

STUDENT NOTES

Should the DoD Go Marching-in? US Innovation Leadership & DoD IP Rights

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INTRODUCTION

The United States is locked in a technological arms race with fierce competitors vying for supremacy.¹ And technological innovation will fuel geopolitical dominance. Once the leader in global innovation, the United States faces a turning point as disruptive technology reconfigures global economies and reshapes warfighting capabilities.² The Center for Strategic and International Studies (CSIS) 2021 report noted that the United States' competitive military advantage in technology has eroded as Russia and China are accelerating efforts to gain technological leadership and military advantage.³ Unlike China and Russia, which rely on state-owned research and defense firms, the American innovation ecosystem heavily depends on the private sector to leverage state-of-the-art technical breakthroughs to foster scientific achievement. Staying ahead of adversaries will require renewed focus and creative innovation acquisition strategies. Accelerating America's innovation ecosystem is vital to U.S. national security and will require capturing new commercial technologies, leveraging nontraditional vendors, and acquiring new tech at a much faster pace. However, a balance must be struck between incentives for private sector engagement in government-funded research and the government's need to control intellectual property (IP) rights to protect the public from harmful monopolies.

This note examines the Bayh-Dole Act's role in national security tech innovation, focusing on the Department of Defense's (DoD) interest in leveraging

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1. JAMES ANDREW LEWIS, CTR. FOR STRATEGIC & INT'L STUD., NATIONAL SECURITY AND THE INNOVATION ECOSYSTEM 10 (2021), <https://perma.cc/CBJ9-KEJG> ("The United States is in an era of competition with powerful authoritarian states that intend to reorder the world to better suit their interests and values.").

2. *Id.* at 1 ("Emerging technologies are reshaping economies, societies, and warfare, but this technology will be designed by the private sector for commercial markets.").

3. *Id.* at 11 ("New commercial technologies will provide dominance in future wars, and while the United States is well placed in the innovation race, maintaining its technological advantage in national security will require new approaches to capturing commercial innovation.").

private-sector technology. The government's twin interests in oversight and its need for speed to attract private sector innovation are at odds under the current statutory regime for patents, technical data rights, and detailed manufacturing or process data (DMPD). This note explores *ex ante* Bayh-Dole mechanisms and *ex post* march-in rights as applied to IP acquisitions for patents and government contract law for technical data rights and DMPD.⁴ This note also explores ways Congress could grant agencies more discretion to make case-by-case determinations when deciding to depart from the usual IP framework to pursue faster IP acquisition with the private sector. Part I provides background on the Bayh Dole Act, the march-in rights debate, and calls for reform. Part II explains how the DoD's contracting scheme supersedes its march-in rights authority as a preferred tool for harnessing private sector innovation. Part III discusses novel approaches to national security innovation, including Puplic-Private Partnership (PPP) models and government-funded venter capital. Part IV concludes with final remarks on proposed innovation reforms. Although this note views rapid innovation acquisition from the lens of the DoD's national security mission, other federal agencies could employ the DoD's innovation strategy to facilitate their R&D objectives. Lessons learned from the DoD's rapid innovation approach could open possibilities for other agencies to similarly balance interests in attracting private research and development (R&D) while safeguarding the public from harmful monopolistic behavior.

I. BAYH-DOLE BACKGROUND AND THE MARCH-IN RIGHTS DEBATE

The Bayh-Dole Act represents the government's primary means for safeguarding the public interest and restricting private sector patent rights. This section briefly summarizes the Bayh-Dole Act to add historical context from which to analyze the scholarly debate surrounding calls for statutory reform. Prior to the Bayh-Dole Act, U.S. policymakers feared a lack of commercialization and private investment in follow-on research for federally funded R&D would lead to a decline in innovation.⁵ Previously, government agencies kept the patent rights to taxpayer-funded inventions and used rigid patent clauses to retain title.⁶ For example, in the 1960s, the National Institute of Health (NIH) required pharmaceutical firms to sign patent agreements restricting private entities' ability to obtain patents on new uses of compounds and obligated firms to report results to

4. DoD IP acquisition entails patent, trademark, copyright, and technical data rights.

5. See April L. Butler, *Stealing Thunder from Government Contractors: Thwarting the Intent of the Bayh-Dole Act in Campbell Plastics v. Brownlee*, 31 U. DAYTON L. REV. 477, 491 (2006) ("By 1978, the Government had around 78,000 patents in its portfolio, of which only five percent had been licensed to industry."); see also *Innovation's golden goose*, ECONOMIST (Dec. 12, 2002) ("More than anything, this single policy [the Bayh-Dole Act] measure helped to reverse America's precipitous slide into industrial irrelevance."); Arti Rai & Rebecca Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 304 (2003) ("The prevailing belief was that U.S. industry was missing opportunities to build upon a national advantage in university-based research because universities had no incentive to patent their discoveries and had to overcome strong bureaucratic resistance on the part of government sponsors to retain patent rights.").

6. Butler, *supra* note 5, at 489–90.

NIH investigators.⁷ The restrictive patent agreements gave the government non-exclusive, royalty-free licenses with the power to disclose test results and obtain sublicenses for governmental purposes.⁸ Restrictive patent agreements negatively impacted the government's private sector collaboration efforts—especially at a time when the government realized its post-WWII resources could not meet its growing demand for more sophisticated military equipment.⁹ Meanwhile, private industry was reluctant to enter government agreements and develop technology when it could not profit from the intellectual property produced. Many private companies rejected restrictive patent agreements due to the loss of prospective proprietary rights, contamination of in-house R&D through exposure to government-sponsored research, and loss of control over testing and reporting results.¹⁰ The inability to commercialize inventions disincentivized further technical development, and U.S. research languished.

