STATEMENT FOR THE RECORD

Conservatives for Property Rights[1]

U.S. Senate HELP Committee

"Taxpayers Paid Billions For It:
So Why Would Moderna Consider Quadrupling the Price of the COVID Vaccine?"

March 22, 2023

Chairman Sanders, Ranking Member Cassidy, and Members of the Committee:

Our coalition, Conservatives for Property Rights, fears the HELP Committee may be missing the forest for the trees, judging from the hearing's title. The fact is, no COVID-19 vaccines would have been developed at all—much less safe and effective ones in so short a time—without a certain "crown jewel" in place in the United States: a dynamic, world-leading innovation ecosystem.

Without the elements of the U.S. innovation ecosystem, there would be little if any invention, little if any private investment in innovative startup companies and early-stage enterprises, and few if any cutting-edge inventions that improve the lives, health, and living standards for the citizens of our nation and humanity beyond. The cornerstone of America's innovation system is private property, and private intellectual property rights in particular. Property rights and secure title to property attract private investors willing to risk their capital on a prospective enterprise and products.

To imply that the "billions" taxpayers "paid" in government's modest, preliminary share—foundational research far removed from any end product—have any connection to the price of any eventual end product is a stretch.

The truth is that about one-quarter of National Institutes of Health grants underwrite discovery of anything connected to a new medicine. Those are basic scientific findings, not commercializable in themselves without a fraught path of applied research and development. While NIH's budget is around $30 billion, private industry invests around $100 billion in research and development each year. The average new drug is backed by $1.3 billion in private investment, faces a 10-year R&D window, and stands a 10 percent chance of successfully clearing approval to go on market.[2]

CPR limits our discussion to the "march-in" provision of the Bayh-Dole Act and 28 U.S. Code section 1498. These are two of the top demanded remedies by those who assert government funding paid the lion's share of discovery and new product development, including biopharmaceuticals.

**Bayh-Dole "March-In"**
The Bayh-Dole Act is the foundation for efficient, effective, decentralized technology transfer of inventions derived from federally funded basic research. Bayh-Dole has proven highly

[1] Conservatives for Property Rights is a coalition of conservative and libertarian organizations that emphasizes the central importance of private property in all its forms — physical, personal, and intellectual.

[2] https://www.cbo.gov/publication/57126; https://www.phrma.org/policy-issues/Research-and-Development-Policy-Framework; https://www.pnas.org/doi/10.1073/pnas.1715368115

effective. Before Bayh-Dole, untold millions of federal research dollars brought about 28,000 government-held patents. However, the government retained the IP rights. Obtaining an exclusive license to attempt commercialization was nearly impossible. And the byzantine, centralized, inconsistent means across agencies of obtaining a license to a federally owned patent kept practical benefit from all that research vastly limited—commercialization was attempted on only 5 percent of pre-Bayh-Dole government patents.

Bayh-Dole has succeeded by leveraging IP certainty for universities and others and handing tech transfer decisionmaking to research institutions, which now typically own the patents to campus inventions. The Congressional Research Service reports, "One of the major factors in the reported success of the Bayh-Dole Act is the certainty it conveys concerning ownership of intellectual property." CRS continues: "Observers generally agree that the Bayh-Dole Act has successfully met its objectives. . . . The government receives a significant payback through taxes on profits and society benefits from new jobs created and expanded productivity. The importance of patent ownership has been reinforced by the positive effects [that] studies have demonstrated P.L. 96-517 [has had] on the emergence of new technologies and new techniques generated by American companies."[3]

The Bayh-Dole Act's march-in provision, found at 35 U.S.C. § 203, specifies four narrow grounds for the government's exercise of march-in rights. None mentions nor implies a resulting product's price. Pricing of end products rests on many, complex factors, often not associated with basic research inputs far back in the rear view mirror. There is rightfully no statutory basis for considering product price in connection with exercise of march-in rights. Indeed, Sens. Birch Bayh and Robert Dole confirmed that price was an intentional omission from the statute. "Bayh-Dole did not intend that the government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional . . . ."[4]

