.ott.emory.edu/about/success/hiv.html

- University of Wisconsin Madison researchers developed a synthetic form of Vitamin D to better control calcium imbalance in patients on kidney dialysis. Paricalcitol (sold commercially as Zemplar™) was brought to market by AbbVie Inc.[10]
- University of California, Berkeley researchers searched for ways to suppress the proliferation of melanoma cells by activating the patient's own immune response.[11] Researchers identified a checkpoint molecule (CTLA-4) that suppressed immune response to cancer cells. When CTLA-4 was targeted by monoclonal antibodies, immune cells could better attack cancer cells. Over a decade later following investments by four companies, Yervoy™ was approved by the FDA.[12]

Placing Arbitrary Pricing Constraints on Potential Commercial Products Will Disrupt Innovation

There is a long history of discussions to include "reasonable pricing" provisions by the NIH Patent Policy Board. In 1989, provisions were adopted to address the pricing of products licensed from federal health research agencies. Reasonable pricing clauses, as has been demonstrated previously by NIH policies from 1989-1996, create an untenable risk calculation to investors and collaborators which discourage them from tapping into federally supported research discoveries made at universities. Given the cost of developing and bringing a medication to market, companies have been and will continue to be reluctant to enter a "reasonable pricing" agreement with the NIH years before a medication has proven that it can be successfully commercialized.

As NIH is aware from other efforts to impose price controls on medications, there is a tradeoff between prices and innovation. The Congressional Budget Office estimated that a legislative proposal introduced by Rep. Nancy Pelosi (D-CA) The Lower Drug Costs Now Act of 2019 (H.R. 3), would reduce the number of drugs available for the market over the next 10 years.[13]

Current calls for Congressional scrutiny of potential levers to reduce the cost of medications, specifically challenges to provisions of the Bayh-Dole Act, will detrimentally disincentivize investment and collaboration as it relates to federally funded research and university-industry partnerships. Without economic incentives to further research, develop, and clinically test university discoveries through private investment, those discoveries will remain in the laboratory and not proceed to the commercial

[10] University of Wisconsin Madison. (2008). Synthetic vitamin D protects bone strength in kidney failure patients. Better World Project. https://autm.net/about-tech-transfer/better-world-project/bwp-stories/paricalcitol-zemplar%E2%84%A2

[11] Fernandes, M. P., Oliveira, C., Sousa, H., & Oliveira, J. (2023). New Approaches in Early-Stage NSCL Management: Potential Use of PARP Inhibitors and Immunotherapy Combination. *International journal of molecular sciences*, *24*(4), 4044. https://doi.org/10.3390/ijms24044044

[12] Hoos, A., Ibrahim, R., Korman, A., Abdallah, K., Berman, D., Shahabi, V., Chin, K., Canetta, R., & Humphrey, R. (2010). Development of ipilimumab: contribution to a new paradigm for cancer immunotherapy. *Seminars in oncology*, *37*(5), 533–546. https://doi.org/10.1053/j.seminoncol.2010.09.015

[13] Swagel, L. P. (2019, October 11). Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare. Washington, DC; Congressional Budget Office.

market. This will result in the creation and distribution of far fewer life-saving drugs and therapies for both the American people and the world.

In addition, these impacts will be concretely felt at the local and regional levels throughout the country, as university-industry collaborations would decline significantly. Because such collaborations attract capital and translate to a wide array of regional economic benefits at the campus level and beyond, the brunt of this impact will be felt not just in key metropolitan areas but in other more rural areas as well and will come at a time when catalysts for regional economic development in the innovation economy is a national economic priority and national security concern (i.e., regional innovation initiatives in the Inflation Reduction Act (IRA) and the CHIPS & Science Act via the National Science Foundation, and the Economic Development Administration (EDA) via the U.S. Department of Commerce).

NIH Levers to Catalyze Technology Transfer

NIH currently has additional levers at hand that may reduce costs in drug development and increase rates of commercialization success. Continued and increased support of these existing levers offers the optimal public policy solution for catalyzing technology transfer. These existing levers include:

- The NIH's National Center for Advancing Translational Sciences (NCATS) seeks to improve the "bench to bedside" translational process and utilizes a variety of tools such as streamlining enrollment in NIH-Funded clinical trials through the SMART IRB program and improved data collection.
- The development of additional artificial intelligence tools, approved by NIH, to help scientists analyze large data sets would improve identification of biomarkers that can be utilized by industry.
- Proposals to expand NCATS both in terms of personnel and role inside NIH would be effective in bringing greater knowledge and efficiency to biomedical translation.
- NIH's Centers for Accelerated Innovations (CAI) and its recently established REACH: Research Evaluation and Commercialization Hubs, which combine public-private expertise to evaluate and develop discoveries for commercialization has shown early promise in efforts to reduce the time period from discovery to therapeutic product.
- NIH's Small Business Innovation Research Program and Small Business Technology Transfer Program (SBIR/STTR) has expanded the provision of vital early-stage capital for technology transfer and commercialization efforts specifically in biomedical innovation. Additionally, recent enhancements to SBIR/STTR's guidance on partnership identification and business development have helped researchers in need of advice on how to better navigate the innovation pipeline.

Other federal agencies such as the Food and Drug Administration and the U.S. Patent and Trademark Office can work more closely with NIH stakeholders to enhance regulatory engagement during the drug development process. This could streamline and make the process of bringing a drug to market more efficient.

Conclusion

We strongly believe that building upon existing NIH programs, as well as cross-collaboration with other federal agencies to improve and streamline the research, regulatory, and approval processes, will bring the best outcomes in catalyzing technology transfer efforts by the NIH overall.

Thank you for the opportunity to engage with NIH regarding its role in the development pipeline. AAU and COGR look forward to future conversations on discovery, innovation and enhancing the health of the nation.

Submission Date: 7/27/2023

Name: Robert Taylor

Name of Organization: Alliance of US Startups and Inventors for Jobs

Comment:

Attached is my written statement for the NIH workshop entitled “Transforming Discoveries into Products: Maximizing NIH’s Levers to Catalyze Technology Transfer.”

I submitting this document as a signed version in PDF format, which includes a signature page and an Appendix. I also am submitting it in Word format without a signature or Appendix, should the agency need to alter the margins or pagination to incorporate into a larger document.

My contact information is below, if you have any questions.

Bob Taylor

PLEASE ACKNOWLEDGE RECIEPT

Robert P. Taylor
RPT Legal Strategies PC

Additional Comment (attachment):

ALLIANCE OF U.S. STARTUPS & INVENTORS FOR JOBS

Prepared Statement of Robert P. Taylor

General Counsel, Alliance of US Startups and Inventors for Jobs ("USIJ")
National Institutes of Health Workshop entitled
Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

My name is Robert P. Taylor, General Counsel for Alliance of U.S. Startups and Inventors for Jobs ("USIJ"). I am pleased with the invitation to appear as a public speaker during the subject workshop to present the views of USIJ and its constituencies, which comprise individual inventors, entrepreneurs, startups, and the investors that fund these entities. Many of USIJ's members and supporters are engaged in developing health care related products such as new drugs, medical devices and health care management tools. USIJ was founded nearly a decade ago to help inform government officials, members of Congress, and the Federal Judiciary regarding the role that patents play in promoting investments, development and technology transfers of these and other products that incorporate new technologies. By ameliorating some of the competitive risks associated with investments in startups and small companies, patents should play a key role in enticing venture capitalists and other investors to fund such activities, particularly in the area of pharmaceuticals, biotechnology and medical devices.

This USIJ cohort is currently responsible for the majority of new health care therapies and products, sometimes in collaboration with a larger company and other times on their own.[1] This is not to suggest that larger healthcare companies do not create new products on their own as well, but the inherent risks associated with investing in such products before they have full FDA approval often make it more attractive to wait until a smaller company has been successful in proving the science and scalability of making a product before committing funds for obtaining full FDA approval. Moreover, for a startup focused on a single technology, the risk of failure is far more likely to be existential than for a larger more diversified company. The key point from our perspective is that entrepreneurs, startups and small companies are an extremely important part of the healthcare ecosystem and present their own need for special consideration.

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[1] A study entitled "The US Ecosystem for Medicines: How new drug innovations get to patients," concludes that for the period 2011 to 2020, "55% of U.S. originated therapies were created by small biotech companies; 45% were created by large companies." https://vitaltransformation.com/2022/12/the-us-ecosystem-for-medicines-how-new-drug-innovations-get-to-patients.

Introduction.

NIH has long been at the forefront of American leadership in scientific research relating to the development of health-related products and services, and our citizens can be justifiably proud of the accomplishments of this agency. That is particularly so for the period since implementation of the bipartisan Bayh-Dole Act ("BDA") (35 U.S.C. §§ 200 – 209) in 1980, which unleashed a staggering amount of entrepreneurial zeal and creative energy. That outcome was entirely predictable because it is precisely the type of creative effort that – when properly incentivized – has driven American innovation since the founding of our republic. Prior to the implementation of the BDA, much of the scientific and technological research carried out by government agencies or developed pursuant to government grants to universities, research labs and others lay fallow in file drawers, notebooks and patents owned by either the government or the contractors that carried out the research. Although many if not most of the patents covering this government funded research were available for licensing, and a handful were in fact licensed, none of those licenses led to products that actually reached the market. This palpable lack of interest in commercializing products based on NIH research is informative – unless investors and private companies can actually own or control the technologies they bring to fruition, they are not likely to commit the time or money needed for this high risk undertaking. Simply put, what Congress learned after years of trying to interest private companies in using the inventions reflected by the patents on government funded research was that full ownership or exclusivity is an essential enticement without which there are far fewer takers, if any.

The BDA corrected this tragic waste of uncaptured value by allowing universities and research labs to own the patents that arise from their research efforts and to license those patents exclusively to private investors willing to provide the capital necessary to develop the manufacturing and delivery capabilities needed and to see the new products through the regulatory approval process.[2] As a result of these licensing relationships, the aftermath of the BDA has been the approval by FDA of hundreds of new drugs and medical devices, with many more in varying stages of completion.

To implement the objective of this workshop – "Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer" – I urge the agency to focus on those aspects of these public/private partnerships created under BDA that are most important in enticing companies to pour money and effort into moving beyond the science to create useful

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[2] The BDA, in Section 202, provides for contractor ownership of patents developed using government research grants. Exclusive licenses, depending on their specific terms, can be tantamount to full ownership. The primary feature of such licenses is that the patent owner is not allowed to license other entities to practice the patent, either within a designated field of use or at all.

products. Most everyone understands that startups, small companies, entrepreneurs and their investors make a major contribution to our nation's development of new products based on research funded by NIH (and other agencies as well). As noted above, more than half of all new drugs come from this cohort. What are not as widely understood are the motivating factors that incentivize and disincentive these entities to start down the lengthy and risky path that leads to the new products. I encourage NIH to examine these factors from the perspective of the entrepreneurs and scientists who will devote the time and energy needed to create a marketable product from a partially proven idea, and the venture capitalists and other investors who must provide the funds necessary to make this process work.

Risk of Failure.

An overarching consideration in the mind of any startup entrepreneur or investor is the high probability at the outset that the enterprise will fail, usually ending in the complete loss of invested time and money by the founders. There are many types of risk that all startups and their investors must contend with – *e.g.*, the technology that works in the lab may not work at a scale feasible for commercial production; the executive team may fail to execute on the business plan; funding may be discontinued before the process is completed as some investors reassess the prospects for success; a newer and better technology may come along that nullifies some or all of the business assumptions; the ultimate cost of production may exceed the achievable selling price; etc.

A particularly daunting risk facing the developers of any new drug or medical device is the enormous and unpredictable cost associated with the need for regulatory approval. It is not unusual for any new drug to require years of experimentation and research before it can be proven to be both effective as a treatment and safe for humans and animals, during which time the developer receives little or no revenue from the product. Although overall costs can vary widely, a new drug can easily require ten or fifteen years of development work and $2B or more from inception to final FDA approval.[3] Even for those drugs that turn out to be successful, the time value of money makes this type of investment even more expensive, particularly for venture capital firms that must show returns on their investments to remain in business. It is also the case that only about 10% of the drugs on which work is initially commenced ever reach the point of market approval, meaning that close to 90% of the initial efforts at drug development fail for

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[3] A report entitled "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," published in the Journal of Health Economics 47 (2016) describes a study of 106 new drugs developed by 10 different companies. The study estimates the average cost per drug at $1.4B without considering the time-value of the out-of-pocket investments. If a reasonable cost of funds is added, the total average cost is $2.8B per drug. https://pubmed.ncbi.nlm.nih.gov/26928437.

one of more of a variety of reasons, even after the science itself is proven and promising, because in clinical trials the product is either not safe or not effective or both.[4] Simply put, this is not an undertaking for the risk averse.

Price Controls Pose an Ongoing Existential Risk to Investing in Drug Development.

A foundational principle for investing in new drug development is that assumption of all the foregoing risks makes sense, if at all, only if the profitability of a successful venture is sufficiently attractive to cover the cost of the inevitable failures. Some critics of drug manufacturers are prone to look only at the product that successfully reaches the market and argue that the operating margin for the product is too high, leading to an uninformed insistence that NIH demand that products stemming from NIH funded research be sold at "reasonable prices." These arguments are wrong for a variety of reasons, most pointedly that bureaucrats have no idea as to what a reasonable price might be, because the actual cost of the risks assumed are not calculable. There are **theories** as to what might be a reasonable price for a specific drug, of course, but these calculations are not made by the people that, years earlier and during the development process, were willing to put up their own capital for funding the enterprise. The imposition of price controls after the fact is particularly damaging to investor confidence, because ownership or exclusive license rights to inventions are the primary basis for making the investments in the first place.[5] That is precisely why only a market-based system that allows the seller to price its product at a level of its own choosing can work effectively. Many startups go bankrupt trying to develop new products in areas dominated by established incumbents, and those that succeed must cover the cost of the failures or the investments will never be made in the first place.[6]

NIH's experience with the BDA actually confirms the difficulty in a governmental agency's efforts to inject itself into the arms-length bargaining that takes place in the real world.[7] NIH's

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[4] The study referred to in the previous footnote puts the success rate for the drugs studied at 11.83%. *Id.* at p.23.

[5] Indeed, the seemingly perpetual demands for price controls is, in itself, a risk factor that must be accounted for in an investor's assessment of whether to accept a license from NIH or a government contractor to develop a new drug.

[6] This should not be controversial. Investing in drug development is somewhat akin to wildcat drilling for crude oil, which has been a common way of locating potential subterranean pools of oil since the early 20th century. The profit from a successful well has to cover the cost of all the dry ones or the entire business model makes no economic sense. Current figures put the success rate at about 10% for on shore drilling, which is roughly on a par with success rates for drug development. https://knowledge.energyinst.org/search/record?id=115186

[7] The provisions in the recently enacted Inflation Reduction Act that give CMS the power to dictate prices have yet to take effect. It seems clear enough already, however, that to whatever extent CMS engages in these "negotiations," it is likely to reduce the number of new drugs that are available for Medicare patients and cause a

effort in 1989 to add a "reasonable price" provision to the licenses that were offered under the BDA had the effect of reducing the number of private enterprises that were willing to assume the risks of developing products under these licenses. In 1995, the agency removed the pricing requirement, acknowledging that the effort had been a mistake.[8] Investor interest thereafter rebounded, but no one will ever know what possible drugs might have been missed for lack of funding during the decline. Nevertheless, the siren song of price controls continues to waft through governmental circles periodically, as it seems to be doing currently, and must be rejected as the bad idea it has always been.

Governmental Contributions to Drug Research Are Grossly Overstated by Proponents of Price Controls.

Because the research for many new drugs is often initiated, in part, through basic scientific research funded by NIH or other governmental agency, we often hear arguments that this contribution gives the government the right to control the price or access to the drug once it is proven. This bogus argument reflects either pure ignorance or ideological foolishness – in either case it is preposterous in light the actual reality. Of course, a seminal research contribution by NIH may be an important contributor, but its principal value is to assist the recipient in attracting the private capital necessary to perform the vast majority of developmental work, assume virtually all of the risk, and bear the bulk (or all) of the cost. The fact is that the NIH contribution is but a tiny fraction of the total investment required to bring a new drug to market, with the remainder coming from investors with a large appetite for risky investments.