The Bayh-Dole Act changed that by tipping the scales in favor of private industry and rewarding patent monopolies to entities that commercialized government-funded research.¹¹ In 1980, the Bayh-Dole Act was codified in 35 U.S.C. §§ 200-212. Congress implemented the statute to help government agencies spur private sector innovation. Its purpose was to promote the commercialization of patentable results of publicly funded research by granting non-profits, small businesses, and universities titles to patents in exchange for royalty-free use.¹² Section 202's provisions were later extended to all contractors, regardless of size.¹³ As a result, commentators hail the Bayh-Dole Act as a boon to innovation, unlocking American R&D and propelling the United States to global leadership and technical dominance.

Under the Bayh-Dole Act, when the recipient of federal funds elects to retain title to the invention, it must grant the government a nonexclusive license and agree to allow the government to march-in and grant licenses to others.¹⁴ Section

7. Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1682-83 (1996). In the 1960s, NIH also required firms contracting with NIH funded investigators agree to license the government invention on new medical chemistry compounds. Firms were also required to license any background patents necessary to practice foreground inventions developed under contract. *Id.*

8. *Id.* at 1682-83.

9. Butler, *supra* note 5, at 490.

10. Eisenberg, *supra* note 7, at 1683 (noting private firms stopped screening NIH compounds resulting in abrupt restrictions to information sharing between NIH and firms).

11. See Butler, *supra* note 5, at 489 (quoting Senator Leahy: "The Bayh-Dole Act has encouraged a momentum of innovation, which 'has contributed billions of dollars annually to the United States economy and has produced hundreds of thousands of jobs.'").

12. 35 U.S.C. § 202(a); see *ECONOMIST*, *supra* note 5.

13. See Exec. Order No. 12591, 3 C.F.R. § 1(4) (1987) ("Executive dept and agencies shall 'promote the commercialization, in accord with my Memorandum to the Heads of Executive Departments and Agencies of February 18, 1983, of patentable results of federally funded research by granting to all contractors, regardless of size, the title to patents made in whole or in part with Federal funds, in exchange for royalty-free use by or on behalf of the government[.]'").

14. 35 U.S.C. § 203(a); see also Federal Acquisition Regulation (FAR) implementing the Bayh-Dole Act. 48 C.F.R. § 52.227-11(d)(2) (2014) ("If the Contractor retains ownership of any subject invention,

202(a) introduces several ways for agencies to restrict patent rights *ex ante*, and section 203's march-in rights provision provides specific *ex post* cases where the government can grant licenses to third parties. March-in rights afford funding agencies broad discretion to compel a contractor to grant another applicant a non-exclusive, partial, or exclusive license.¹⁵ To date, no agency has used march-in authority to restrict patenting of federally funded inventions.¹⁶ Several groups have petitioned the NIH to use its march-in authority, and in each case, the NIH denied the request.¹⁷

The following subsections dive deeper into the Bayh-Dole Act's statutory provisions to provide a foundation for assessing proposed reform. Section A discusses Bayh-Dole *ex ante* mechanisms for government agencies to restrict contractor patenting before executing agreements. Next, Section B discusses a funding agency's *ex post* mechanisms for restricting contractor patent rights. After describing the statutory scheme, Section C analyzes scholarly arguments favoring Bayh-Dole Act reform and assesses their merits in light of recent DoD calls for rapid IP acquisition.

A. Bayh-Dole Ex Ante Patent Restriction Mechanisms for Exceptional Circumstances

The Bayh-Dole Act affords substantial flexibility to funding agencies, giving them expansive authority to restrict private sector patenting before entering into agreements. Upfront patenting restrictions are better suited for basic research and early-stage R&D. Under section 202(a)(ii) "exceptional circumstances" determinations, an agency can restrict or eliminate the contractor's right to obtain title.¹⁸ Unlike *ex-post* or retroactive march-in rights, exceptional circumstances determinations occur prospectively.¹⁹ A government agency enjoys broad discretion to

the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world."); *e.g.* 48 C.F.R. § 52.227-11(h) (2014) ("The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210 (c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.").

15. See 35 U.S.C. § 203.

16. Alexander Kersten & Gabrielle Athanasia, *March-In Rights and U.S. Global Competitiveness*, CSIS (2022), <https://perma.cc/Q767-PVYF>; see generally Michael Brodowski, *NIH Again Refuses to Exercise March-In Rights to Control Drug Price*, JDSUPRA (Mar. 27, 2023), <https://perma.cc/A7GP-GWH4> (discussing NIH's March 21, 2023 refusal to exercise march-in rights to control Xtandi cancer drug price).

17. Ryan Whalen, *The Bayh-Dole Act & Public Rights in Federally Funded Inventions: Will the Agencies Ever Go Marching in?*, 109 NW. U. L. REV. 1083, 1099 (2015) (discussing how NIH has developed its own body of precedent for march-in petition denials and cites back to previous petition decisions); see FRANCIS COLLINS, NIH, NATIONAL INSTITUTES OF HEALTH OFFICE OF THE DIRECTOR DETERMINATION IN THE CASE OF NORVIR MANUFACTURED BY ABBVIE 9 (2013), <https://perma.cc/E6QU-VRKT>.

