March 17, 2023

Senator Bernie Sanders
Chairman
Senate Committee on Health,
Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Senator Bill Cassidy
Ranking Member
Senate Committee on Health,
Education, Labor, and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Chairman Sanders and Ranking Member Cassidy,

On behalf of the Council for Innovation Promotion, I am writing to express concern over calls to misuse the Bayh-Dole Act of 1980 and 28 U.S.C. §1498(a) for purposes they do not and were never intended to authorize.

The Council for Innovation Promotion is a bipartisan coalition chaired by two former directors of the U.S. Patent and Trademark Office. We aim to promote innovation in the United States and global economic competitiveness by championing strong intellectual property rights.

The Bayh-Dole Act reformed patent licensing to allow universities and other nonprofit research institutions to retain the patent rights to discoveries made with federal funds. Prior to Bayh-Dole, the federal government held these patents -- and therefore the authority to license them. Yet only approximately 5% of 28,000 federally-held patents were licensed, effectively depriving taxpayers of any benefit from the research they funded.

The Bayh-Dole Act unleashed unprecedented innovation, as universities established technology transfer offices to license patents to private-sector partners. The system established by Bayh-Dole is credited with creating up to $1.9 trillion in economic output and launching more than 15,000 startups.

The Bayh-Dole Act does include a limited right to "march-in" and license patents to third parties -- but only in exceptional circumstances, such as national emergencies when the patent-holder is unable to meet the nation's "health or safety needs."

Some lawmakers have argued that this provision authorizes the government to re-license patents on brand-name medicines to generic manufacturers. But this argument relies on a twisted reading of the law. Indeed, Senators Birch Bayh (D-IN) and Robert Dole (R-KS) said as much when this "theory" of the law's application first emerged in the early 2000s. That's why every administration -- Democratic and Republican alike -- has rejected every single march-in petition.

Some lawmakers have also claimed that 28 U.S.C. §1498(a) empowers the government to relicense patents on drugs sold to government health insurance programs like Medicare, claiming that a government purchase agreement would immunize the generic manufacturer from any infringement claims.

Once again, this is a distortion of the law. In short, 28 U.S.C. §1498(a) does not provide a broad warrant for patent infringement. Rather, it provides for "reasonable and entire compensation" when the government infringes, as it might have to in a wartime emergency.

We should also note that while advocates of these radical interpretations of the Bayh-Dole Act and 28 U.S.C. §1498(a) have framed their arguments around drug prices, such actions would upend the reliability of all patent rights. If the government could suddenly nullify a patent because a medicine is priced above some arbitrary threshold, all patent protections would rightly be called into question.

The effects on innovation would be disastrous.

If these issues come before your committee, we urge you to thoroughly investigate the claims of those who advocate to upend patent rights, as well as the broader policy implications of such actions. And we invite you to consider the Council for Innovation Promotion a resource as you research these matters.

Respectfully,

Frank Cullen
Executive Director
Council for Innovation Promotion