A study published in September 2022, entitled "The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals,"[9] showed that upwards of 95% of the total cost of developing a new drug to the point of clinical trials market is born by private investors, with the NIH contribution less than 5%. Moreover, for drugs that actually received FDA approval, the disparity is even more striking, with 98.5% of the total coming from private funding. For oncology drugs, the private contribution to cost is almost 99%. The study was based on NIH records covering the period between 1984 and 2021, during which NIH made 23,230 extramural grants for drug research, which in turn led to a total of 8126 patents that could be linked to discoveries funded by these grants. The study identified 41 therapies traceable to

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significant loss of jobs in the biopharma industry. https://vitaltransformation.com/2023/06/the-impact-of-ira-policy-expansion-proposals-on-the-us-biopharma-ecosystem

[8] https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf and https://ipwatchdog.com/2019/03/12/new-study-shows-bayh-dole-working-intended/id=107225

[9] Journal of Therapeutic Innovation & Regulatory Science (2023) Vol. 57:160 – 169. TIRS publishes peer-reviewed original research, review articles, commentaries, and letters to the editor on medical product discovery, development, regulation, access, and policy. https://www.springer.com/journal/43441

some portion of this universe of patents that reached the clinical trial stage successfully, and determined that 18 of the 41 received FDA approval. For the 41 therapies that underwent clinical trials, the aggregate contribution of NIH grants totaled $2.4B while the private contribution was $50.7B, or 95.5% of the total. This number did not include any post-approval contributions which make the disparity even greater. For drugs that actually received FDA approval, NIH funding accounted for $670M of the total cost while private sector investment totaled $44.3B or 98.5% of the total. Appendix A replicates Table 1 of the study listing all 41 therapies individually and showing the private versus public funding ratio for each.

The arguments favoring price controls – whether they come in the form of requests for the unlawful exercise of "march-in rights" that would distort the statutory language of 35 U.S.C. §203 or a request that NIH revert to the inclusion of a "reasonable price" requirement in its basic licenses to universities and other government contractors, as it did in 1989, are bereft of any proper basis in law or fact. Neither NIH nor any other government agency has any way of knowing or calculating what a "reasonable" risk-adjusted return should be, and the history of governmental efforts to control prices for the benefit of the public works out to have the opposite effect.[10] There is no more justification for NIH to try and control the price of drugs made under the BDA than there is for NIH or other government agency to argue that use of the federally funded interstate highway system entitles it to impose price restrictions on goods hauled to their destination that way; the suggestion is preposterous. This particularly so in light of the cost and risk factors discussed above and the need to attract new capital in order to have them at all.

Conclusion.

Apart from the brief (and unsuccessful) experiment in the early 1990s, NIH has successfully resisted numerous invitations to reinterpret the intent of Congress as to "march-in rights" or to impose unmanageable price restrictions on the universities and research labs that develop new therapies. Contrary to the false premise that this will lower drug prices for the benefit of the American public, we do not believe that to be the case. Were either of those efforts to succeed, the most likely outcome is that investment in new drug development will decline, as it did in the early 1990s, to the detriment of those that might need the drugs that never are discovered or developed.

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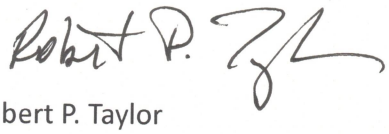
[10] The basic economic fallacy in attempts to control the price of goods or services is deftly explained by Robert L. Schuettinger in "Forty Centuries of Wage and Price Controls: How Not to Fight Inflation," published by Heritage Foundation (1979). https://cdn.mises.org/Forty%20Centuries%20of%20Wage%20and%20Price%20Controls%20How%20Not%20to%20Fight%20Inflation_2.pdf. The book recounts numerous historical examples of such efforts, dating back to the Code of Hammurabi, the Egyptian Pharaohs and continuing today, all notable failures.

Respectfully submitted,



Robert P. Taylor
General Counsel, USIJ
July 27, 2023

Table 1 Total Public (NIH) and Private Funding for Cohort of Forty-One Therapies.

Therapy	Total Public Funding ($ Mil)	Total Private Funding[a] ($ Mil)	Year Approved
IMMU-132 /(Trodelvy)	$0.850	$22,519.457	2020
Tysabri	$7.575	$8756.691	2004
Myalept	$8.332	$3179.600	2014
Nexavar	$5.305	$1384.030	2005
Stivarga	$5.072	$1384.030	2012
Bexxar	$6.616	$1093.400	2003
Zelboraf	$7.144	$1047.950	2011
Spinraza	$1.604	$965.400	2016
Emtriva/Genvoya	$6.407	$951.000	2003
RTA-408	$71.746	$850.000	–
Diamyd	$5.799	$639.000	–
Zarnestra	$16.380	$628.000	–
RcoPro	$104.354	$625.000	1995
CMX001	$4.151	$613.500	–
Surfaxin	$38.388	$558.140	2012
Ixinity	$3.598	$508.300	2015
DTX301	$124.321	$481.733	–
Obizur	$7.014	$400.000	2014
haNK	$5.143	$350.460	–
Neuradiab	$313.768	$326.600	–
Increlex	$1.172	$326.270	2005
Treg	$1.804	$325.000	–
Prochymal	$4.959	$279.250	–
Amdoxovir	$19.124	$245.000	–
Horizant	$453.074	$219.990	2011
PA-457	$10.773	$218.830	–
TNFerade	$197.250	$205.900	–
Daytrana	$4.151	$200.000	2006
V2006	$11.215	$184.270	–
Gencaro	$2.377	$174.955	–
ThermoDox	$79.250	$170.000	–
SR9025	$36.127	$160.000	–
Rintega	$314.546	$145.100	–
GI-5005	$2.788	$122.600	–
Tolsura	$5.401	$96.700	2018
RiVax	$1.717	$93.000	–
Levovir	$41.201	$73.500	–
AEOL 10,150	$64.835	$69.460	–
Combipatch/Vivelle-dot	$4.150	$65.000	1998
Oncoprex	$404.693	$34.120	–
MBX-400	$10.934	$0.000	–
Total	$2,415.108	$50,671.236	
Total (approved only)	$670.208	$44,280.958	

Private funding excludes post-FDA approval funding

Submission Date: 7/27/2023

Name: Cassidy Parshall

Name of Organization: Public Citizen

Comment:

Hello,

Please find attached comments from Public Citizen regarding the National Institutes of Health Office of Science Policy's July 31, 2023 workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

Thank you for the opportunity to provide written comments.

Sincerely,
Cassidy Parshall

Additional Comment (attachment):

PUBLICCITIZEN
1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

Public Citizen Comments to the National Institutes of Health re: Maximizing NIH's Levers to Catalyze Technology Transfer

July 27, 2023

Thank you for the opportunity to provide written comments regarding the National Institutes of Health (NIH) Office of Science Policy's July 31, 2023 workshop on policies and practices that shape biomedical innovation and promote access to NIH-funded discoveries.

Public Citizen is a nonprofit consumer advocacy organization with more than 500,000 members and supporters. Public Citizen's Access to Medicines Program works with partners across the United States and around the world to make medicines available for all through tools in policy and law.

Our comments will deliver two key messages:

- NIH has considerable power, and therefore responsibility, to improve affordable access to medicines in the United States and around the world.
- NIH's licensing policies, research and development (R&D) contract conditions, and rights under the Bayh-Dole Act are powerful tools to improve access to the medicines the agency helps develop.

NIH has considerable power, and therefore responsibility, to improve affordable access to medicines in the United States and around the world.

The United States government is the largest funder of biomedical research in the world, foremost through more than $40 billion dollars in annual funding of NIH, the vast majority of which supports extramural research at universities and other research

institutions.[1] Recent research found that NIH funding contributed to research associated with 354 out of 356 new drugs approved from 2010-2019, totaling $187 billion in public funding.[2] This extensive public investment in drug R&D gives the U.S. government and NIH significant power to condition the pricing and technology sharing behavior of manufacturers, and to facilitate access to publicly funded medicines.[3] In our view, the agency has underused these powers, with serious consequences for global health and costs to U.S. consumers. In a report released in June 2023 by the Majority Staff of the United States Senate Health, Education, Labor and Pensions (HELP) Committee, it was found that "the average (median) price of new treatments that NIH scientists helped invent over the past twenty years is $111,000."[4]

The federal government's early and robust investment in coronavirus research laid the foundation for the rapid development of many COVID-19 vaccine candidates.[5] In a 2020 report titled "Leading COVID-19 Vaccine Candidates Depend on NIH Technology," Public Citizen revealed that several first-generation candidates were using the 2P approach that was developed by NIH scientists.[6] Among these manufacturers, Moderna uniquely benefited from federal support. "We did the front end. They did the middle. And we did the back end," said Dr. Barney Graham, a former top NIH official, referring to the process for designing the spike protein sequence, manufacturing vaccines, and running clinical trials.[7]

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[1] Public Citizen, Civil Society Organizations Call on the Department of Health and Human Services to Combat Excessive Drug Prices, https://www.citizen.org/wp-content/uploads/cso-letter-to-biden-re-nih-director.pdf; https://www.nih.gov/about-nih/what-we-do/budget

[2] Comparison of Research Spending on Ekaterina Galkina Cleary, PhD1,2,3; Matthew J. Jackson, PhD1,4; Edward W. Zhou, PharmD1,4; et al. New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019. https://jamanetwork.com/journals/jama-health-forum/fullarticle/2804378

[3] *See* Robert Weissman, Public Citizen, 'Preparing for the Next Public Health Emergency: Reauthorizing the Pandemic and All-Hazards Preparedness Act,' https://www.citizen.org/wp-content/uploads/Weissman-Senate-HELP-testimony-5.4.23.pdf

[4] Senate Health, Education, Labor, and Pensions Committee, Majority Staff, 'Public Investment, Private Greed,' https://www.sanders.senate.gov/wp-content/uploads/Sanders-Public-Medicines-Report.pdf

[5] Zain Rizvi, Public Citizen, 'Blind Spot: How the COVID-19 Outbreak Shows the Limits of Pharma's Monopoly Model,' https://www.citizen.org/article/blind-spot/

[6] Zain Rizvi, Public Citizen, 'Leading COVID-19 Vaccine Candidates Depend on NIH Technology,' https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology

[7] 'Rich Countries Signed Away a Chance to Vaccinate the World,' https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html; Zain Rizvi, Public Citizen, 'Sharing the NIH-Moderna Vaccine Recipe,' https://www.citizen.org/article/sharing-the-nih-moderna-vaccine-recipe/

Despite significant taxpayer investment in the NIH-Moderna vaccine, the U.S. government failed to include safeguards for global access in its contracts with Moderna. The manufacturer went on to generate tens of billions in Covid vaccine sales while leaving the world with insufficient vaccine supply for more than a year. In a Public Citizen report, researchers showed that it was possible to manufacture enough vaccine for the world much more quickly – if the technology was shared by Moderna.[8]

Now Moderna is quadrupling the price of its Covid vaccines, which are expected to be needed annually.[9] This exceptional cost to U.S. consumers should have been avoidable. One approach would have been to include reasonable pricing provisions in the licenses NIH gave Moderna for use of government technology.

We appreciate the steps that the U.S. government and NIH have since taken to improve access to medicines globally. In 2022, President Biden announced licenses for 11 publicly owned medical technologies to the World Health Organization's (WHO) COVID-19 Technology Access Pool (C-TAP).[10] We commended this, noting that, "The announcement is a turn toward sharing not only doses, but knowledge, which is the difference between charity and justice. This path, if pursued with seriousness of purpose, can improve resilience to future pandemics and bring a measure of justice to a terribly unjust time." The collaborative research agreement between the National Institutes of Allergy and Infectious Diseases and South African manufacturer Afrigen is another positive step forward towards equitable access through sharing the latest science and technology.[11]

We call on NIH to shepherd global access and commit its full resources to this path of technology sharing by adopting licensing policies and R&D contract standards that proactively support medicines access. We believe it is both within NIH's power and responsibility to help ensure that taxpayers get a fair return on their investment while maximizing the impact of NIH's critical health technologies by making them available

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[8] Public Citizen, 'How to Make Enough Vaccine for the World in One Year,' https://www.citizen.org/article/how-to-make-enough-vaccine-for-the-world-in-one-year/

[9] Robert Weissman, Public Citizen, 'Preparing for the Next Public Health Emergency: Reauthorizing the Pandemic and All-Hazards Preparedness Act,' https://www.citizen.org/wp-content/uploads/Weissman-Senate-HELP-testimony-5.4.23.pdf

[10] NIH Makes COVID-19 Technologies Available to Global Manufacturers Through WHO Program, https://www.techtransfer.nih.gov/policy/ctap; https://www.who.int/initiatives/covid-19-technology-access-pool/us-nih-licenses

[11] Public Citizen, 'NIH-Afrigen Agreement Will Help WHO's Fight Against Pandemics,' https://www.citizen.org/news/nih-afrigen-agreement-will-help-whos-fight-against-pandemics/

equitably and globally.[12]

In a June 2022 letter to President Biden, Public Citizen and 20 other civil society organizations called for the nomination of an NIH Director who will "prioritize patient access and public health in their role as the world's premier steward of biomedical research." We noted that, "the NIH Director is empowered to remedy price gouging and access constraints through licensing competition using march-in and worldwide royalty-free rights. The NIH can also proactively support access by adopting upstream policies that build transparency and reasonable pricing conditions into funding and cooperative research and development agreements."

NIH's licensing policies, research and development contract conditions, and rights under the Bayh-Dole Act are powerful tools to improve access to the medicines the agency helps develop.

Licensing NIH-owned inventions

NIH can increasingly use licensing agreements to support global and equitable access to NIH technologies, including through reasonable pricing provisions and non-exclusive licensing practices.

The Bayh-Dole Act requires NIH and other government agencies granting partially-exclusive or exclusive licenses to U.S. government-owned inventions to ensure that the scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.[13] We urge NIH to take seriously this requirement and rigorously and transparently assess whether a license should be nonexclusive or have its exclusivity limited, for example, by omitting low- and middle-income countries from the geographic scope of exclusivity or by providing that a licensee will have its exclusivity curtailed or eliminated after certain revenue benchmarks have been achieved. Exclusive licenses grant corporations monopoly power, leading to high drug prices and in many cases rationing of essential medicines, where individuals or state programs cannot pay. As a result of monopoly pricing, Americans pay more than two-and-a-half times as much for prescription drugs than people in other countries.[14] One-in-

[12] Public Citizen, Letter to President Biden calling for a pro-access to medicines NIH Director, https://www.citizen.org/wp-content/uploads/cso-letter-to-biden-re-nih-director.pdf

[13] 35 U.S.C. § 209, Licensing Federally Owned Inventions. Knowledge Ecology International, Joint Comments by KEI, UACT, Social Security Watch and Health Gap on the proposed NIH Exclusive License in CAR Therapy to Lyell Immunopharma (Sept. 19 2019), https://www.keionline.org/31713.; Zain Rizvi, Public Citizen, 'Blind Spot: How the COVID-19 Outbreak Shows the Limits of Pharma's Monopoly Model,' https://www.citizen.org/article/blind-spot/

[14] RAND, Prescription Drug Prices in the United States Are 2.56 Times Those in Other Countries,

four Americans report they have been unable to afford their medicines.[15] Exclusivities can also throttle supply and allow companies to profiteer from taxpayer funded technologies.[16] If the government nonetheless grants an exclusive license, it should ensure that the exclusivity is appropriately limited as required under law.

Nonexclusive licenses should be the norm and leverage must be exercised at the outset to induce manufacturers to share technology, price reasonably, deliver transparently, and otherwise contribute to ensuring access. We appreciate NIH's nonexclusive licensing of the proline-substituted coronavirus spike protein. Nonetheless, NIH could have gone further to facilitate vaccine access, given its essential contribution. In a March 2021 letter to the Department of Health and Human Services and NIH, Public Citizen and other civil society organizations specified that the licensing agreement should "1. Empower the U.S. government to authorize manufacturing of mRNA-1273 – including by government-owned production facilities, 2. Require technology sharing with the World Health Organization to help ramp up global production, and 3. Include requirements for accessible pricing universally." These safeguards could have ensured that NIH technology maximized its impact on protecting public health in the United States and globally.