18. 35 U.S.C. § 202(a)(ii).

19. KATHRYN ARDIZZONE, KNOWLEDGE ECOLOGY INT'L, KEI BRIEFING NOTE 2020: 2. THE FEDERAL GOVERNMENT'S AUTHORITY TO RESTRICT OR ELIMINATE CONTRACTORS' RIGHTS TO FEDERALLY-FUNDED INVENTIONS IN "EXCEPTIONAL CIRCUMSTANCES" 3 (2020), <https://perma.cc/52E5-M26T>.

determine if exceptional circumstances are present, and such a finding allows the agency to restrict or eliminate a contractor's right to retain title as a term of the agreement.²⁰ Federal agencies must include exceptional circumstances determinations in funding agreements and requests for proposals; thus, prospective contractors are aware of limitations on the right to elect title upfront.²¹ Although section 202(a)(ii)'s exceptional circumstances language implies the provision should be seldom invoked, federal agencies exercise this provision to dedicate federally funded research to the public domain. For example, Harold Varmus, former NIH Director, and the National Cancer Institute used exceptional circumstances clauses to enter sequences of cDNA into the public domain, creating a publicly accessible platform enabling biomedical research.²² Consequently, contractors working on the project were barred from filing patent applications on their inventions as a condition of the grant award.²³

Additionally, exceptional circumstances contract clauses facilitate public, open source/open access public-private partnerships where parties are required to publish research or make it publicly available to a smaller community.²⁴ Even though exceptional circumstances contract clauses are powerful vehicles for government patent restriction, these clauses are better suited for basic research rather than late-stage R&D. Few private entities would enter such agreements, investing the capital necessary to develop and commercialize inventions, if they knew they ultimately could not obtain a patent and profit from their efforts.

B. Bayh-Dole Ex Post Patent Restriction Mechanisms & March-in Rights

After an agreement is signed and executed, the Bayh-Dole Act's march-in provisions provide ex post mechanisms for government agencies to claw back private patent licensing of government-funded research and technology.²⁵ Section 203(a) provides several specific instances where a funding agency has the right to require the contractor to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to another applicant via march-in rights. Three march-in rights scenarios relevant to this discussion include—(1) if the contractor is not

("[T]he exceptional circumstances clause, like march-in rights, is an important safeguard to protect the public interest in federally-funded research and development (R&D).").

20. 35 U.S.C. § 203(a)(ii); see generally JOHN THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT (2016) 6, <https://perma.cc/QBD9-HAEA> ("Additionally, the government may withhold title if the contractor...in situations associated with national security; or when the work is related to the naval nuclear propulsion or weapons programs of the Department of Energy.").

21. See ARDIZZONE, *supra* note 19, at 4.

22. Vanessa Bell, *The State Giveth and the State Taketh Away: Patent Rights Under the Bayh-Dole Act*, 24 S. CAL. INTERDISC. L.J. 491, 511–13 (2015); see also ARDIZZONE, *supra* note 19, at 4.

23. ARDIZZONE, *supra* note 19, at 4.

24. VANESSA PEÑA, MARKO SLUSARCZUK, JAY MANDELBAUM, MARGARET TUCKER, ABBY GOLDMAN, EMILY GRUMBLING & EMMA THRIFT, INST. FOR DEF. ANALYSES SCI. & TECH. POL'Y INST., LESSONS LEARNED FROM PUBLIC-PRIVATE PARTNERSHIPS (PPPs) AND OPTIONS TO ESTABLISH A NEW MICROELECTRONICS PPP 28 (2021), <https://perma.cc/R5DG-EDGH> [hereinafter PPP LESSONS LEARNED].

25. Rai & Eisenberg, *supra* note 5, at 294.

taking effective steps to achieve practical application within a reasonable time;
(2) if exercising march-in rights is necessary to alleviate health or safety needs;
(3) if action is necessary because requirements for public use are not reasonably satisfied.²⁶

Despite the Bayh-Dole Act's praised success record, legal scholars and march-in petitioners point to statutory flaws giving rise to problematic patent monopolies that harm the public. Most NIH march-in petitions have centered on affordable drug therapies, lack of reasonable public availability of medicines due to high prices, or the need to lower drug prices to alleviate health and safety needs.²⁷ One reason for the DoD never exercising march-in authority might be that the DoD has additional safeguards protecting the public from the harmful consequences of private monopolies (e.g., the Invention Secrecy Act, United States Patent and Trade Mark Office (USPTO) Secrecy Orders, Export Control, and International Traffic in Arms Regulations).²⁸ The Bayh-Dole Act also has embedded national security exceptions in section 202(a)(iii)-(iv) that mitigate potential harms flowing from a private entity retaining title to critical technology. In contrast, the NIH's march-in authority must rely on section 203(a)(1)-(3) (failure to achieve practical application, alleviation of health and safety needs, and reasonable public use requirements).²⁹ As a result, the DoD's threat of march-in rights equates to mythical deterrence for the defense industrial base (DIB) rather than march-in rights being a practical consideration at the forefront of contract negotiations. Questions remain about how the DoD would employ its march-in authority, particularly where budgetary concerns are the main impetus but do not give rise to scenarios triggering section 202(a)(iii) national security exemptions. However, when *ex ante* patent restriction mechanisms prove inept at handling affordable or accessible DoD sustainment solutions, march-in rights could present an alternative remedy.