March-in is not legally permissible nor available as a price control mechanism for resulting drugs or any other product. The consistent reading of this law by both Democratic and Republican administrations has resulted in all march-in petitions to be denied. Bipartisan officials have refused to legitimize numerous petitions over many years seeking exercise of march-in based on a product's price, as there is no basis in law. In fact, to misuse march-in in the requested manner would violate the letter and the spirit of the law and of the law's authors.[5]

Further, the federal government stumbled into a real-world experiment that produced results similar to what march-in based on the illegitimate basis of product price would likely cause. In 1989, the NIH began including a "reasonable pricing" provision in its Cooperative Research and Development Agreement federal contracting vehicle in order for private firms to obtain an exclusive license to NIH-funded technologies. The requirement caused a significant drop in NIH CRADAs, which fell from 42 in 1989 to an average of 32 the next six years. The uncertainty, diminished IP value, and weakened property rights of this CRADA provision led NIH to drop the pricing clause. CRADAs with NIH then quickly rose to 87 agreements in 1996 and 153 in 1997. This misadventure should be a cautionary tale.

**Section 1498**

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[3] https://sgp.fas.org/crs/misc/RL32076.pdf

[4] https://ipwatchdog.com/2021/03/02/setting-record-straight-nist-public-meeting-senators-bayh-dole-didnt-sell-out-law/id=130443/

[5] https://ipwatchdog.com/2022/03/11/conservatives-urge-hhs-deny-turning-bayh-dole-march-provision-price-controls/id=147345/

Rather than a tool for expropriation of IP, Title 28 U.S. Code section 1498 protects IP owners against patent infringement by the government. It provides a means for compensating takings of private intellectual property, requiring government's payment of "reasonable and entire compensation" to the private property owner. In the case of a pharmaceutical product, compensation alone will exceed a billion dollars.

Properly understood, § 1498 may not serve as a type of "march-in." Clearly, this law is designed to compensate private owners of IP, not force them to submit to the government exercising "taking" of their inventions and then setting up shop selling knockoffs in the commercial market.

Instead, § 1498 provides the owner of a patent or copyright used without permission by the government a means of recouping damages from the government's IP infringement. This provision waives the U.S. government's sovereign immunity in order to secure private IP rights.

While the Constitution permits the federal government the power to take private property for a legitimate public use, that authority is limited by the Fifth Amendment's requirement that the government pay the property owner "just compensation." That is, the government must pay the IP owner what the property is worth. Again, in the case of a pharmaceutical product, its value is likely to be in the billions.

Section 1498(a) specifies that "the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his *reasonable and entire compensation for such use and manufacture*" (emphasis added). An infringed patent owner that is an independent inventor, nonprofit, or small business may also recoup litigation costs. The court determines damages in these patent infringement cases, applying factors set out in *Georgia-Pacific* and contemplating a hypothetical negotiation.

The total costs to taxpayers of the 1498 scheme don't end there. Beyond paying the infringed IP owner "reasonable and entire compensation" for the infringement, the government must expend billions more taxpayer dollars on a contract manufacturer to produce the knockoff drug. The copied version must undergo approval by the Food and Drug Administration. Assuming FDA approval eventually ensues, all the costs of practical and logistical matters, such as packaging and labeling, storage, distribution, etc., would raise taxpayers' costs for actions following the IP infringement, take several years to complete, and perhaps cause supply shortages of key ingredients, with supply and price implications across the board.

Further, the contract manufacturer and other parties to the government's misapplication of 1498 face liability for their manufacture, sale, and use of the patented product under normal remedies for infringement. Pursuant to *Systron-Donner Corp. v. Palomar Scientific Corp.* (1965), § 1498 applies only to use of products "by and for the government." Additional liability from he absence of the government's use of the knockoff product, coupled with the commercial sale and use by contracted third parties, private persons, and entities calls into question just how effective § 1498 could possibly be at reducing drug prices. Misuse of 1498 likely would result in no change in drug prices or cause prices of the drugs in question to rise.

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Conservatives for Property Rights urges the committee to abandon the course of unadvised misuse of these or any other provisions of law that carefully, properly balance the interests of innovation, private IP rights, taxpayers, and society. Rather than government price controls, the more prudent, productive route is to incentivize innovation and competition through strong, reliable IP.