Additionally, NIH should work to identify qualified international licensees, and work closely on licensing and access strategies for key technologies with WHO and the Medicines Patent Pool. The Covid technologies recently licensed to WHO through C-TAP should set a precedent for NIH sharing technology globally. This would allow manufacturers from around the world to help scale-up production and prevent rationing.[17] The Medicines Patent Pool (MPP) aims to help solve the challenges faced by developing countries in accessing medical technologies by negotiating deals that are acceptable to both patent holders and generics firms. The U.S. licensed government-owned patents related to the HIV medicine darunavir to MPP in 2010, the first license

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https://www.rand.org/news/press/2021/01/28.html; https://www.citizen.org/wp-content/uploads/Becerra-antimonopoly-letter-for-sign-on-1.pdf

[15] Gallup, Medication Insecurity by Race and Political Identity, https://news.gallup.com/poll/316052/large-racial-divide-covid- cost-concerns.aspx; https://www.citizen.org/wp-content/uploads/Becerra-antimonopoly-letter-for-sign-on-1.pdf

[16] Public Citizen, Letter to NIH Director Francis Collins: Ensure Access, Affordability and Open Science in COVID-19 Treatments and Vaccines, https://www.citizen.org/wp-content/uploads/Public-Citizen-letter-to-Francis-Collins-re-COVID-19-treatment-plans.pdf

[17] Zain Rizvi, 'The NIH Vaccine,' https://www.citizen.org/article/the-nih-vaccine/

granted to MPP.[18] This forward-looking contribution helped establish MPP and encourage subsequent licenses from the pharmaceutical industry. We hope NIH will build on this precedent and work increasingly closely with WHO and MPP.

Conditions in R&D funding agreements

Conditions in NIH research and development contracts are another powerful policy tool that NIH can use to support affordable access to the medicines and technologies that the agency helps fund. It should be a requirement that the corporations benefiting from public funding and public science act in the public interest.[19] This should include standard clauses ensuring federally funded inventions are priced reasonably. Reasonable pricing clauses were first introduced in 1989 and routinely used by the NIH in the early 1990s, and their reintroduction has been called for today by Senate HELP Committee Chair Bernie Sanders (I-VT).[20]

Most Favored Nations (MFN) clauses are one example of reasonable pricing that should be routine in any NIH R&D funding agreement. The Senate HELP Majority Staff recently found that "U.S. taxpayers virtually always pay more than people in other countries for treatments that NIH scientists helped invent."[21] At a bare minimum, Americans should not have to pay more than people in other rich countries for medicines our country helped to develop.[22] The MFN clause included in the United States' agreement for Pfizer's Paxlovid ensured that the U.S. received the lowest price for the drug among the G7 countries + Switzerland.[23]

Public Citizen's comments recently submitted to the Senate HELP Committee state: "[Operation Warp Speed] episodically used Most Favored Nations (MFN) clauses

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[18] US National Institutes of Health (NIH) First to Share Patents with Medicines Patent Pool As it Opens for Business, https://medicinespatentpool.org/news-publications-post/us-national-institutes-of-health-nih-first-to-share-patents-with-medicines-patent-pool-as-it-opens-for-business

[19] Zain Rizvi, Public Citizen, 'Leading COVID-19 Vaccine Candidates Depend on NIH Technology,' https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology

[20] New Report Shows How Badly Big Pharma Is Ripping Off American People With Publicly Funded Medications, https://www.sanders.senate.gov/press-releases/news-new-report-shows-how-badly-big-pharma-is-ripping-off-american-people-with-publicly-funded-medications/

[21] Senate Health, Education, Labor, and Pensions Committee, Majority Staff, 'Public Investment, Private Greed,' https://www.sanders.senate.gov/wp-content/uploads/Sanders-Public-Medicines-Report.pdf

[22] Public Citizen Comments to the Senate HELP Committee re: Discussion Draft Legislation to Reauthorize the Pandemic and All-Hazards Preparedness Act, https://www.citizen.org/article/public-citizen-comments-to-the-senate-help-committee-on-the-pandemic-and-all-hazards-preparedness-act/

[23] Knowledge Ecology International, 'Pfizer Agrees to International Reference Pricing in US Government Contract for COVID-19 Therapeutic,' https://www.keionline.org/37294

allowing the government to purchase medicines at the lowest price available in 'covered nations.' When the government substantially subsidizes and de-risks R&D for a drug or vaccine, then a reasonable price should be substantially lower and reflect that public investment, rather than future supra-competitive profits, is the primary driver of innovation...Drug corporations and other opponents of reasonable pricing requirements often claim that when a version of reasonable pricing policy was in place in the early 1990s, that it chilled collaborations between the U.S. government and private collaborators, and that when the policy was lifted, that the number of cooperative agreements 'increased significantly and quickly.'[24] However, opponents' narrative of historical experience with reasonable pricing fails to withstand examination." Knowledge Ecology International's James Love has repeatedly debunked this argument before:[25,26]

> *This claim, made frequently by the technology transfer community, bears some scrutiny. KEI obtained data from the NIH on CRADAs under the Freedom of Information Act (FOIA), which is available here.[27] Until 1996, the NIH only reported what are now called "Standard" CRADAs. Beginning in 1996, the NIH added a new category, "Materials" CRADAs. All of the CRADAs involving the reasonable pricing clause were standard CRADAs.*
>
> *From 1990 to 1994, the calendar years when the reasonable pricing clause was used for the whole year, the average number of standard CRADAs executed was 33. There was also a significant biotech stock market crash in 1992 and 1993. From 1996 to 2000, the number of standard CRADAs increased, to an average of 46 per year. But a lot was happening that had nothing to do with the reasonable pricing clause.*
>
> *The average NIH budget was 55% higher in 1996 to 2000 than in 1990 to 1994. Probably more consequential, from year end 1992 to year end 1994, the NASDAQ*

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[24] James Love. "Jamie Love Responds to Criticism of Knowledge Ecology International Letter," IP Watchdog, May 15, 2019. https://ipwatchdog.com/2019/05/15/jamie-love-responds-criticism-knowledge-ecology-international-letter/id=109239/

[25] KEI Comments on:
KEN23378 1T draft of the 2023 Reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), https://www.keionline.org/wp-content/uploads/KEI-comments-2023-pahpa.pdf

[26] Ibid.; James Love. "The number of standard and material CRADAs executed by the NIH from 1985 to 2020 and the relationship to NIH reasonable pricing clause," Knowledge Ecology International. April 5, 2021. https://www.keionline.org/wp- content/uploads/KEI-BN-2021-3.pdf

[27] "Cooperative Research and Development Agreements (CRADAs)," Drug Database. http://drugdatabase.info/cradas/

biotech index declined from 170.64 to 81.54, a decline of 48%, whereas from year end 1995 to year end 2000, the same index increased from 133.77 to 634.32, an increase of 374%.

More significantly, regarding the CRADA data, the number of standard CRADAs fell to 28 by 2005, and was relatively flat from 2000 to 2013, despite a massive 17-fold increase in the NASDAQ biotech index, and a 64% increase in the NIH budget. Are we supposed to conclude that increases in the NIH budget or rising share prices and new private investments aren't good for innovation because the number of CRADAs did not increase from 2000 to 2013?

March-in and paid-up rights under the Bayh-Dole Act

In addition to proactively establishing pro-access licensing policies and contract conditions, NIH should march-in and use its worldwide paid-up rights under Bayh-Dole to support access at home and abroad.[28] Publicly funded and publicly owned inventions developed through federal funding are governed through rules under the Bayh-Dole Act. These rules afford funding agencies, like NIH, certain rights over inventions developed with taxpayer funding to protect the public interest, including:

1) the right to "march-in" and license competition when a drug corporation is failing to make a medicine available on reasonable terms, or to alleviate health or safety needs not being met by the manufacturer;[29] and
2) a nontransferable, irrevocable, paid-up license to practice or have practiced the invention for or on behalf of the United States throughout the world.[30]

Patients and activists have long fought for the Department of Health and Human Services to use these rights to lower the price of the prostate cancer medicine enzalutamide (brand-name Xtandi), a medicine invented at University of California Los Angeles with NIH funding.[31] The Average Wholesale Price of Xtandi in the United States is six times the price of Xtandi in Japan.[32] More than 40 civil society organizations, in a letter to Secretary

[28] Public Citizen, Letter to President Biden calling for a pro-access to medicines NIH Director, https://www.citizen.org/wp-content/uploads/cso-letter-to-biden-re-nih-director.pdf
[29] 35 USC 203(a)(1) & (2)
[30] 35 USC 202(c)(4)
[31] Public Citizen & Partners Urge President Biden to Lower Price of Xtandi, https://www.citizen.org/wp-content/uploads/xtandi-march-in-request-cso-support-letter-2022.10_final-1.pdf
[32] Letter to Secretary Becerra and Acting Director Tabak on Xtandi March-in Petition and Most Favored Nation Clause in Pfizer Contract, Clare M. Love, Eric L. Sawyer, Robert Sachs, Universities Allied for

Becerra, have also called on the Department of Health and Human Services to use its march-in authority under the Bayh-Dole Act as a key policy option to combat excessive drug prices:

> *The federal government has the power under existing law to increase competition and lower drug prices...the Bayh–Dole Act allows the federal government to "march-in" on drug patents developed with federal funding, or to use such patents royalty-free on behalf of the United States.*[33] *These actions can help introduce additional producers. Generic competition, the Food and Drug Administration has found, can lead to price reductions of 95 percent.*[34]

We appreciate the opportunity to comment. Thank you.

Essential Medicines, February 3, 2022, https://www.keionline.org/wp-content/uploads/Love-Sachs-Sawyer-UAEM-Letter-Xtandi- PfizerContract-3Feb2022.pdf

[33] KEI, KEI Briefing Note 2017:1. Bayh-Dole Act and difference between March-In Rights and the world wide royalty free rights in patents, https://www.keionline.org/24132

[34] FDA, Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices, https://tinyurl.com/uxdc9

Submission Date: 7/27/2023

Name: Stephen Susalka

Name of Organization: AUTM

Comment:

Dear Director Jorgenson,

Please find attached AUTM's written comments for the NIH's Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

Sincerely,
Steve

Stephen J. Susalka, PhD, CLP, RTTP (He/Him)
Chief Executive Officer

Additional Comment (attachment):

July 27, 2023

Lyric Jorgenson, PhD
Acting NIH Associate Director for Science Policy
National Institutes of Health
Office of Science Policy
6705 Rockledge Drive
Suite630
Bethesda, MD 20892
SciencePolicy@od.nih.gov

AUTM's Written Comments Regarding the Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

Dear Director Jorgenson:

Thank you for the opportunity to provide written comments for the NIH Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

AUTM is the non-profit leader in efforts to educate, promote, and inspire professionals to support the further development of academic research that drives innovation and changes the world. Our community is comprised of more than 3,000 members who work in more than 800 universities, research centers, hospitals, businesses, and government organizations around the globe. AUTM's members are primarily from academic settings (67%). 15% are practicing attorneys; 5% are from industry; and 22% of our members are international.

AUTM members in academic settings are focused on advancing early-stage inventions and other technologies to the marketplace primarily through licensing to partners (i.e., implementers). Between 2012 and 2021 (the most recent decade for which we have data), our skilled professionals filed over 150,000 patents for academic inventors and over 16,000 in 2021 alone.

Between 2012 and 2021, our U.S. members negotiated over 60,000 intellectual property license agreements on behalf of U.S. universities and academic research institutions, and in 2021 alone over 8,000 such license agreements.

For these reasons, AUTM has valuable insights and an important voice regarding all aspects of technology transfer including the critical decisions about what to patent and what to license as well as how to do so in the most efficient manner.

Introduction

AUTM believes strongly in the importance of catalyzing technology transfer. Technology transfer has resulted in immeasurable societal benefits since 1980 when the Bayh-Dole Act ushered in the current technology transfer system. Studies have shown that since 1980, technology transfer has resulted in billions of dollars of private-sector investment, thousands of new companies formed, countless high-paying jobs, and the introduction of hundreds of new products and services that have improved the standard of living of Americans and contributed significantly to the growth of the American economy.

This history demonstrates the quantitative and qualitative benefits of increased technology transfer. AUTM believes that additional efforts to make technology transfer more efficient and more prevalent will lead to even more life-changing and economy-boosting innovations.

The good news is we know how to ensure the continued growth of technology transfer because we can look back and identify what has worked—namely, promoting innovation, ensuring strong and reliable property rights in inventions, allowing partnerships with industry for testing and development of such inventions, and access to the free market for the products that ultimately emerge from this process. The best way to promote these foundational elements of technology transfer is to provide as much predictability as possible in our currently balanced, yet fragile, innovation ecosystem. This includes supporting and defending strong patent rights and the Bayh-Dole Act while opposing the inclusion of reference price provisions in government funding, collaboration, and license agreements.

The Bayh-Dole Act (the "Act") has been in existence for more than 40 years now and, for most of those years, the Act has been faithfully executed, the United States has had the world's strongest patent system and, save for a 5-year period in the early 1990s, has promoted free market access by avoiding the imposition of reference price provisions.

As recommended below, efforts to weaken technology transfer should be rejected. The Act's march-in provisions were not designed to (and would not) lower drug prices. The same is true of efforts to weaken patents or burden technology licenses with provisions directed to reference pricing. Such efforts will harm innovation and will not have the desired effect of lowering drug prices.

Recommendations

AUTM recommends that the NIH's Office of Science Policy (OSP) take a leadership role on this issue to support strong patent rights, enable robust technology licensing rights, and oppose any policies or regulations that would weaken the American innovation ecosystem. This leadership will maximize NIH's own technology transfer, which would provide a significant carryover effect for all technology transfer. NIH OSP leadership will go a long way toward supporting the limitless benefits of technology transfer.

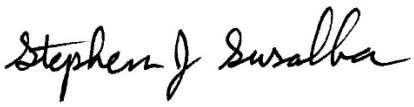
AUTM recommends that the NIH OSP support the NIH in (i) maintaining its consistent stance that the march-in provisions of the Bayh-Dole Act are not to be used as a mechanism to attempt to lower drug prices and (ii) continuing to reject all such petitions. Eliminating the threat of price-based march-in will remove a major obstacle to the partnerships that are necessary to further develop and commercialize the promising new technologies that come out of federally funded research laboratories.

AUTM also recommends that the NIH OSP insist on maintaining the ability of federally funded research organizations to grant licenses, including exclusive licenses, to their partners and the private sector. Exclusivity is sometimes an essential component of the commercialization process—without it, partners would be understandably leery of investing the time and resources necessary to develop a successful product. And without such investment, the technology stays in the lab and never becomes a product with the potential to benefit society.

Finally, AUTM recommends that the NIH OSP strongly oppose any inclusion of reference pricing language in government funding, collaboration, or license agreements. Including such language in any of those agreements will devastate university technology transfer as well as government technology transfer by impeding both universities and government research facilities from entering into the private-sector partnerships necessary to turn early-stage technologies into products and services. Such a result would cause great harm to the U.S. economy and, as just one example, to patients around the world who desperately await new treatments for devastating diseases—such as cancer, Alzheimer's Disease, heart, lung, and kidney disease—and for ever-evolving pathogens.

Thank you again for the opportunity to comment on this crucially important issue. AUTM looks forward to further engagement with the NIH both now and in the future.

Sincerely,



Stephen J. Susalka, Ph.D.
Chief Executive Officer

Submission Date: 7/27/2023

Name: Fred Ledley, Paula Chaves da Silva, & Edward Zhou

Name of Organization: Bentley University

Comment:

Please accept our written comments concerning the Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

We are looking forward to joining this workshop on Monday.