C. Bayh-Dole Criticism & Suggested Reforms

Arti Rai and Rebecca Eisenberg point out that despite the Bayh-Dole Act's success, it gives private entities unfettered discretion to determine when

26. 35 U.S.C. § 203(a)(1)-(3). Note that 35 U.S.C. § 203(a)(4) outlines the fourth march-in rights scenario. Section 203(a)(4) provides that if the contractor or licensee breaches its agreement and does not meet its U.S. manufacturing commitment pursuant to section 204, then the funding agency can exercise its march-in rights authority. *See id.* § 203(a)(4).

27. *See Whalen, supra* note 17, at 1099-1107 (discussing common assertions about unreasonable pricing and public safety arguments made in NIH march-in petitions).

28. Invention Secrecy Act, USPTO Secrecy Orders, Export Control, and International Traffic in Arms Regulations are beyond the scope of this paper. For additional details, *see* W. Jay Devecchio & Fernand A. Lavallee, *Intellectual Property in Government Contracts*, 21 *GOV'T CONTRACTS YEAR IN REVIEW BRIEFS* 1, 5 (2022) ("[B]ecause the contractor/developer owns (and retains ownership in) the IP rights in the data and software, the contractor can use, sell, lease, or license the data or software as it pleases, subject to national security rules and export controls or, less commonly, a unique contract clause limiting the contractor's use.").

29. 35 U.S.C. § 203(a)(1)-(3).

intellectual property rights are appropriate.³⁰ They argue that unbounded discretion led to large corporations and universities claiming broadly enabling upstream rights to basic research tools.³¹ An example is the pre-Bayh-Dole, Cohen-Boyer method for gene splicing, which combines DNA from different organisms.³² Rai and Eisenberg note that although this fundamental biotechnology tool was patented, it was licensed non-exclusively and cheaply, encouraging widespread dissemination.³³ Nevertheless, had profits been the sole motivation for the Cohen-Boyer patent holders, steep licensing fees might have restricted access to the tool and stifled life sciences innovation rather than enabling further advances in molecular biology. Mindful of the harms of patenting basic research tools, Rai and Eisenberg advocate amending the Bayh-Dole Act. They propose giving funding agencies even more discretion to determine when IP rights are detrimental to the public interest and should be dedicated to the public domain.³⁴ In essence, Rai and Eisenberg assert that Congress should liberalize circumstances where agencies can depart from the presumption that the contractor retains title on a case-by-case basis.³⁵ However, as Gary Pulsinelli points out, reforms rebutting the presumption that contractors retain the patent rights to government-sponsored R&D threaten to undo the Bayh-Dole Act's intent to incentivize private sector investment and commercialization. Such a reform, in essence, advocates for rewinding the clock to the pre-Bayh-Dole era, when default funding agreements awarded patent titles to funding agencies. The proposal could result in the perceived pre-1980s U.S. innovation decline.³⁶

Rai and Eisenberg also propose eliminating the “exceptional circumstances” language from the statute because of the presumption that agencies should seldom exercise march-in rights to restrain patenting.³⁷ They also suggest modifying section 203(b) to eliminate protracted delays holding agency decisions in abeyance pending exhaustion of all court appeals.³⁸ However, as mentioned in Section

30. Rai & Eisenberg, *supra* note 5, at 291.

31. *Id.* at 300.

32. *Id.*

33. *Id.*

34. *Id.* at 291.

35. *Id.* at 310.

36. Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 MINN. J.L. SCI. & TECH. 393 (2006) (“[Rai and Eisenberg]. . . argu[e] that the tide has turned in the last twenty-five years and that the NIH now understands and embraces its role in technology transfer. Although that may be true in the short term, it is entirely plausible that the NIH, freed from the shackles of Bayh-Dole, will eventually revert to its old instincts and again become reluctant to allow funding recipients to obtain patents and grant exclusive licenses.”).

37. Rai & Eisenberg, *supra* note 5, at 310.

38. *Id.* at 311; 35 U.S.C. § 203(b) (“Additionally, any contractor, inventor, assignee, or exclusive licensee adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Court of Federal Claims, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand or modify, as appropriate, the determination of the Federal agency. In cases described in paragraphs (1) and (3) of subsection (a), the agency’s determination shall be held in abeyance pending the exhaustion of appeals or petitions filed under the preceding sentence.”).

A, given that funding agencies use exceptional circumstances clauses for early-stage research, eliminating this language may hinder efforts to dedicate R&D to the public domain. Instead, a similar effect could be achieved without dispensing with the exceptional circumstances provision. Congress could cabin its reform to allow more agency latitude for case-by-case assessment to invoke march-in rights while streamlining the review process, avoiding bureaucratic back and forth with the Department of Commerce.³⁹