Fred Ledley
Paula Chaves da Silva
Edward Zhou

Fred Ledley, M.D.
Professor, Departments of Natural and Applied Sciences, Management
Director, Center for Integration of Science and Industry
Bentley University

Additional Comment (attachment):

Written comments re:	**Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer**
Submission to:	**Office of Science Policy, National Institutes of Health SciencePolicy@od.nih.gov**
Event Date:	07/31/2023
Response to notice:	https://osp.od.nih.gov/events/workshop-on-transforming-discoveries-into-products-maximizing-nihs-levers-to-catalyze-technology-transfer/
Comments by:	Fred D. Ledley, M.D.[1] Director, Center for Integration of Science and Industry Professor, Departments of Natural & Applied Science, Management Bentley University, Waltham, MA Edward Zhou, Pharm. D. Center for Integration of Science and Industry Bentley University, Waltham, MA Paula Chaves da Silva, Ph.D. Center for Integration of Science and Industry Bentley University, Waltham, MA
Submitted:	July 27, 2023

[1] Contact information: Center for Integration of Science and Industry, Jennison 143, Bentley University, 175 Forest Street, Waltham, MA; email: fledley@bentley.edu; tel: +1.781.891.2046; web: www.bentley.edu/sciindustry

We are pleased to offer written comments to this workshop focused on "*… making federally funded inventions more accessible to the public…* ." These comments are informed by recent research from the Center for Integration of Science and Industry at Bentley University that has:

- Quantified the scope of NIH funding for basic or applied research, clinical development, or patents associated with drugs approved by the FDA 2010-2019. [2] This work identified $187 billion in NIH-funded research directly related to these drugs (applied research – 17%) or their biological targets (basic research – 83%),[3] representing a (discounted) investment comparable to reported levels of investment by industry, thus reducing the investment required by industry by approximately half.[4] These studies further show that less than 3.5% of this funding contributing to phased clinical trials[5] and <1% resulted in patents cited as providing market exclusivity and subject to the public interest protections of Bayh-Dole.[6]
- Compared the financial returns of biotechnology license from academic institutions with those between commercial firms.[7] This work demonstrated that the effective royalty rates and other payments associated with licenses of academic technologies under Bayh-Dole were less than half of those between commercial firms independent of the development stage of products anticipated under these Agreements or other intrinsic terms of the Agreements.
- A novel approach to quantify the "health value" or direct health benefit realized by individuals taking specific pharmaceutical products independent of impacts on economic activity or indirect, econometric inferences.[8]

Specifically, we would like to offer four comments:

1. The NIH makes investments in new drug approvals comparable to those of industry. While the NIH contributes primarily to early-stage, basic research, rather than applied research or development, evidence shows that this established foundation of basic science is requisite for successful product development. As such**, the public sector should expect normative returns on NIH investments in new drugs comparable to those of the biopharmaceutical industry.**
2. The restriction of the Bayh-Dole Act to "subject inventions" limits the Act's applicability to the results of basic research. **Effort should be directed at demonstrating the utility and enablement**

[2] Cleary, EG, Beierlein, JM, Khanuja, NS, McNamee, LM, & Ledley, FD (2018). Contribution of NIH funding to new drug approvals 2010–2016. Proceedings of the National Academy of Sciences, 115(10), 2329-2334. https://www.pnas.org/doi/abs/10.1073/pnas.1715368115; Cleary, EG, Jackson MJ, Zhou EW, Ledley FD. (2023) Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019. JAMA Health Forum. 2023;4(4):e230511, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0288447; Zhou, Edward W., Matthew J. Jackson, and Fred D. Ledley. "Spending on Phased Clinical Development of Approved Drugs by the US National Institutes of Health Compared With Industry." *JAMA Health Forum*. Vol. 4. No. 7. American Medical Association, 2023. https://jamanetwork.com/journals/jama-health-forum/fullarticle/2807184; Ledley and Cleary (2023) NIH funding for patents that contribute to market exclusivity of drugs approved 2010–2019 and the public interest protections of Bayh-Dole. PLOS ONE https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0288447; Cleary, E.G., Jackson, M.J., Ledley, F.D. (2020) Government as the First Investor in Biopharmaceutical Innovation: Evidence From New Drug Approvals 2010–2019 Institute for New Economic Thinking, Working Paper No. 133, August 5th, 2020 (Revised July 19th , 2021) https://www.ineteconomics.org/uploads/papers/WP_133-Revised-2021.0719-Cleary-Jackson-Ledley.pdf

[3] Cleary et al., (2018) op cit; Cleary et al (2020) op cit; Cleary et al (2023), op cit.

[4] Cleary et al. (2023) op cit

[5] Zhou et al., (2023) op cit

[6] Ledley and Cleary (2023) op cit

[7] Shah, P., Vaughan G., Ledley, F.D. (2023) Comparing the economic terms of biotechnology licenses from academic institutions with those between commercial firms. PLOS ONE journals.plos.org/plosone/article?id=10.1371/journal.pone.0283887;

[8] Chaves da Silva, P. and Ledley, FD unpublished data

provided by NIH-funded basic science to ensure that the public interest provisions of the Act apply to a larger fraction of NIH-funded research.

3. Licenses of biotechnologies originating in academic institutions embody financial terms that are significantly less favorable than those of comparable licenses between commercial firms. **Additional effort needs to be made to establish that a "reasonable royalty rate" for academic licenses requires financial terms comparable to those of corporate licenses.**
4. **Impact indicators should be developed that measure the direct, measurable impacts of innovative pharmaceuticals on individuals and their health rather than indirect impacts on economic indicators or broad measures of population health.**

Background

The Bayh-Dole Act represents the only significant statutory instrument for promoting and protecting the public's interest in the health benefits arising from government-funded biomedical research and the products enabled by this research, direct economic returns from commercialization of these products, and indirect returns impacts on jobs, productivity, and economic growth. This is evident in the stated objectives of the Bayh-Dole Act to "*…promote the utilization of inventions arising from federally supported research or development…*," advance "*…the commercialization and public availability of inventions made in the United States by United States industry and labor…*," and protect the public "*…against nonuse or unreasonable use of inventions"*.[9]

By promoting commercialization of practical applications enabled by federally funded research, Bayh-Dole was designed to provide returns to the public sector in the form of commercial products to address unmet public needs, create jobs, stimulate economic growth, and expand the tax base.[10] Additionally, by ceding the revenues from technology licenses to non-profit institutions incorporated in the public interest,[11] Bayh-Dole positioned these institutions as proxies for the public sector in securing a direct return on public investment. To this end, Bayh-Dole further authorized these institutions to retain the proceeds from such licenses, providing that the proceeds are shared with the inventor and that institutional funds "*will be utilized for the support of scientific research or education*."[12]

Recent economic studies contextualize government's contributions to innovation as that of an "*early-stage investor*" and government funding for research as an "*investment.*" As such, these studies argue there should be an equitable balance of investment risk and return between the public and private sectors and frame the role of policy as shaping this balance[13] in which the public and private sectors both receive returns on investment commensurate with the risk of these investments.

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[9] CFR. Code of Federal Regulations, Title 37 Part 401 RIGHTS TO INVENTIONS MADE BY NONPROFIT ORGANIZATIONS AND SMALL BUSINESS FIRMS UNDER GOVERNMENT GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS Code of Federal Regulations 2010 [cited 2020 July 3, 2020]. Available from: https://www.govinfo.gov/content/pkg/CFR-2010-title37-vol1/pdf/CFR-2010-title37-vol1-part401.pdf.

[10] Sampat BN. Patenting and US academic research in the 20th century: The world before and after Bayh-Dole. Research Policy. 2006;35(6): p. 772–789; Federal Council for Science and Technology, Effects of Government Policy on Commercial Utilization and Business Competition, Government Patent Policy Study, final report. Federal Council for Science and Technology, 1968; Bray MJ, Lee JN. University revenues from technology transfer: Licensing fees vs. equity positions. J Bus Ventur. 2000;15(5-6): p. 385–392.

[11] Salamon LM. The new governance and the tools of public action: An introduction. Fordham Urb. LJ. 2000;28: p. 1611.

[12] Ouellette LL, Weires R. University Patenting: Is Private Law Serving Public Values? Michigan State Law Review. 2020;2019(5): p. 1328-1387.

[13] Mazzucato M, Li H. The entrepreneurial state: socializing both risks and rewards. Real-World Economics Review. 2018;84; Mazzucato M. An entrepreneurial society needs an entrepreneurial state. Harv Bus Rev. 2016:1-4; Lazonick W, Mazzucato M.

Based on our research, we offer three specific suggestions:

1. The public sector should expect normative returns on NIH investments in new drugs comparable to those of the biopharmaceutical industry.

Figure 1 shows a schematic of NIH funding for basic or applied research prior to first approval of drugs approved from 2010-2019.[14] NIH data includes NIH-funded projects related to: (i) the drug target (basic research) after accounting for spillover effects in which research on each drug target is associated with 2.85 approved products[15] (ii) the drug product (applied research) including phased clinical trials. Industry costs include the costs of phased clinical trials and "pre-human" studies. Statistical analysis demonstrates that the NIH spending on each new drug prior to first approval was not less than reported industry costs using different scenarios.[16] We call on the NIH to promote policies based on the expectation that the return on public investments in pharmaceutical innovation should not be less than the returns on private investment.

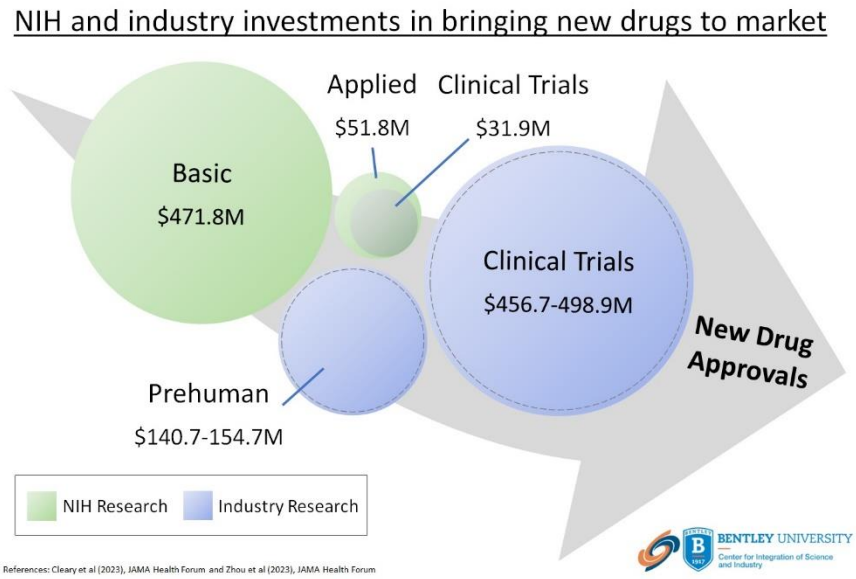

Figure 1. Average contributions of NIH and industry to first approval of novel pharmaceuticals 2010-2019. Data is based on NIH funding for basic research on drug targets, applied research on the drug (including clinical trials), and reported investments by industry from DiMasi et al (2016) or Wouters (2020).

The risk-reward nexus in the innovation-inequality relationship: who takes the risks? who gets the rewards? Industrial and Corporate Change. 2013;1093-1128; Laplane A, Mazzucato M. Socializing the risks and rewards of public investments: economic, policy, and legal issues. Research Policy. 2020;49: ; Cleary EG, et al (2023) op cit; Cleary EG, et al (2020) op cit G

[14] NIH data from Cleary et al., (2023) op cit; Zhou et al., (2023) op cit. Industry data from DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: new estimates of R&D costs. Journal of health economics. 2016 May 1;47:20-33. https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291; Wouters OJ, McKee M, Luyten J. Estimated research and development investment needed to bring a new medicine to market, 2009-2018. Jama. 2020 Mar 3;323(9):844-53. https://jamanetwork.com/journals/jama/article-abstract/2762311

[15] The number of drug approvals/target was estimated from Santos R, Ursu O, Gaulton A, Bento AP, Donadi RS, Bologa CG, Karlsson A, Al-Lazikani B, Hersey A, Oprea TI, Overington JP. A comprehensive map of molecular drug targets. Nature reviews Drug discovery. 2017 Jan;16(1):19-34. https://www.nature.com/articles/nrd.2016.230%E2%80%B3

[16] Cleary et al. (2023) op cit.

2. Effort should be directed at demonstrating the utility and enablement provided by NIH-funded basic science to ensure that the public interest provisions of the Act apply to a larger fraction of NIH-funded research.

It is generally recognized that government plays a central role in funding the basic science that underlies innovation. Basic research is defined as "*…experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view,*"[17] though it may be "*use inspired.*"[18]

Table 1 shows the NIH-funded publications, project years of NIH funding, and costs associated with basic or applied research for drugs approved by the FDA from 2010-2019.[19] The method involves identifying publications in PubMed (PMID) related to the drug target (basic research) or the drugs (applied research), estimates the number of years of project funding related to that research (project years) and costs for those project years.[20] These data show that approximately 83% of the government-funded research related to these products represented basic research on the drug targets, rather than applied research on the drugs themselves.

Table 1. NIH funding for basic and applied research related to 356 NMEs approved by the FDA, 2010-

	DRUG Search[a]	TARGET Search[b]	Total
PubMed search results			
# Searches	356	217	
# Publications in PubMed (1985-2019)	229,401	1,911,507	2,017,408[c]
RePORT NIH-funded publications			
# Publications with NIH funding (1985-2019)	36,195	409,123	424,293[c]
% Publications with NIH funding	16%	21.4%	21%
Totals			
# Searches identifying publications with NIH funding	310	217	
% Searches identifying publications with NIH funding	87%	-100%	
RePORT Project Years and Costs	**Applied Research[d]**	**Basic Research[d]**	**Total**
# Project Years	42,549	317,354	359,903
Project Years costs ($ millions)	$30,954	$156,429	$187,383
% Total NIH funding	17%	83%	

[a]PubMed search performed with drug name and synonyms. [b]PubMed search performed with name of biological target. [c]Total is nonadditive due to publications identified in both drug and target searches. [d]Publications identified in a drug search are classified as applied research. Publications identified in a target search, but not a drug search, are classified as basic research.

While there is evidence that an established body of basic biomedical research on drug targets or technological components of a product is requisite for drug approval[21] basic research is not primarily

[17] NSF. Definitions of Research and Development: An Annotated Compilation of Official Sources. 2018.
[18] Stokes DE. Pasteur's quadrant: Basic science and technological innovation. Brookings Institution Press; 2011.
[19] Cleary E et al (2023) *op cit*; see also working paper Cleary et al., (2020) Institute for New Economic Thinking, *op cit*.
[20] The method is described in detail and available as a dashboard for public use at https://www.bentley.edu/centers/center-integration-science-and-industry/nih-funding-drug-innovation-dashboard

[21] McNamee LM, Ledley FD. (2017) Modeling timelines for translational science in cancer; the impact of technological maturity. PLOS ONE 12.3, e0174538, journals.plos.org/plosone/article?id=10.1371/journal.pone.0174538; McNamee LM, Walsh MJ, Ledley FD. (2017) Timelines of translational science: From technology initiation to FDA approval. PLOS ONE. 12.5 e0177371; Beierlein JM, McNamee LM, Walsh MJ, Kaitin KI, DiMasi JA, Ledley FD. (2017) Landscape of innovation for cardiovascular pharmaceuticals: from basic science to new molecular entities. Clinical Therapeutics. 39: 1409-1425 e20

concerned with applications and, thus, less like to generate a "subject invention"[22] than applied research and less likely to satisfy USPTO standards for patentability, which requires demonstration of utility and enablement in addition to novelty.[23]

This dynamic may be responsible for the observation that <1% of this NIH funding was represented in patents cited in DrugPatentWatch[24] (which includes the FDA Orange Book) and that these patents arose disproportionately from applied, rather than basic, research.[25] Our research identified NIH funding for basic or applied research related to each of the 313 drugs approved 2010-2019 with entries in DrugPatentWatch.[26] Table 2 shows that there were 6,344 patents in DrugPatentWatch associated with drugs approved 2010-2019. There were 22,409 patents identified as arising from NIH-funded projects that produced basic or applied research related to these products in RePORTER.[27] Only 104 of these

Table 2. Number of new drug approvals 2010–2019 associated with NIH-funded patents.