Rai and Eisenberg also assert that the Bayh-Dole Act resulted in a lack of information sharing, especially by universities, disrupting traditional norms of open science.⁴⁰ As active patent claimants, universities are eager to generate licensing revenue from patenting their discoveries, and scientists bear the costs, unable to get prompt access to proprietary technologies.⁴¹ Even though patents are enabled with written descriptions of the claimed invention, 35 U.S.C. § 112 does not require the disclosure of trade secrets or what the DoD defines as “technical data,” the scientific information pertaining to studies and research results.⁴² To remedy the information hoarding of preliminary research findings, some legal scholars suggest a Bayh Dole Act reform measure to force research entities receiving federal funding to publish results or enter them into a national database.⁴³ This measure would mitigate the cost of duplicative research efforts and combat corporate data hoarding to protect potentially profitable discoveries from competitors.⁴⁴ Ideally, mandated disclosures would force timely transparency, even of federally funded private research failures, reducing costs to develop biotech innovations and benefiting taxpayers and society while still rewarding private sector innovation.⁴⁵ Similarly, to broaden access to basic research technology Pulsinelli proposes giving all government-sponsored researchers limited, royalty-free licenses to make and use federally funded inventions for

39. See generally Pulsinelli, *supra* note 36, 466-67 (proposing Congress add a new subsection to the Bayh-Dole Act that allows agencies grant licenses when a nonprofit, or small business unduly encumbers future research); see also 35 U.S.C. § 203(b) (allowing the Commerce Department to establish regulations for administrative appeals for march-in rights); 35 U.S.C. § 206; 35 U.S.C. § 208 (“The Secretary of Commerce is authorized to promulgate regulations specifying the terms and conditions upon which any federally owned invention. . . may be licensed on a nonexclusive., partially exclusive, or exclusive basis.”).

40. Rai & Eisenberg, *supra* note 5, at 305.

41. *Id.*

42. See 35 U.S.C. § 112 (defining patent enablement and written description requirements); 48 C.F.R. § 52.227-14(a)(2) (2014) (defining technical data as recorded scientific or technical information including computer databases and software documentation).

43. Noel Christian Pace, *The National Security Implications and Potential Solutions for the Unintended Consequences of the 1980 Bayh-Dole Act on Brain-Injured Veterans from the Wars in Iraq and Afghanistan*, 4 U. MIAMI NAT’L SEC. & ARMED CONFLICT L. REV. 241, 265 (2014) (explaining that in the biotech context, this would include disclosing Phase I and potentially Phase II studies that did not work).

44. *Id.*

45. *Id.*

research purposes.⁴⁶ One way to implement both ideas is by creating a national patent pool database.

In 2022, the National Institute of Standards and Technology (NIST) launched the interagency iEdison database designed around the Bayh-Dole Act reporting requirements and implementing regulation.⁴⁷ The iEdison database integrates with the USPTO and allows a funding recipient to submit a utilization report to multiple government agencies, updating them on subject invention licensing and commercialization activities.⁴⁸ Likewise, Congress could implement Pulsinelli's proposal and allow researchers royalty-free use of federally funded inventions for research purposes. Congress could also direct NIST to add patent pooling capabilities to iEdison, requiring federal funding recipients to report best efforts to develop a subject invention, including reports about failed experimentation.⁴⁹ Additional patent pooling features could allow federally funded researchers to access technical data and studies pertaining to government-sponsored research. Despite the advantages of open-science data-sharing, critics note the serious IP risks such proposals impose on contractors: sharing best efforts data with all interested government-sponsored researchers would include researchers working at competing companies.⁵⁰ Thus, a company's proprietary know-how could be inadvertently shared with a competitor.⁵¹ Nonetheless, robust firewalls and conflict checks could mitigate inadvertent data-sharing concerns.

Another possible Bayh-Dole reform is to narrow the statutory definition of "subject invention." Doing so would constrict government patenting while tipping the balance in favor of private industry, giving them more flexibility to maintain control over their IP when entering government contracts. Under section 201(e), a subject invention is "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement."⁵² A former chief patent counsel for 3M stated in congressional testimony that the Bayh-Dole Act presented a situation where the government was granted rights to an invention patented before a government contract.⁵³ Even if the invention was later reduced to practice under a government contract at significantly lower costs than the initial research investment that led to a patent, the government

46. Pulsinelli, *supra* note 36, at 442.

47. *About iEdison*, NIST (Aug. 8, 2022), <https://perma.cc/YMQ2-9UN6>.

48. *Id.*

49. Whalen, *supra* note 17, at 1112.

50. Kristen O. Riemenschneider & R. Tanny Kang, *IP Rights in U.S. Government Covid-19 Vaccine and Therapeutics Contracts*, 15 *LANDSLIDE* 36, 38 (2022).

51. *Id.*

52. See 35 U.S.C.A. § 201(e) (2002) (providing an exception for variety plants: "[T]he date of determination (as defined in section 41(d) of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance."); William L. Geary, Jr., *Protecting the Patent Rights of Small Businesses: Does the Bayh-Dole Act Live Up to Its Promise?*, 22 *PUB. CONT. L.J.* 101, 121, 124 (1992).

53. Richard N. Kuyath, *Barriers to Federal Procurement: Patent Rights*, *PROCUREMENT L.*, Fall 2000, at 13.

could still obtain an exclusive license.⁵⁴ However, William Geary argues that a subject invention should only include those inventions conceived under a funding agreement and reduced to practice.⁵⁵ In other words, if a contractor files a patent application before a government contract is signed, the patented invention should not be considered the “subject invention” as defined by section 201(e). Likewise, the subject invention definition could be amended to require a patent actually issue prior to signing a funding agreement.⁵⁶ The same logic could apply to inventions made and patented prior to signing government procurement contracts.⁵⁷

Regardless, Geary asserts that march-in rights should still apply to protect the government’s interests. In balancing the funding agency’s interest in retaining title to publicly funded inventions with the contractors’ incentive to develop and commercialize inventions, modifying the subject invention definition sides with the private sector. Such a modification would restrain the government’s exclusive licensing authority. A situation could arise where a contractor invests minimal funds and patents a small component before signing a contract yet predominantly relies on federal funds to bring the subject invention to market. Under Geary’s proposal, that scenario represents a commercial IP windfall for the contractor but a significant financial loss for the government.