	# drugs
Drugs approved 2010-2019 with entry in FDA Orange Book or DrugPatentWatch[1]	313
…with at least one patent in FDA Orange Book or DrugPatentWatch	297
	# patents
…associated patents in FDA Orange Book or DrugPatentWatch	3,644
	Cleary dataset[2]
NIH-funded patents related to drugs approved 2010–2019	22,409
…number in FDA Orange Book or DrugPatentWatch (% associated patents)[3]	104 (2.9%)
	# drugs
Drugs with NIH-funded FDA Orange Book or DrugPatentWatch patents (% drugs)[4]	29 (9.3%)

[1] DrugPatentWatch includes all active and expired patents from the FDA Orange Book and certain additional patents on biological products identified by companies or patent search. [2] Cleary identified NIH-funded projects associated with drugs approved 2010–2019 or their targets as well as patents arising from these projects [2]. [3] Percentage of patents in FDA Orange Book or DrugPatentWatch associated with drugs approved 2010–2019. [4] Percentage of drugs approved 2010–2019 listed in FDA Orange Book or DrugPatentWatch. n/a – not applicable.

patents were cited in DrugPatentWatch in association with these products. Moreover, while NIH-funded research was associated with each of the 313 drugs approved 2010-2019 with citations in

[22] The Bayh-Dole Act defines a subject invention as "*…any invention of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement" and further requires that it must be "conceived or first actually reduced to practice in performance of the project.*" See: 27.Title 35 U.S. Code Chapter 18—Patent rights in inventions made with federal assistance, as amended Nov 1, 2000 (1980).

[23] USPTO. Manual of Patent Examining Procedure. Requirements for Specification Under 35 U.S.C. 112, First Paragraph 2020. https://mpep.uspto.gov/RDMS/MPEP/e8r9#/result/d0e213359.html?q=enablement&ccb=on&ncb=off&icb=off&fcb=off&ver=e8r9&syn=adj&results=compact&sort=relevance&cnt=10&index=1

[24] DrugPatentWatch is a registered trademark of thinkBiotech LLC available at www.drugpatentwatch.com. The dataset incorporates patents cited in the FDA Orange Book or cited in litigation regarding market exclusivity.

[25] Ledley and Cleary (2023) op cit

[26] This dataset for this project was somewhat smaller than the 356 drug approvals from 2010-2019 and $187 billion in NIH funding described in Cleary et al (2020) and Cleary et al (2023) due to the fact that not all approved products are covered by the Hatch-Waxman Act and included in the FDA Orange Book. While the DrugPatentWatch database expands on Orange Book dataset to include certain biological product, the current project restricted the dataset to the 313 products with at least one patent cited in this database.

[27] Note: The RePORTER database does not allow association of patents with specific project years of research funding. Thus, the 22,409 patents include research funded by the same project that contributed to basic or applied research on these drugs, but not necessary the publications directly related to these drugs or their targets. See Ledley and Cleary (2013) *op cit* for details.

DrugPatentWatch, only 29 (9.3%) had patents arising from this NIH-funded research. Overall, only 0.56% of NIH funding for research directly related to the drugs approved by the FDA from 2010-2019 was represented in patents cited in DrugPatentWatch, including only 0.38% of NIH funding for basic research on drug targets and 1.5% of NIH funding for applied research on the drugs themselves.

There is little publicly available data on the fraction of NIH-funded projects that produce disclosure of possible subject inventions or the fraction of such disclosures that lead to patent filing or licenses.[28] It is, thus, unclear whether the basic science research that enables drug approvals is not reported as a possible subject invention, is not pursued by technology transfer offices, or leads to patent applications that are rejected by the USPTO for inadequate demonstration of utility or enablement. In any case, the result is that little of the NIH-funded research that enables new drug approvals is subject to the public interest protections of Bayh-Dole designed to promote commercialization of products that represent practical applications of this research and the reasonable availability of these products to the public.

While the patent-centric design of the Bayh-Dole Act is beyond the scope of this research, we call on the NIH to support research on an experimental and theoretical basis for establishing that NIH-funded basic science, in fact, enables new drug discovery and development sufficient to satisfy the definition of a "subject invention" as well as USPTO standards of "utility," and "enablement." Information should also be collected and made public concerning the scope of disclosures under Bayh-Dole, the reasons universities or the NIH may choose not to pursue a provisional or full patent filing on subject inventions as well as the reasons that a patent application may be abandoned or rejected by the USPTO. Only by working to make NIH-funded basic research subject to the public interest provisions of Bayh-Dole can the technology transfer process operationalized by the Act ensure that the public interest in the fruits of this research is protected and the public receives an equitable return on their investment in pharmaceutical innovation.

3. Additional effort needs to be made to establish that a "reasonable royalty rate" for academic licenses requires financial terms comparable to those of corporate licenses.

Figure 2[29] shows the economic returns from academic licenses to commercial firms as well as those between commercial entities derived from BioSciDB[30] including the effective royalty rate on $500M in net sales, total reported deal size; and total precommercial payments. There were statistically significant differences between the returns to academic institutions from biotechnology licenses and those of licenses between commercial entities. Academic licenses had lower effective royalty rates (median 3% versus 8%, $p<0.001$), deal size (median $0.9M versus $31.0M, $p<0.001$), and precommercial payments (median $1.1M versus $25.4M, $p<0.001$) than corporate licenses. Controlling for the clinical phase of the most advanced product included in the license reduced the median difference in effective royalty rate between academic and corporate licenses from 5% (95% CI 4.3–5.7) to 3% (95% C.I. 2.4–3.6) but did not change the difference in deal size or precommercial payments. Excluding licenses for co-commercialization did not change the effective royalty rate but reduced the median difference in deal size from $15.8M (95% CI 14.9–16.6) to $11.4M (95% CI 10.4–12.3) and precommercial payments from

[28] While there is mandatory reporting of these events under Bayh-Dole, the Act also prohibits public disclosure of this information See: Rai AK, Sampat BN. Accountability in patenting of federally funded research. Nature biotechnology. 2012 Oct;30(10):953-6. https://www.nature.com/articles/nbt.2382

[29] From Shah et al.,(2023) *op cit*. Tables and portions of the text have been extracted from that publication.

[30] The BioScience database (now BioSciDB, part of Evaluate Ltd.) was provided courtesy of Mark Edwards.

$9.0M (95% CI 8.0–10.0) to $7.6M (95% CI 6.8–8.4). Controlling for deal terms including exclusivity, equity, or R&D in multivariable regression had no substantive effect on the difference in economic terms.

This research demonstrated that the economic returns to academic institutions from licenses of biotechnologies arising from federally funded research are substantially lower than those of comparable licenses between commercial firms. While the absolute value of the economic returns is influenced by the development stage of products, whether the licensee was a biotechnology or large pharmaceutical company, and whether the license agreement involved co-commercialization, the disparity between academic and corporate licenses is largely independent of these factors. There is currently no data resource available to systematically assess the returns to licenses granted pursuant to Bayh Dole[31] and whether or not these returns satisfy the legal standard of a "reasonable royalty rate."[32]

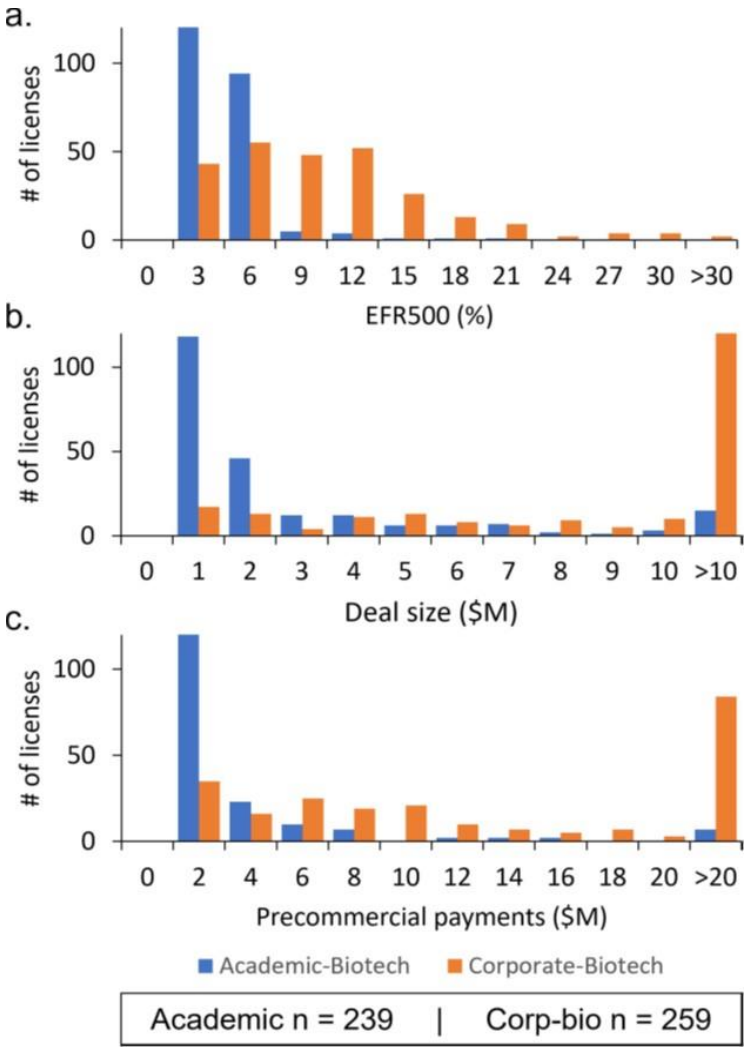

Figure 2. Histogram showing distribution of: (a) effective royalty rate; (b) deal size; and (c) precommercial payments associated with licenses from academic institutions to biotech or between commercial firms. Fom Shah et al (2023) op cit

We call on the NIH to engage in further research directed at establishing the principle that a "reasonable royalty rate" on academic licenses of

[31] Data in the BioScience database contains licenses agreements reported to the SEC obtained through FOIA petitions. The dataset is thus limited to licensed that a company considers "material" to their valuation. "Materiality" is legally defined as *"a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information*" and is assessed in relation to the significance of an item to users of a registrant's financial statements" (SEC, 1999). See: FASB, Amendments to Statement of Financial Accounting Concepts No. 8. Conceptual Framework for Financial Reporting Chapter 3, Qualitative Characteristics of Useful Financial Information. 2018, Financial Accounting Standards Board; Securities and Exchange Commission (SEC), SEC Staff Accounting Bulletin: No. 99–Materiality, August 1999; SCOTUS, MATRIXX INITIATIVES, INC., ET AL. v. SIRACUSANO ET AL. CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT No. 09–1156. SCOTUS 2011.

[32] A "reasonable royalty rate" is defined as "t*he amount which a prudent licensee who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.*" See Ouellette LL, Weires R. University Patenting: Is Private Law Serving Public Values? Michigan State Law Review. 2020;2019(5): p. 1328-1387; Jarosz JC, Chapman MJ. The Hypothetical Negotiation and Reasonable Royalty Damages: The Tail Wagging the Dog. Stan. Tech. L. Rev. 2012;16: p. 769; Seaman CB. Reconsidering the Georgia-Pacific standard for reasonable royalty patent damages. BYU L. Rev. 2010: p. 1661.

biotechnologies should not be lower than the rate associated with comparable corporate licenses. This requires greater attention to the reasons that technology transfer offices are not able to negotiate more equitable returns and addressing any systematic deficiencies in the research or licensing process that are identified.[33] It is also necessary to establish the legal principle that the reasonable royalty rate for academic licenses must be comparable to the rates of similar corporate licenses.

3. Impact indicators should be developed that measure the direct, measurable impacts of innovative pharmaceuticals on individuals and their health rather than indirect impacts on economic indicators or broad measures of population health.

Current methods for assessing the impact of technology transfer and the return on government investments in R&D are based largely on economic impact studies and impacts on metrics of employment, productivity, or economic growth. Such metrics, along with population measures of overall morbidity or mortality, do not measure the direct effects of new products on individuals, their state of health, or their wellbeing. Moreover, these methods cannot delineate the impact of individual products. A true measure of the impact of products licensed from academic or government institutions requires new methods that can delineate the impacts of individual products.

We are exploring methods for estimating the "health value" generated by development and dissemination of a specific pharmaceutical product. The method uses established measures of the quality of life gained (measured in Quality-adjusted life years [QALYs]) by use of a pharmaceutical product times the number of individuals using that product. The "value" of improved health is then calculated using a globally adjusted value for the "willingness to pay" (measured in WTP/QALY). Willingness to pay is classically recognized in marketing a mechanism for assessing the value ascribed to a product by an individual. An example of this analysis is shown in Table 3.

Table 3. Health value provided to CMS beneficiaries and US population by treatment with products to treat hepatitis C developed by Gilead Sciences.

		CMS beneficiares				*US population*			
Brand name	**QALY gained**	**individuals benefited**	**Health value**	**Drug spending**	**Residual Health Value**	**individuals benefited**	**Health Value**	**Drug spending**	**Residual Health Value**
Sovaldi	2.61	90,700	$12.1	$8.3	$3.8	156,655	$20.8	$13.1	$7.7
Harvoni	3.26	271,429	$44.5	$23.5	$20.9	388,105	$63.7	$33.4	$30.2
Epclusa	3.94	126,619	$24.0	$7.2	$16.8	176,332	$33.6	$9.0	$24.6
Total		*488,748*	$80.5	$39.1	$41.5	*721,093*	$118.0	$55.5	$62.4

All $ values in billion USD inflation adjusted to 2016. Health Value is calculated using a globally adjusted willingness to pay (WTP) of $52,619.4/QALY (Kouakou and Poder, 2022). Product names: Sovaldi (sofosbuvir); Harvoni (ledipasvir-sofosbuvir); Epclusa (sofosbuvir and velpatasvir). Data sources. QALY data represents average QALY gained compared to no antiviral treatment identified through literature review. Number of individuals benefited obtained from Market Information Data Analytics System (MIDAS) or Centers for Medicare & Medicaid Services (CMS). Reference: Chaves da Silva, P, Conti, R, Ledley FD (unpublished data).

This example estimates the "health value" generated by use of three drugs for treating hepatitis-C developed by Gilead Sciences. In this experiment, the number of QALY gained by an individual using the product is expressed relative to individuals not receiving antiviral drugs.

[33] Various postulated rationale are discussed in Shah et al (2023) op cit.

The results are expressed in two ways. First: total health value represents the number of QALY gained by taking the product times the number of individuals treated (benefiting) times a globally adjusted WTP of $52,619/QALY.[34] Second, the residual health value is calculated by subtracting the price paid for these drugs (i.e. retail price including Medicare out of pocket, or insurance). The results demonstrate the total health value realized by patients under Medicare Part D was >$80 billion with a residual health value of >$41 billion. Nationwide, the total health value realized through use of these products was >$118 billion with a residual health value of >$60 billion. While these studies are in their early stages, we would note that these results are not typical and reflect the value of drugs that cure a significant, endemic disease and have been made widely available through donations and emergence of generic products. These early results suggest it will be possible to directly measure the health value to individuals of novel pharmaceutical products in addition to the broad economic benefits to society. We encourage NIH to further support development of direct measures of pharmaceutical innovation on health.

Fred D. Ledley, M.D.
Paula Chaves da Silva, Ph.D.
Edward Zhou, Pharm.D.
July 27, 2023

[34] Kouakou CR, Poder TG. Willingness to pay for a quality-adjusted life year: a systematic review with meta-regression. The European Journal of Health Economics. 2022 Mar;23(2):277-99. https://link.springer.com/article/10.1007/s10198-021-01364-3

Submission Date: 7/27/2023

Name: Alex Moss

Name of Organization: Public Interest Patent Law Institute

Comment:

Please find attached the comments of the Public Interest Patent Law Institute regarding the upcoming NIH Workshop. Please let me know if there are any problems with the transmission.

Regards,
Alex Moss

_____
Executive Director
Public Interest Patent Law Institute

Additional Comment (attachment):

Public Interest
Patent Law Institute

COMMENTS OF THE PUBLIC INTEREST PATENT LAW INSTITUTE FOR WORKSHOP ON TRANSFORMING DISCOVERIES INTO PRODUCTS: MAXIMIZING NIH'S LEVERS TO CATALYZE TECHNOLOGY TRANSFER

The Public Interest Patent Law Institute ("PIPLI") is grateful for the opportunity to participate in and provide comments for the Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer ("Workshop").