However, a scenario where the private contractor wins more IP control is precisely the outcome Congress aimed to achieve when implementing the Bayh-Dole Act. Legislators balanced the private sector and government interests when crafting the Bayh-Dole Act to boost American innovation and intentionally tipped the scale toward private contractors. Thus, the very purpose of the Bayh-Dole Act is to entice private entities with lucrative patent rights stemming from government-funded research. Therefore, narrowing the subject invention definition to cover only inventions conceived and reduced to practice under a funding agreement is consistent with the statute’s purpose. The modified definition could encourage new DoD R&D partnerships with nontraditional vendors and enable agencies to capture new commercial technologies.

II. DoD CONTRACT FRAMEWORK PATENTS, TECHNICAL DATA RIGHTS, AND DMPD

Section II briefly describes the DoD’s technology and R&D ecosystem and its supplemental contract framework for innovation acquisition. In addition to military system procurement, the DoD supports applied and basic research through military research labs and the Defense Advanced Research Projects Agency (DARPA), its research arm. Like NIH, the DoD and DARPA are active participants in cutting-edge research and harvest DIB know-how to leverage high technology to protect the nation. The DIB consists of public universities, private

54. *Id.*

55. Geary, *supra* note 52, at 121, 124.

56. *Id.* at 121.

57. See 35 U.S.C.A. § 201(g) (2002) (“‘[M]ade’ when used in relation to any invention means the conception or first actual reduction to practice of such invention.”).

research institutions, large corporations, and small businesses that compete for government contracts and research funds.⁵⁸

The DoD contracting regime includes provisions for ex ante Bayh-Dole contractor patent right restrictions and DoD-specific measures for acquiring technical data and DMPD (which operate outside the Bayh-Dole Act's purview). As noted earlier, the DoD has never asserted Bayh-Dole march-in rights to restrict contractor patenting. Instead, the DoD relies heavily on a sophisticated contracting scheme outlined in its internal guidance or IP Instructions, the Federal Acquisition Regulation (FAR), and Defense Federal Acquisition Regulation Supplement (DFARS), which implement Bayh-Dole Act legislation. Therefore, the Bayh-Dole Act operates in the shadow of the FAR and DFARS and applies to patent clauses in DoD funding agreements, procurement contracts, grants, and cooperative agreements.⁵⁹ The Bayh-Dole Act also gives the government and private entities broad discretion to negotiate over the ownership and employment of IP, including patents and technical data rights.⁶⁰

Even though agencies like the DoD and NIH may issue guidance on technology, federal agencies do not have the authority to issue substantive regulations concerning patent licensing under the Bayh-Dole Act.⁶¹ However, the Bayh-Dole Act permits ex ante contracting as a workaround. Moreover, the DoD's IP guidance provides agency rules and governance for DoD contract negotiations for acquisition, operation, maintenance, modernization, and sustainment of defense products and services compliant with the FAR and DFARS.⁶²

The following subsections focus on DoD contracting as a means for gaining IP rights related to Bayh-Dole subject inventions, including contractor technical data and DMPD produced as a byproduct of DoD-funded R&D. First, Section A provides an overview of the DFARS contracting regime for acquiring contractor technical data. Second, Section B highlights the shortcomings of the DFARS approach to trade secret protectable material encompassed by DMPD. Third, Section C examines the role of other transaction authority (OTA) in allowing the DoD flexibility to skirt rigid Bayh-Dole Act requirements and DFARS regulations for patenting.

58. ROBERT FARLEY & DAVIDA ISAAC, PATENTS FOR POWER: INTELLECTUAL PROPERTY AND THE DIFFUSION OF MILITARY TECHNOLOGY 48 (2020).

59. James McEwen, *Protecting Valuable IP In the Government Contracting Process in a Turbulent Procurement Market*, in INSIDE THE MINDS: TRENDS IN GOVERNMENT CONTRACTING, 2012 WL 191204, at *3; 35 U.S.C. § 201(a)-(c).

60. FARLEY & ISAAC, *supra* note 58, at 53.

61. Rai & Eisenberg, *supra* note 5, at 308; see U.S. GOV'T ACCOUNTABILITY OFF., GAO-22-104752, DOD SHOULD TAKE ADDITIONAL ACTIONS TO IMPROVE HOW IT APPROACHES INTELLECTUAL PROPERTY 1, 14 n.37 (2021), <https://perma.cc/ZJ3V-4GCD> [hereinafter GAO-22-104752] ("DOD Instruction 5010.44 does not apply to patent licensing or other technology transfer of U.S. Government-owned IP or technology covered by DOD Directive 5535.03 and DOD Instruction 5535.8, or branding and trademark licensing by DOD Components covered by DOD Directive 5535.09 and DOD Instruction 5535.12.").

62. *Id.* at 14 ("DOD integrated existing IP guidance and requirements, highlighted six core principles, and set a department-wide expectation for DOD personnel to prioritize IP planning early in the acquisition life cycle in its 2019 IP Instruction.").

A. DFARS Provisions for Technical Data Rights—Unlimited, Government Purpose, and Limited Rights

Under the Bayh-Dole Act, a contractor cannot keep a patentable subject invention as a trade secret.⁶³ However, the Bayh-Dole Act is silent on the issue of technical data—information that could otherwise be protected under trade secret law—generated in the performance of a government grant or contract. Instead, the DoD relies on the FAR and DFARS to obtain technical data related to patentable inventions. Recognizing trade secret know-how is critical for using patented technologies, DFARS establishes a secondary framework, outside the Bayh-Dole Act, for licensing and delivering data rights.⁶⁴ DFARS (and many other agency-specific supplements) define data rights broadly. Technical data encompasses recorded scientific or technical information, including databases, software documentation, and training material for installation, operation, and routine maintenance.⁶⁵ While other IP licensing agreements are available, the DoD uses three standard licensing agreements to acquire technical data: (1) unlimited rights, (2) government purpose rights, and (3) limited rights.⁶⁶

Under DFARS 227.7103-5, the government obtains “unlimited” rights in technical data pertaining to items developed exclusively with government funds.⁶⁷ In the context of 227.7103-5, technical data relates to the invention’s form, fit, and function, including studies, analysis, and test data produced throughout a contract’s performance.⁶⁸ While the government receives unlimited rights to technical data necessary for installation, operations, maintenance, or training purposes, it does not automatically obtain a contractor’s DMPD.⁶⁹ Unlimited rights allow the government to use and freely disclose technical data to anyone without restriction. However, when a contractor develops an item with mixed, private and federal funds, the government obtains “government purpose” rights to the technical data.⁷⁰ Although the effective period of government enforcement rights is negotiable, the rights commence upon contract execution.⁷¹ After the effective

63. Kuyath, *supra* note 53, at 12; *see also* GAO-22-104752, *supra* note 61, at 5-6. The FAR and DFARS implement the Bayh-Dole Act into government contract law. Together FAR and DFARS provide the regulatory framework governing how the DoD licenses and acquires contractor patents as well as trade secrets in the form of technical data rights. *See* GAO-22-104752, *supra* note 61, at 5-6.

64. Riemenschneider & Kang, *supra* note 50, at 38.

65. 48 C.F.R. § 52.227-14(a)(2), (b)(1)(iii) (2014).

66. 48 C.F.R. § 227.7103-5 (1991) (DFARS).

67. 48 C.F.R. § 227.7103-5(a) (1991) (DFARS).

68. *Id.*

69. 48 C.F.R. § 227.7103-5(a)(5) (1991) (DFARS).

70. 48 C.F.R. § 227.7103-5(b) (1991) (DFARS). Section 227.7103-5(b)(4) provides two exceptions to the prohibition of government disclosure of technical data to third parties: when third-party data recipients (1) sign non-disclosure agreements or (2) when data markings, subject to 252.227-7025, accompany the technical data limiting subsequent disclosure beyond the third-party government contractor recipient.

71. 48 C.F.R. § 227.7103-5(b)(3) (1991) (DFARS).

period expires, the DoD's government purpose rights convert to unlimited rights in technical data.⁷²

Alternatively, the government only receives "limited rights" to technical data when an invention is developed exclusively with private funds.⁷³ When a private entity creates technical data at its own expense pursuant to a contract, the DoD may not use, release, or disclose that technical data outside the government without the contractor's permission.⁷⁴ Limited rights allow the DoD to use the contractor's technical data to perform emergency repairs or overhauls, to share technical data with a foreign government (if it is in the interest of the United States), and to require non-government recipients to sign non-disclosure agreements if the contractor permits the DoD to release the technical data.⁷⁵

Consistent with the DoD's role as a technology purchaser, the DFARS tri-part technical data licensing scheme gives the DoD enhanced capabilities to tackle constrictions on contractor data sharing.⁷⁶ Even if an initial DoD government contract was for a "government-purpose" license, the DoD's license converts to unlimited rights to technical data after five years. Thus, the DoD can share the information with third parties to further develop research or combat unreasonable contractor price gouging.⁷⁷ Conversely, agencies like NIH have a mandate focused on research rather than procurement. As of 2022, the NIH's grant policy allows grant recipients to own data rights resulting from grant-supported projects.⁷⁸ NIH even allows grant recipients to protect their data rights via copyright without NIH approval.⁷⁹ NIH could use similar DFARS technical data contract clauses to restrict grantees' data rights and mitigate high drug prices resulting from IP monopolies on pharmaceutical R&D. However, a stricter NIH data rights grant policy would likely face massive pushback from the pharmaceutical industry. If NIH were to implement DFARS-like provisions (i.e., unlimited, government purpose, and limited rights) into its funding agreements, the effect might deter private sector engagement with the biotech industry.

B. Detailed Manufacturing and Process Data Acquisition

DMPD acquisition presents a particularly complex area of tension for the DoD when contracting with DIB entities. The FAR and DFARS contracting scheme

72. *Id.*

73. 48 C.F.R. § 227.7103-5(c) (1991) (DFARS).

74. *Id.*

75. *Id.*; 48 C.F.R. § 227.7102-2(a) (1991) (DFARS).

76. See Rai & Eisenberg, *supra* note 5, at 305.

77. 48 C.F.R. § 252.227-7013 (1995).

78. *NIH Grants Policy Statement 8.2.1 Rights in Data (Publication and Copyrighting)*, NIH OFF. OF EXTRAMURAL RSCH. (Dec. 2022), <https://perma.cc/5LTK-XJ6R>.