PIPLI is a nonprofit, nonpartisan public interest organization dedicated to ensuring the patent system promotes innovation and access for the public's benefit. Because the lives and livelihoods of countless Americans depend on access to medical advances, their interests should be central to policy decisions affecting the advancement and accessibility of medical research, but members of the public rarely participate directly in the institutions responsible for these policies, such as the National Institutes of Health and U.S. Patent and Trademark Office.

PIPLI's mission is to enhance public participation and representation in institutions such as these that shape the nation's science and technology policies so that they promote the advancement and accessibility of scientific advances more effectively and equitably. In service of its mission, PIPLI conducts policy research; provides pro bono assistance to individuals and organizations on patent-related matters; advocates for greater transparency in courts and government agencies; and submits amicus briefs and policy comments to courts and government agencies.

I. OVERVIEW

The National Institutes of Health (NIH) plays a crucial role in advancing life-saving medical breakthrough, such as its contribution to the development of mRNA technology, which underlies highly effective COVID-19 vaccines is a remarkable achievement of great societal value. Given the significance of NIH research, it is essential to maximize its ability to facilitate the development and widespread access to medical technology.

In connection with these goals, we have identified three key areas where the NIH can further enhance public benefits from its work. First, NIH patents should be of the highest quality to ensure their effectiveness and integrity as well as to serve as models of patent quality for others to follow. Second, the NIH should carefully consider and develop guidelines for researchers deciding whether, when, and why to file patent applications. Third, the NIH should provide more information about its patent licenses for the benefit of licensees, policymakers, scholars, patients, and the overall efficiency of licensing markets.

We sincerely appreciate the opportunity to share our comments on these vital matters and commend the NIH for engaging in constructive discussions with scholars, policy advocates, and patients. We hope that this marks the beginning of a series of fruitful conversations leading to policies and practices that amplify the impact and benefits of the NIH's invaluable work on enhancing scientific progress, public health, and the nation's well-being moving forward.

II. COMMENTS

A. NIH Patents Should Be High Quality Patents.

Ensuring that the NIH patents are high quality patents is critical to the agency's mission of promoting research and development in the medical field, enhancing public health, and expanding the base of scientific knowledge. High quality patents can help drive innovation by clearly defining the subject of patent protection and thus of technology transactions for licensing partners and the NIH itself to determine whether and what kind of licenses are required. Patents that provide information that allows others to make and use the claimed invention fuel further research and ensure the public gets its full share of the patent bargain. And patents that claim genuinely novel and non-obvious inventions contribute to the stock of available knowledge, fulfilling the patent system's fundamental objective. Low quality patents, however, can have adverse effects. For example, they may provide excessive rights beyond their contributions; create uncertainty about space for research, development, and competition by others; and deprive the public of access to information required to make medical technology accessible on a wide scale.

While issuing high quality patents is the USPTO's top priority,[1] But given the USPTO's workload, their heavy workload makes it challenging to prevent low quality patents from being granted. At the beginning of 2023, the USPTO's approximately 8,000 examiners faced a backlog of 694,600 unexamined patent applications, expecting a similar number of new filings as the previous year (457,500).[2] Moreover, a Government Accountability Office report revealed that 69% of patent examiners handling biology and organic chemistry applications felt they had insufficient time for effective prior art searches.[3] This leads to a concerning situation where around 40% of granted patents are later found invalid when challenged.[4]

The NIH possesses a unique opportunity to aid the USPTO in ensuring and enhancing patent quality. Patents resulting from NIH-funded research can serve as examples of patent quality, alleviating the USPTO's burden and providing a model for grantees and other research entities, both public and private, to follow. Key characteristics of high-quality patents include well-defined and appropriately limited claims; comprehensive and understandable disclosures enabling others to make and use the invention; and claims meeting substantive patentability requirements of eligibility, novelty, and non-obviousness. Furthermore, by mandating that patent agents and

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[1] *See, e.g.*, Remarks by USPTO Director Kathi Vidal to the Public Patent Advisory Committee, May 10, 2022, https://www.uspto.gov/about-us/news-updates/remarks-uspto-director-kathi-vidal-ppac-0 ("Today's discussion centers around patent quality. This is job number one. It is the most important aspect of our operations. We are constantly looking at ways to improve the examination of patent applications and the claims within them. We want our examiners to know how important their work is to the success of the patents they allow.").

[2] Statement of USPTO Director Kathi Vidal before the U.S. House of Representatives, April 27, 2023, https://www.uspto.gov/about-us/news-updates/statement-under-secretary-commerce-intellectual-property-and-director-united.

[3] Gov. Accountability Office, *Intellectual Property: Patent Office Should Strengthen Search Capabilities and Better Monitor Examiners' Work*, July 20, 2016, at 76, https://www.gao.gov/assets/gao-16-479.pdf.

[4] Josh Landau, *A Little More Than Forty Percent: Outcomes At The PTAB, District Court, and the EPO*, Patent Progress, May 1, 2018, https://www.patentprogress.org/2018/05/a-little-more-than-forty-percent/.

attorneys filing NIH patents adhere to patent quality guidelines, these practices will become ingrained in their approach and, over time, permeate the entire patent bar.

We respectfully urge the NIH to conduct additional workshops or public consultations to establish patent drafting guidelines for NIH researchers and grantees. This proactive step will lead to improvements in the quality of patents arising from NIH-funded research, helping to maximize the benefits they provide to the agency, licensing partners, researchers, and patients alike.

B. The NIH Should Carefully Consider Whether, When, and How to File Patent Applications.

Granted patents are not necessarily the sole or most optimal means of accomplishing the NIH's objectives of fostering scientific research. Therefore, we strongly encourage the NIH to proactively assess the advantages of patent protection in each case. Some situations may call instead for ensuring that advancements are openly available to all, without being subject to patent protection.

However, there is a potential risk that other entities may attempt to patent such advancements, which could hinder access for researchers and patients. In such scenarios, the NIH might consider seeking patent protection. Nonetheless, an alternative approach should also be considered: filing patent applications with comprehensive disclosures, ensuring they are published and thus become accessible prior art, without proceeding with the subsequent steps (or incurring related fees) necessary for them to mature into granted patents.

While printed publications are technically considered prior art references during patent examination, it is evident that patent documents are "[b]y a substantial majority, the principal references utilized by examiners."[5] This gives rise to significant problems, primarily because "patent literature is not likely to contain a complete description of technologies in new and emerging markets or markets that have not traditionally been characterized by heavy patenting activity, . . . yielding questionable patent grants in these fields that can easily be called into question by taking common sense and general knowledge into account."[6] Encouraging researchers to submit their work in the form of a patent application, even if they might not intend to obtain an issued patent, for the purpose of ensuring it is available to examiners (and potential patent challengers) as prior art would be a valuable measure to address these challenges.

Published applications are especially useful because they expand the base of available prior art without burdening the agency with the work and cost of obtaining and maintaining granted patents, increasing transaction costs for private entities, or imposing the costs of excessive exclusivity on the public.

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[5] Jorge L. Contreras, *Common Knowledge and Non-Patent Literature in the Internet Age*, Berkeley Tech. L. J., Mar. 12, 2016, at 1, https://btlj.org/2016/03/common-knowledge-and-non-patent-literature-in-the-internet-age-2/#easy-footnote-bottom-1-4842 (citing John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 Vand. L. Rev. 2099, 2130-32, 2158-60 tbl.13 (2000); Julie Callaert et al., *Traces of Prior Art: An Analysis of Non-Patent References Found in Patent Documents*, 69 Scientometrics 3, 7, tbl.1 (2006) (observing that 83% of USPTO references were patents); Christopher A. Cotropia, Mark A. Lemley & Bhaven Sampat, *Do Applicant Patent Citations Matter*?, 42 Research Policy 844, 847 (2013)).

[6] *Id.*

Evidence shows that patent applications are also uniquely valuable to patent examiners when compared to granted patents.[7] As one study explains:

> Patent examiners use abandoned published applications more often than issued patents when issuing anticipation rejections (concluding the applied-for invention is not novel—i.e., it has been done before) and obviousness rejections (concluding the applied-for invention is obvious—i.e., enough of a technical advance over what has been done before) in an office action. Beyond just rejections, our study finds that abandoned applications are more likely than issued patents to be cited as relevant by patent examiners during patent prosecution. The office actions require applicants to narrow and amend their claims or include specific arguments as to why the USPTO incorrectly determined that the claims are anticipated or obvious. Given our empirical findings that the USPTO rejected a large number of applications based on published yet abandoned art, a significant quantity of patent scope was narrowed because of abandoned applications. These abandoned published applications appear to be quite valuable disclosures, at least from the USPTO's perspective; yet, the applicants received no patent reward.[8]

In other words: patent examiners are more likely to cite published applications than granted patents when rejecting unpatentable applications. These rejections can prevent invalid patents from issuing or increase the quality of granted patents by leading applicants to clarify and/or narrow the scope of their claims.

Submitting patent applications with the intent of obtaining their publication as prior art references rather than pursuing their issuance as granted patents has great promise as a means of enhancing access to scientific knowledge. To facilitate this approach, we encourage the NIH to develop clear guidelines for determining when published applications would be more conducive to advancing technology development and transfer than obtaining granted patents. Furthermore, we recommend close collaboration with the USPTO to streamline the process, making it easier for applicants (within and outside the NIH) to submit such filings.

C. NIH Patent Licensing Information Must Be More Transparent to Policymakers, Scholars, and the Public.

The American public has a strong interest in accessing more information about NIH patent licenses than is currently available. Information about royalty rates and licensing revenue generated from these patents is essential for policymakers, scholars, and the public to understand and improve the effect that public policy and funding decisions have on the development and accessibility of medical advances.

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[7] Christopher A. Cotropia & David L. Schwartz, *The Hidden Value of Abandoned Applications to the Patent System*, 61 B.C.L. Rev. 2809 (2020), https://scholarship.richmond.edu/cgi/viewcontent.cgi?article=2623&context=law-faculty-publications.

[8] *Id.* at 2812–13.

While some information may need to be kept confidential for a limited period, perpetual confidentiality is not warranted. Even data with national security implications must be disclosed after a reasonable time frame.[9] The importance of public access to information about government activities information must not be taken lightly: "Our democratic principles require that the American people be informed of the activities of their Government," and "our Nation's progress depends on the free flow of information both within the Government and to the American people."[10] Information about patent licensing is relevant to policy issues of paramount importance, such as the high drug prices in the U.S., shortages in drug manufacturing supply chains, and corporate tax avoidance strategies.

At the very least, the public should be able to access royalty rate information in a manner that incorporates confidentiality protections when appropriate—for example, through redactions of identifying information about licensees or regular reports of aggregated royalty and revenue data—as well as at times when such protections are no longer appropriate—for example, within a reasonable time after the expiration of a license or patent.

Recent reports indicate that the NIH is licensing at least some of its patents under highly generous yet undisclosed terms. For instance, the Senate HELP Committee found that one licensing agreement provided for royalty payments of approximately 1% on product sales without ensuring that product prices would be reasonable or limited in any respect.[11]

This information raises serious concerns about the extent to which the public is benefiting from publicly funded research. When the public takes on investment risks, it should receive a reasonable rate of return through licensing revenue, reduced market prices, or a combination of both. Given this context, we urge the NIH to consider reintroducing reasonable pricing clauses to its licenses and licensing requirements at least when licenses offer royalty rates that appear unreasonably low, such as rates of 5% or less. Additionally, the NIH should consider including such clauses when licensees utilize tax shelters, such as operating as subsidiaries of foreign corporations paying most of their taxes overseas.[12] It is economically and morally inappropriate for the American public to invest in research while other countries pay less for resulting products and receive more of the tax income generated.

That said, greater transparency might provide valuable context or provide other public benefits. For example, if the NIH regularly licenses patents at rates as low as 1%, the disclosure of this information could support generic drug manufacturers in obtaining similarly low rates during

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[9] *See, e.g.,* Executive Order 13526—Classified National Security Information, Dec. 29, 2009, ("If the original classification authority cannot determine an earlier specific date or event for declassification, information shall be marked for declassification 10 years from the date of the original decision, unless the original classification authority otherwise determines that the sensitivity of the information requires that it be marked for declassification for up to 25 years from the date of the original decision.").

[10] *Id.*

[11] U.S. Senate HELP Committee, *Public Investment Private Greed*, June 12, 2003, at 2, https://www.sanders.senate.gov/wp-content/uploads/Public-Medicines-Report-updated.pdf.

[12] *See, e.g.*, Jesse Drucker, *Ireland central to alleged $1.4bn 'abusive' tax shelter by pharma giant: Accidental disclosure by IRS exposes $1bn tax fight with Bristol Myers Squibb*, Irish Times, April 3, 2021, https://www.irishtimes.com/business/health-pharma/ireland-central-to-alleged-1-4bn-abusive-tax-shelter-by-pharma-giant-1.4527583.

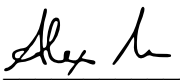
negotiations or litigation against private patent owners, which would lead to reduced production costs and market prices for generic medicines. In the long run, such transparency could also decrease transaction costs and prevent patent litigation by increasing the clarity and predictability of patent royalties and making licensing markets more efficient and symmetrical.

The potential value of patent licensing information is especially great because of the law governing damages for patent infringement. By law, patent owners are entitled to receive no more and no less than a "reasonable royalty" for patent infringement (35 U.S.C. § 284). Comparable licenses are often used as evidence of what constitutes a "reasonable" royalty. Therefore, providing information about government patent licenses can be invaluable evidence for generic drug manufacturers, particularly those without access to such data due to not being government licensees.

III. CONCLUSION

PIPLI appreciates the opportunity to provide comments on these important issues and commends the NIH for organizing this Workshop. We eagerly anticipate future opportunities for public consultation as well. Specifically, we strongly urge the NIH to conduct workshops or create other avenues for public feedback concerning guidelines on NIH patenting decisions, patent application drafting, and the transparency of patent license information. Progress in these areas is vital for maximizing the NIH's influence on technology transfer and public health outcomes.

Respectfully submitted,



Alex H. Moss
Executive Director
Public Interest Patent Law Institute
alex@piplius.org

July 27, 2023

Submission Date: 7/28/2023

Name: Jocelyn Ulrich

Name of Organization: Pharmaceutical Research and Manufacturers of America

Comment:

Dear Dr. Jorgenson,

Please find attached comments from PhRMA to inform the proceedings of NIH's Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

Sincerely,

Jocelyn

Jocelyn Ulrich, MPH
she/her/hers
P*h*RMA
Deputy Vice President
Policy, Research and Membership

Additional Comment (attachment):

July 27, 2023

SUBMITTED VIA EMAIL to sciencepolicy@od.nih.gov

RE: Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

Dear Dr. Jorgenson,

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments to inform the proceedings of NIH's Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer. PhRMA believes that maximizing the timely transfer of federal investments in science and technology and attracting greater private sector investment to create innovative products, processes, and services as well as new businesses and industries, is critically important for America's patients, the U.S. economy, and our national security.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to researching and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA's member companies have invested more than $1.1 trillion in the search for new treatments and cures, including an estimated $102.3 billion in 2021 alone.[1]

The U.S. biopharmaceutical industry relies on a well-functioning, science-based regulatory system, strong and reliable intellectual property (IP) protections, and coverage and payment policies that support and encourage medical innovation to thrive. This framework, in addition to the collaborative biopharmaceutical research ecosystem that includes both the private and public sectors, yields more innovative medicines than any other country in the world. The American biopharmaceutical research ecosystem is among our country's greatest strengths – largely due to policies enacted by Congress to ensure that federally funded inventions can move from the laboratory to the marketplace for the public good.

Congress passed the Bayh-Dole Act in 1980 with bipartisan support to incentivize the private sector to transform discoveries resulting from government funded early-stage research into useful products. By allowing grant recipients such as universities to retain the title to the patents covering their inventions and enabling them to license the patents and the right to use those inventions to private sector partners, the Bayh-Dole Act facilitates the development of commercially available medical treatments. Prior to enactment of the Bayh-Dole Act, the government retained the patents on federally funded inventions – and only 5% of those patents

[1] 2022 PhRMA Annual Membership Survey, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/P-R/PhRMA_membership-survey_2022_final.pdf

were ever licensed for use in the private sector.[2] Collaboration was further incentivized by The Federal Technology Transfer Act of 1986, which authorized Federal laboratories to enter into cooperative research and development agreements (CRADAs) with private businesses and other entities. These policies have proven critical to maximizing taxpayer benefit for government-funded research. Several studies have demonstrated that increases in NIH-funded basic research results in increased private R&D investment and innovation.[3] One study found that in the decade following an increase in NIH funding, private R&D spending grew by about eight times as much as the increase.[4] Another study found that each $10 million increase in NIH funding resulted in private sector investment yielding a net increase of 2.7 patents.[5]

Although many medical discoveries have their origin in the research laboratories at the NIH or federally funded academic medical centers, technology transfer is what allows these discoveries to be developed, reduced to practice and made available to improve public health through licensing and collaboration agreements with the private sector. According to the NIH Office of Technology Transfer, "technology transfer moves medical innovation from the benchtop through additional research and development, testing, regulatory approval, manufacturing, and finally to distribution as a medical product which will improve the health of everyone."[6] Partnership between the government and the private sector is critical because each plays a fundamentally different but complementary role in the biopharmaceutical R&D ecosystem. According to the Congressional Budget Office (CBO), "the complementary relationship between public and private R&D spending arises mainly because NIH funding focuses on basic research that leads to the discovery of new drugs and vaccines, whereas private spending focuses on applications of such research."[7] While NIH plays an important role in fostering basic research in genomics, molecular biology and other life sciences that have identified new disease mechanisms, these discoveries are far from fully developed therapies for patients. These discoveries only become fully developed therapies available to patients because of private industry contributions, both financial and technical.

The biopharmaceutical industry's unique role in the research ecosystem is to utilize its scientific and industrial expertise and invest at risk to build upon and further advance basic science research to determine if safe and effective treatments can be developed and made available to patients. The federal government cannot research, develop and manufacture vaccines and other new treatments without the resources, scientific expertise, R&D, manufacturing and

[2] Mittal, A. K. (2009). *Federal Research: Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions*. Available at: https://www.gao.gov/assets/gao-09-742.pdf

[3] Schacht, Wendy H. (2012). *Federal R&D, Drug Discovery, and Pricing: Insights From the NIH-University-Industry Relationship*, Congressional Research Service Report RL32324.

[4] Toole, Andrew A. (2007). *Does Public Scientific Research Complement Private Investment in R&D in the Pharmaceutical Industry?* Journal of Law & Economics, 50(1) 81–104, https://doi.org/10.1086/508314.

[5] Azoulay, Pierre et al. (2019*). Public R&D Investments and Private-Sector Patenting: Evidence From NIH Funding Rules*, Review of Economic Studies, 86(1)117–15. Available at: https://academic.oup.com/restud/article/86/1/117/5038510?login=true

[6] https://www.techtransfer.nih.gov/nih-and-its-role-technology-transfer

[7] https://www.cbo.gov/publication/57126

technological platforms and financial investment from private sector biopharmaceutical companies.

A rich body of research documented the nature of the complementary roles of the public and private sectors in advancing medical treatments. In 2001, the NIH concluded in a study for Congress that the biopharmaceutical industry was responsible for the discovery and development of 91 percent (43 out of 47) of all the top-selling marketed drugs in 1999.[8] A 2010 analysis of 252 drugs approved between 1998 and 2007 found that 76 percent originated in industry vs. 24 percent in academia.[9] A 2014 study of the most transformational drugs of the 25 prior years, as identified by over 200 physicians, found that the private sector was responsible for the vast majority of the work required to develop a therapy.[10] An analysis of the contribution of NIH funding to new drug approvals 2010 – 2016 found that although NIH funding contributed to published research associated with every one of the 210 new drugs approved by the FDA in those years, 90% of the NIH funding supported basic research related to the biological targets for drug action rather than the drugs themselves.[11] And an analysis of 23,230 NIH grants awarded in the year 2000 that were ultimately linked through the reported patent filings to 18 FDA-approved therapies showed that NIH funding totaled $0.670 billion, whereas private sector funding totaled $44.3 billion.[12] Accordingly, the private sector makes a substantial investment in research and development of biopharmaceuticals that far exceeds the contribution of the public sector.

The NIH has certain rights and procedures when it considers licensing a patented invention for further development by the private sector. Companies that want to obtain a license to develop an NIH invention must complete an application, and if the applicant has requested an exclusive or partially exclusive license the NIH will publish a notice in the Federal Register, as required by law, and after review and evaluation of public comments will make a final determination regarding the license.

NIH considers several factors when determining whether to grant a license, and what kind of license. The criteria for consideration as to exclusive licenses include whether an exclusive license serves the best interest of the public and whether it is a reasonable and necessary incentive to promote the investment of risk capital to bring the invention to practical application

[8] Department of Health and Human Services (DHHS), National Institutes of Health (NIH). (2001). *Report to the United States Congress, NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected.* Available at: https://www.techtransfer.nih.gov/sites/default/files/documents/policy/wydenrpt.pdf
[9] Kneller, R. (2010). *The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs*. Nature Reviews/Drug Discovery, 9, 867-82. Print.
[10] Chakravarthy R, Cotter K, DiMasi J, et al. (2016). *Public- and private-sector contributions to the research and development of the most transformational drugs in the past 25 years: from theory to therapy*. Ther Innov Regul Sci. 2016;50(6):759-768.
[11] Galkina Cleary, E., Beierlein, J. M., Khanuja, N. S., McNamee, L. M., & Ledley, F. D. (2018). *Contribution of NIH funding to new drug approvals 2010-2016*. Proceedings of the National Academy of Sciences of the United States of America, 115(10), 2329–2334. https://doi.org/10.1073/pnas.1715368115
[12] https://vitaltransformation.com/2022/09/the-relative-contributions-of-nih-and-private-sector-funding-to-the-approval-of-new-biopharmaceuticals/

by a licensee. NIH can negotiate to ensure that exclusive or partially exclusive license terms and conditions are not broader than necessary.[13,14]

Private companies often understandably prefer exclusive licenses that allow them to be the sole user of a patented invention for certain uses for a specified period of time in order to provide a measure of certainty and predictability during the highly risky, lengthy, and costly drug development process. The investment necessary to develop a new medicine can cost an average of several billion dollars and take 10-15 years, and only 12% of medicines entering clinical trials ever obtain an FDA approval.[15] NIH is also aware of these risks when making licensing decisions. As part of licensing agreements NIH receives royalties from the private sector which can be reinvested in research and potential new discoveries by the agency. GAO has found that NIH received up to $2 billion in royalties between 1991 and 2019.[16]

Given the high costs and length of time to research and develop new medicines and vaccines, as well as to invest in manufacturing facility enhancements and to invest in new facilities altogether, strong and reliable IP rights are critical for providing the potential for returns and spurring companies to make the needed investments needed to develop future medicines. Manufacturers seek the certainty and predictability provided by IP protections to make the decades long investments in new technologies, and in building and expanding upon state-of-the-art manufacturing facilities. Strong and reliable IP protections are also critical to fostering public-private partnerships and other forms of collaboration, including investment in emerging innovator companies.

Though the Bayh-Dole Act allows the federal government to "march-in" under a narrow set of circumstances, "march-in" was never intended to serve as a mechanism for regulating the pricing of any products, including prescription medicines. The provisions provide the right for the government to "march in" under a narrow set of circumstances and force patent holders to grant a license to a "responsible applicant" able to utilize the technology to address an unmet need. In the nearly four decades that the Bayh-Dole Act has been in place, NIH, after careful review, has rejected each of the seven march-in petitions based on pricing that have been submitted to the agency. In each case, NIH consistently concluded that the products subject to a march-in petition had reached practical application and met health or safety needs. Even in an instance where march-in was requested to respond to a manufacturing supply challenge, NIH concluded that the manufacturer was "working diligently to resolve its manufacturing difficulties"[17] and "no

[13] https://www.techtransfer.nih.gov/licensing
[14] See 37 CFR § 404.7
[15] DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of health economics*, *47*, 20-33.
[16] https://www.gao.gov/products/gao-21-52
[17] Thomas, J. (2016). March-In Rights Under the Bayh-Dole Act. CRS. Available at: https://fas.org/sgp/crs/misc/R44597.pdf.

remedy that is available under the march-in provision would address the problems identified by the requestors."[18]

In an Op-Ed to the Washington Post, the bill's authors, Senators Birch Bayh and Bob Dole, stated: "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."[19] Similar provisions cover the licensing of NIH inventions, which empower the NIH to terminate the license in whole or in part if the agency determines that the licensee is not executing its commitment to achieve practical application of the invention, the licensee is in breach of an agreement, termination is necessary to meet requirements for public use, or the licensee has been found by a court to have violated Federal antitrust laws in connection with its performance under the license agreement.[20] Changing policy on these provisions to allow price to be considered as a factor for action on the part of NIH could chill the private sector's willingness to enter into contractual agreements and licenses with the agency.

PhRMA is also strongly opposed to any proposals to add "reasonable pricing" requirements to agreements between the NIH and private companies. Policy proposals to place pricing restrictions on the private sector as a condition of partnering with the government have been tried before with disastrous results for patients and taxpayers. In 1989, the NIH imposed "reasonable pricing" conditions in all Cooperative Research and Development Agreements (CRADAs) between federal labs and outside parties to conduct research or development. The policy was revoked in 1995 after public meetings were held with companies, patient advocates and researchers after which the agency concluded that these pricing conditions significantly chilled collaboration between the public and private sectors.[21] In his announcement of the decision, then Director of the NIH, Harold Varmus, M.D., said, "An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public." Dr. Varmus further said, "Eliminating the clause will promote research that can enhance

[18] National Institutes of Health (NIH). (2010). National Institutes of Health Office of the Director: Determination in the Case of Fabrazyme Manufactured by Genzyme Corporation. Available at: https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf.

[19] Bayh, B. and Dole, R. (2011). Our Law Helps Patients Get New Drugs Sooner. Washington Post op-ed. Available at: https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=sr_1

[20] https://www.techtransfer.nih.gov/licensing

[21] National Institutes of Health. (1994). Reports of the NIH Panels on Cooperative Research and Development Agreements: Perspectives, Outlook, and Policy Development. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH_%20CRADA_Report_on_Reasonable-Pricing_Clause_1994.pdf

the health of the American people." [22] After the removal of the clause, there was a subsequent rebound in CRADAs.[23]

Policies enabling the government to determine the "reasonable price" of medicines developed with support from NIH also fail to recognize that reducing the incentives for the private sector to invest in the future development of medicines could have serious unintended consequences for our national security and ability to respond to public health emergencies. The NIH and BARDA routinely partner with biopharmaceutical companies to support medical countermeasure (MCM) development through funding, technical assistance, and core services like clinical trial site management and manufacturing scale-up. Several MCMs, such as monkeypox vaccines, smallpox antiviral drugs, H5N1 influenza vaccines and anthrax vaccines are maintained in the strategic national stockpile, where they can be made available in the face of a public health threat.[24] Pipeline products being explored have potential but there is no guarantee they will ultimately receive FDA approval or have more than limited commercial utilization, and thus seeking to inject further uncertainty by setting an arbitrary price at the outset may simply serve to further chill critical R&D investments and collaborations between the public and private sectors with the end-result leaving the United States unprepared to quickly respond to emerging health threats.

As NIH considers the feedback from this Workshop's proceedings, PhRMA suggests the agency can learn from other similar efforts from agencies such as NIST, who published a roadmap for "Unleashing American Innovation" in 2019 through its Return on Investment Initiative Green Paper.[25] Among other things, the authors of the report found that federal officials must better engage with the private sector, strengthen IP protections, and incentivize technology transfer.[26]

The biopharmaceutical industry is proud to be a key player in the U.S. biopharmaceutical research ecosystem. We rely on a well-funded and robust public research infrastructure to generate meaningful scientific exchange and partner with to advance science for the benefit of American patients. We look forward to ongoing dialogue on these issues. Please free to reach out to David Korn, Vice President, IP and Law at dkorn@phrma.org or me at julrich@phrma.org with any questions or for additional discussion.

Sincerely,

Jocelyn Ulrich, MPH
Deputy Vice President
Policy and Research
PhRMA

[22] Press Release, NIH News, April 11, 1995. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf
[23] https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf
[24] https://aspr.hhs.gov/SNS/Pages/Requesting-SNS-Assets.aspx
[25] https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf
[26] See page 5 at; https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf

Submission Date: 7/28/2023

Name: Hans Sauer

Name of Organization: Biotechnology Innovation Organization

Comment:

Please find attached BIO's comment in preparation for the NIH upcoming technology transfer workshop. Thank you in advance for considering our comments; we look forward to the workshop on Monday.

Sincerely,
Hans Sauer

Hans Sauer, Ph.D., J.D.
Deputy General Counsel,
Vice President, Intellectual Property
—
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Additional Comment (attachment):

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Comments of the Biotechnology Innovation Organization (BIO) to the July 31, 2023 NIH Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

Vial email to SciencePolicy@od.nih.gov

July 27, 2023

On behalf of its member organizations, the Biotechnology Innovation Organization ("BIO") is pleased to submit this Comment in preparation for the NIH July 31 Workshop on Technology Transfer.[1] BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members range from startup companies developing their first commercial products to multi-national Fortune 500 pharmaceutical corporations. BIO's members routinely collaborate and interact with researchers in NIH's intra- and extramural programs, and have long supported the NIH in its critically important role of funding and advancing biomedical science in the United States and throughout the world.

As an initial matter, we are pleased to participate in the NIH's upcoming workshop, and we look forward to learning more about any specific interests or concerns the NIH may have identified with how it currently "approaches the patenting and licensing of biomedical inventions," and with its role "in the broader biomedical research enterprise in promoting the application of knowledge to enhance human health." Articulating those interests or concerns will help enable informative and focused comments in ongoing dialogue between the NIH and its stakeholder community. We appreciate the NIH's outreach and look forward to learning more at the workshop.

Biomedical research productivity in the United States is the highest in the world, with 62% of new drugs first approved by the FDA having their origins in the U.S., more than the rest of the world combined.[2] This high biomedical research productivity depends on a fluid system of technology transfer, licensing, and partnering that was first perfected in the United States, and in which both the private and the public sector participate. For example, in a cohort of 223 new U.S. drug approvals from 2011-2020, thirty drugs (13.5%) originated in public sector institutions and all were licensed to biopharmaceutical firms for development and regulatory submission.[3] In another study of 248 small molecule drugs approved by the FDA between 2008-2017, thirty-five (14%) had evidence of U.S. academic or public research institution involvement in their creation (about half of which were specifically found to have a US government

[1] See https://osp.od.nih.gov/events/workshop-on-transforming-discoveries-into-products-maximizing-nihs-levers-to-catalyze-technology-transfer/

[2] The US Ecosystem for Medicines. How New Drug Innovations Get to Patients. White paper available at: https://vitaltransformation.com/2022/12/the-us-ecosystem-for-medicines-how-new-drug-innovations-get-to-patients/

[3] See id. Another 33 drugs (15%) were first conceived in large biopharmaceutical firms and transferred to small- or medium-sized firms during development; and 20 drugs (9%) were first conceived by small or medium-sized enterprises and transferred to large ones prior to FDA approval.

contribution);[4] and another 13 drugs (5%) involved inventive contributions from *foreign* public research institutions; all of which were licensed to the private sector for development and commercialization. These studies are consistent with earlier reports that found the U.S. public sector to have contributed *directly* to the invention of about 10-15% of new drugs over the past several decades.[5]

In addition to direct contributions to the invention of at least some new drugs, public sector research also plays an important enabling role by funding basic research and generating new insights into biology and disease. For example, NIH-supported published research was found to be relevant to each of 210 new medicines first approved by the FDA from 2010-2016. Over 90% of this research related to the underlying mechanism of disease and the drug targets (not the drugs themselves), and thus represents an indirect, but important, contribution to the generation of new therapies.[6] This in itself should be unsurprising, as all new drugs are built on a solid foundation of earlier research, which itself built on yet earlier research, much of which was publicly-funded.

In fact, our system is very effective in funding basic research that the private sector is not in a position to conduct. The results of this publicly-funded research in the vast majority of cases enters the public domain through scientific publications, scholarly exchange, generally-accessible databases and other mechanisms that are accessible to anyone. At times, publicly funded research also results in technology that is suitable for patenting (either by the government or by the academic institutions it funds), and is then offered for licensing to suitable private firms better able to translate those early discoveries into FDA approved therapies. This collaboration between the public and private sectors forms the foundation for US leadership in this field. In evaluating our tech transfer system, BIO urges NIH to examine what has made this partnership so successful so that we can build on that success.

Because taxpayers support a great amount of basic biomedical research, many people believe that the public pays twice for drugs; once by funding underlying research and once when payors and patients buy drugs for personal use. This has led to calls for measures that tie medicine prices to public science funding, such as an (renewed) implementation of “reasonable pricing clauses” in government research grants and contracts. Explicit in such proposals is a belief that taxpayers are being insufficiently rewarded for their contributions to the creation of new drugs and therapies.

U.S. investment from all sources in both basic and applied biomedical R&D in 2020 was estimated to amount to approximately $245 billion, of which $61.5 billion was attributable to the federal government; $16.8 billion to academic and research institutions; $3 billion to foundations, philanthropies, and professional societies; and $161.8 billion (66% of the total) to the private sector.[7]

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[4] Nayak, Avorn, and Kesselheim, Public Sector Support for Late-Stage Discovery of New Drugs in the United States: Cohort Study, *BMJ* 2019;367:l5766; available at: https://doi.org/10.1136/bmj.l5766 . A US government contribution was defined as the drug originating in a federal laboratory, or a patent assignment to a federal agency, or a patent declaring US government funding of the invention.

[5] See, e.g. Sampat and Lichtenberg, What are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation? Health Aff. 30 (2011), 332-339; Stevens et al., The Role of Public-Sector Research in the Discovery of Drugs and Vaccines, N. Engl. J. Med. 364 (2011) 535-541.

[6] Cleary et al., Contribution of NIH Funding to New Drug Approvals 2010-2016, Proc. Natl. Acad. Sci. USA 115 (2018) 2329-2334.

[7] Research!America, U.S. Investments in Medical and Health Research and Development 2016-2020; available at: https://www.researchamerica.org/wp-content/uploads/2022/09/ResearchAmerica-Investment-Report.Final_.January-2022-1.pdf

By this measure, the federal government does indeed contribute a significant chunk of the total national biomedical R&D spend – about 25% of the total. Great difficulties arise, however, when trying to quantify the public contribution to new drug development in the context of ongoing debates over drug prices. For example, in an effort to quantify the NIH contribution to the creation of remdesivir, one of the first COVID antiviral compounds, study authors added up decades of NIH-supported basic research publications in the general fields of nucleoside analogue chemistry (the drug molecule's chemical class) and RNA-dependent RNA polymerase (the enzyme on which remdesivir acts), to arrive at an eye-popping public contribution of $6.5 billion in basic research funding that, they propose, "led to" the drug and should be counted when considering its pricing.[8] A subsequent GAO study, however, found only a much smaller public contribution of $161 million to preclinical and clinical investigations of remdesivir itself (a 40-fold difference) and no inventive government contribution to the drug product at all. Meanwhile, the manufacturer of remdesivir estimates its financial outlays for the drug's preclinical and clinical development at approximately $1.3 billion.[9]

This example illustrates some of the many conceptual and practical problems with comparing the public funding of research in the field to which a drug pertains against the cost of subsequent R&D on the drug itself. Government funding makes vast and critical contributions to the advancement of medicine by furthering our understanding of human disease and pointing in promising directions for applied drug research, but the weight of the evidence shows that in most cases the private sector invents the drugs that are based on that research and assumes the cost and risk of translating new scientific insights into practical new products.[10]

It is true that direct returns to the government from licensing, in monetary terms, constitute only a small fraction of the NIH budget,[11] but criticisms of insufficient returns do not account for the vast indirect benefits and externalities that accrue to the public in the United States (and in foreign countries around the world) in the form of improved health outcomes, job creation, research productivity, education, economic development, and tax revenues. When the government's *direct* financial contribution to drug development is assessed (i.e. not counting basic research in the general field to which the drug pertains), the picture is quite different. For example, a prospective study of >23,000 NIH grants in FY 2000, representing $7.1 billion in public funding, showed that only a small fraction could be linked to only 18 new drug approvals over the subsequent two decades. And for these 18 drugs, the government's contribution to their creation constituted $640 million whereas the private sector firms that developed

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[8] Cleary et at., Foundational Research and NIH Funding Enabling Emergency Use Authorization of Remdesivir for COVID-19, available at: https://www.bentley.edu/news/65-billion-nih-funding-foundational-research-enabled-emergency-use-authorization-remdesivir

[9] US Government Accountability Office Report GAO-21-272, Information on Federal Contributions to Remdesivir, available at: https://www.gao.gov/assets/gao-21-272.pdf

[10] Developing a new drug through clinical trials and regulatory approval has been estimated to consume about 10 years and require an investment ranging from 0.7-2.5 billion dollars at an approximately 90% chance of development failure. These risks and costs are borne almost entirely by the private sector.

[11] NIH Technology Transfer Report FY 2021, available at: https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/FY2021%20NIH%20Technology%20Transfer%20Annual%20Report.pdf . NIH licensing revenue for FY 2021 was reported at approximately $127 million.

these drugs to approval contributed $44.3 billion.[12] This study, as well as other accumulated evidence, indicates that the government's direct monetary returns may be small in relative terms, but generally commensurate with its proportionally small direct investment in drug development.

Conversely, the lion's share of public research funding does not go towards new product development, but towards advancing science and enriching the public domain with new knowledge, thus creating opportunity, and stimulating commercial risk-taking and vast amounts of private follow-on investment. Seen this way, most public research funding is properly viewed as an infrastructure investment where the resulting body of scientific knowledge becomes available to anyone, anywhere – it is non-excludable - and where one entity's use of that knowledge does not diminish another entity's ability to use it too – it is non-rivalrous. In this sense the NIH helps fund a public good whose importance cannot be overstated. If entrepreneurial businesses, inspired by scientific knowledge that was funded by the public and made available to anyone, decide to invest capital and take on business risk, they are doing exactly what the system intends. In addition to the direct public health benefits derived from the invention of new therapies, this private follow-on investment then generates even more jobs, and fuels economic development.

And in instances where publicly-funded institutions *do* make direct contributions to the invention and development of new products, direct benefits can flow back through profit sharing, royalty payments, repayment of the initial investment, or some other bargained-for mechanism. Indeed, publicly-funded institutions around the country routinely, in appropriate circumstances, acquire proprietary rights in their inventions which they use for partnering, licensing, or other valorization of their institutions' research, in keeping with federal technology transfer statutes and their institutions' policies.

Nonetheless, some members of Congress, advocacy groups, and opinion journalists persist in wanting to link public research spending to the price of downstream products, regardless of the investments made and risks taken by the biopharmaceutical businesses that develop these products. In instances where companies benefited from decades of prior basic research that has long been in the public domain, these companies are said, effectively, to owe a scientific debt to the public, and they should price their products accordingly. And in instances where companies licensed publicly-funded proprietary technology, met their due diligence obligations, and paid milestones and royalties, the licensing institution is nonetheless said to have struck a bad bargain and should have insisted on lower consumer prices of the licensed product. Either way, the narrative goes, taxpayers have generously funded biomedical research and are therefore "owed" more "reasonable" prices for medicines.

Such pseudo-transactional notions[13] - that the current system of public biomedical research funding justifies a form of drug price control – not only misstate the realities of our public-private R&D ecosystem; they are also profoundly infeasible. For example, if public research funding entitles taxpayers to a discounted price for a successful drug, how much of a discount would be justified? Should that price reduction be commensurate with how much public funding was involved, relative to how much private funding went into commercializing the drug? In the much-publicized march-in petition for Xtandi®, the US government's contribution has been stated as approx. $500,000 in the form of initial research funding,

[12] Schulthess *et al.* The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals. *Ther Innov Regul Sci* **57**, 160–169 (2023). https://doi.org/10.1007/s43441-022-00451-8

[13] See, for example, the statement made by Rep. Ocasio-Cortez in a January 2019 hearing of the House Committee on Oversight and Reform: "[T]he public is acting as early investor, putting tons of money into the development of drugs that then become privatized, and then they receive no return on the investment that they have made."

whereas the manufacturer of the drug and its commercial partners estimate their subsequent investment at approx. $2.2 billion[14] – how much of a lower price could the public be deemed to have "earned" by virtue of a federal research grant in such situations?

In general, arguments that the public is owed lower prices ignore the fact that the public and the private sectors, for the most part, fund research that is different but complementary, that the private sector spends significantly more than the public sector in monetary terms, and that the private sector assumes basically the entire risk that an experimental product will fail on the path of drug development.

Most important, proponents of so-called "reasonable pricing" fail to understand that their concept cannot work in the absence of a framework where *ex ante* bargaining can occur. At the time when a typical biomedical research grant is awarded, or a license to untested technology is offered, the parties will generally not know if the funded research will ever contribute to a drug product, when that drug product will come into existence, or who will bring it into existence. It will not be known how much it will cost to develop that drug, which conditions it will treat, or how it will be used in clinical practice. In such situations it is impossible to bind future parties to an agreement under which, if a drug is eventually developed against all odds, they could lose their investment and their rights if the government doesn't deem the drug's price reasonable. Businesses would simply walk away and invest their time and capital elsewhere.

Our current tech transfer system has been enormously successful. In 1980, prior to the enactment of the Bayh-Dole Act, less than 5% of the federal government's nearly 30,000 patents had been licensed for commercial development.[15] By empowering federally-supported universities and small businesses to hold and license patents, the Bayh-Dole Act fueled a vibrant innovation sector that, between 1996 and 2017, contributed to the development of more than 200 new drugs and vaccines, $865 billion in added GDP, 5.9 million jobs, and more than 13,000 startups.[16] It is hard to see how the American public could be said to have been "ripped off," as some critics now argue.

It may be superficially appealing to argue that U.S. payors should pay less for a new drug that was developed on the basis of seminal publicly-funded research. But it would be neither feasible nor rational to control a drug's price based on relative appraisals of the value and amount of underlying public research. Doing so would only put brakes on the pace of biomedical innovation and distract from other, more rational efforts to lower the cost of healthcare in the United States.

BIO looks forward to engaging further with the NIH on these important questions and thanks the agency for the opportunity to submit these comments.

Respectfully submitted,

Hans Sauer, Ph.D.
Deputy General Counsel, BIO

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[14] https://newsroom.astellas.us/Astellas-Quote-and-Statement-on-the-Bayh-Dole-Act-and-XTANDI-June-14,-2022

[15] Government Accountability Office, Administration of the Bayh-Dole Act by Research Universities, GAO/RCED-98-126 at 3 (May 1998).

[16] AUTM, Driving the Innovation Economy (2018). Available at: https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM_FY2018_Infographic.pdf

Submission Date: 7/30/2023

Name: Mark Emalfarb

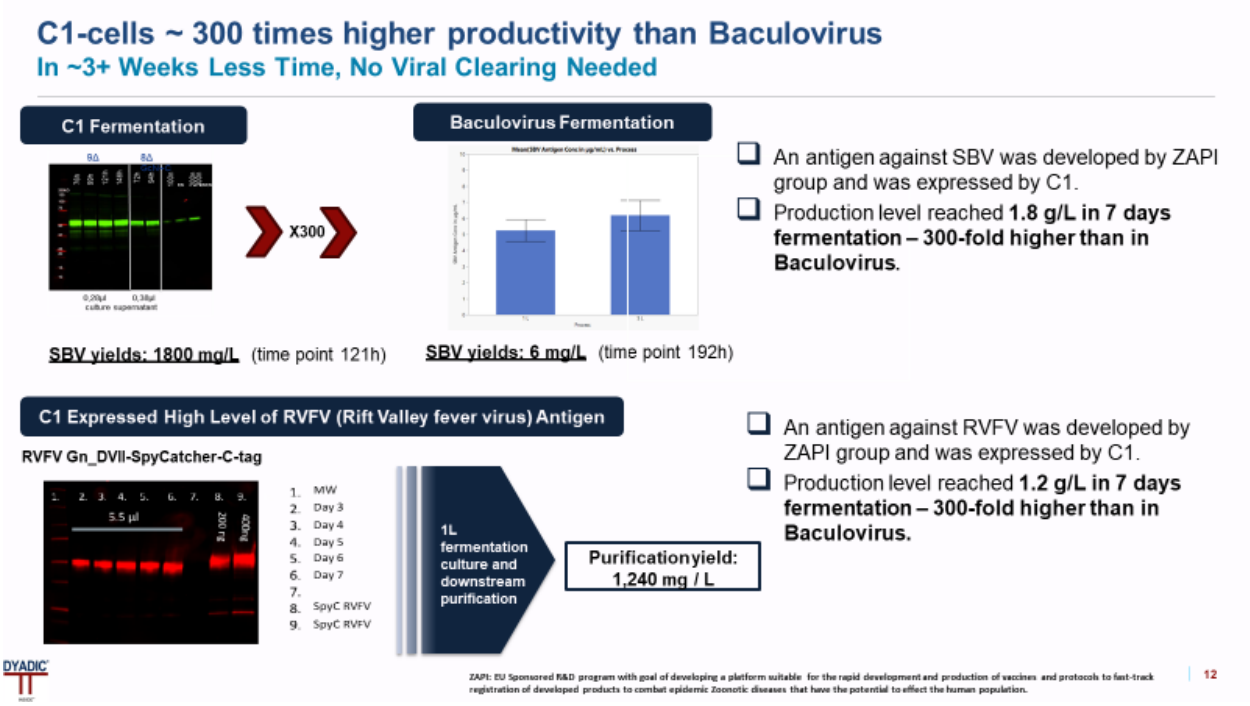
Name of Organization: Not Provided

Comment:

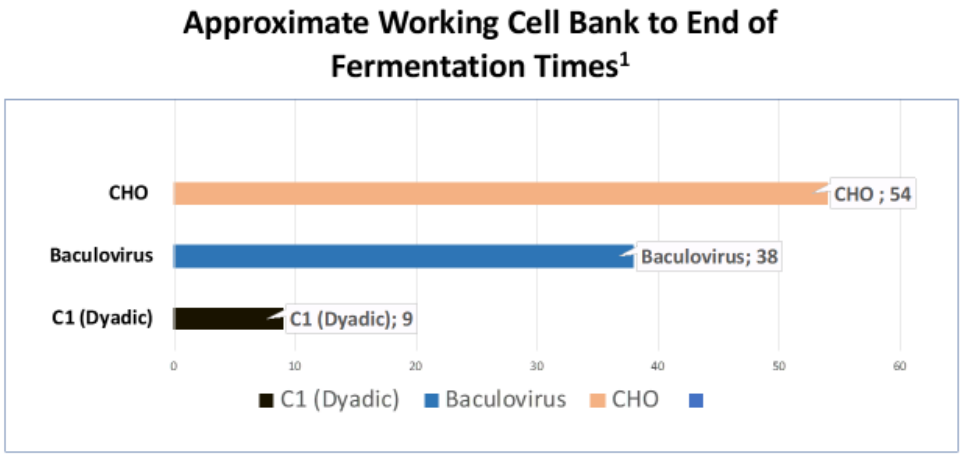
NIH and biotech/pharmaceutical companies need their scientists to utilize the most efficient cell lines in their discovery and development programs.

Too often this is overlooked by scientists early on, inefficiencies are locked in, and if a biologic makes it to commercialization the poor choice of inefficient cell lines at the beginning of the research and development stage ends up with less doses of a vaccine or a drug being available and the cost of manufacturing each dose is greater than it should be wasting tax payer's dollars and making the vaccine and/or drug less available for middle & lower income countries.

An example of this is as follows see two slides comparing yield (c1 cells are ~ 300 times more productive) and speed of manufacturing C1-cells vs Baculovirus and CHO cells (C1 production batches are much shorter).



Short Fermentation Timeline



[1]Ranges: C1 6-9 days; Baculovirus 28-38 days; CHO 41-54 days

Additional Comment (attachment): None