79. NIH grant policy defines "data" similarly to the DFARS definition of technical data: "'data' means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other technical research data." *Id.*

enhances the DoD's ability to obtain contractor technical data and share it with other third parties to reduce weapon system sustainment costs. However, the DFARS contracting scheme is not without flaws. Technical data and DMPD are often needed to repair, overhaul, and competitively re-procure weapons systems.⁸⁰ Although the government can obtain rights to operation, maintenance, installation, and training data, the government must negotiate for access to contractor DMPD.⁸¹ A 2022 Government Accountability Office (GAO) report expressly recommended that the DoD issue guidance to clarify details about DMPD acquisition.⁸² Supporting its recommendation, the GAO cited several notable blunders stemming from a lack of clarity and resulting in high sustainment costs for defense technology.⁸³ In July 2006 the DoD's lack of technical data rights for several Army weapon systems disrupted sustainment plans for cost savings and legislative requirements for depot maintenance capability.⁸⁴ The contractor declined to sell the Stryker armored vehicle's technical data package, and the cost was most likely prohibitively expensive at fielding.⁸⁵ Again in March 2020, maintainers could not repair navy ship systems with the IP available, and the fiasco cost billions in sustainment expenses. And yet another incident surfaced in September 2014, when the Air Force neglected to acquire the technical data needed to compete for subsequent F-35 subsystems awards under previous systems development contracts.⁸⁶ Thus, while contracting allows for substantial flexibility, each of these examples indicates that DFARS and FAR contracting schemes are not a silver bullet for protecting the public's interest in affordable innovation.

C. Other Transaction Authority

OTAs represent a potential solution to the Bayh-Dole Act's rigidity while allowing the government to leverage private sector ingenuity. As of 2016, Congress extended OTA to eleven agencies, including NASA, the Department of Transportation, the Department of Energy, NIH, DoD, and DARPA.⁸⁷ Congress's extension of OTA to DARPA and the DoD offers flexibility to flout rigid

80. GAO-22-104752, *supra* note 61, at 14.

81. 48 C.F.R. § 227.7103-5(a)(5), (c)(iii) (1991) (DFARS).

82. GAO-22-104752, *supra* note 61, at 29 ("The Under Secretary of Defense for Acquisition and Sustainment should ensure that DOD's planned guidebook on IP clarifies how DOD personnel can pursue detailed manufacturing or process data.").

83. *Id.* at 12-13.

84. *Id.*

85. *Id.* at 12; *see also* U.S. GOV'T ACCOUNTABILITY OFF., GAO-06-839, WEAPONS ACQUISITION: DOD SHOULD STRENGTHEN POLICIES FOR ASSESSING TECHNICAL DATA NEEDS TO SUPPORT WEAPON SYSTEMS 1, 9 (2006), <https://perma.cc/7L8A-TR4N> (providing background on Stryker procurement issues).

86. GAO-22-104752, *supra* note 61, at 12-13.

87. U.S. GOV'T ACCOUNTABILITY OFF., GAO-16-209, FEDERAL ACQUISITIONS USE OF 'OTHER TRANSACTION' AGREEMENTS LIMITED AND MOSTLY FOR RESEARCH AND DEVELOPMENT ACTIVITIES 1, 6 (2016), <https://perma.cc/UXY5-4G49> [hereinafter GAO-16-209].

Bayh-Dole and DFARS mandates.⁸⁸ OTA empowers the DoD to enter agreements that give contractors even more power to retain patent rights without the burden of march-in rights, fixed deadlines for electing to retain title, and domestic manufacturing requirements.⁸⁹ Additionally, OTA allows federal agencies, businesses, and researchers to contract around the Bayh-Dole Act's restrictions, enabling faster acquisition of emerging technology than traditional DFARS procurement contracts.⁹⁰

The added OTA flexibility is also a powerful tool to attract private sector partners. For instance, in initiating biological warfare defense research programs, DARPA noted that most pharmaceutical and biotech firms would not accept cost-type procurement contracts but were amenable to Other Transactions (OT) agreements with milestone payments to perform government-funded R&D.⁹¹ This example suggests that when executed properly, OT agreements are an effective way to attract private entities to government-funded R&D. Moreover, OT agreements allow federal agencies to negotiate IP rights while securing a tailored, case-by-case fit for the government's minimum program needs. For example, standard patent clauses in OT agreements can be modified to allow the contractor to keep an invention as a trade secret.⁹² OT patent clauses can also eliminate the Bayh-Dole Act's reduction to practice provisions, eliminate statutory forfeiture and timely disclosure provisions, and delay the effective date for government purpose licenses.⁹³

Although OT agreements are flexible and attractive workarounds to rigid patent clauses rooted in the FAR and Bayh-Dole Act, OTA is not a one-size fits all solution. OTA entices private sector engagement at the expense of government oversight and march-in authority under the Bayh-Dole Act.⁹⁴ OT agreements depend on case-by-case agency determinations about IP acquisition and do not address the harmful effects that arise with patent monopolies.⁹⁵ Hence, OTA is

88. See 10 U.S.C. § 4021.

89. See Riemenschneider & Kang, *supra* note 50, at 39 (noting that the DoD's 2020 OT agreement with AstraZeneca for the COVID-19 therapeutics explicitly waived march-in rights and domestic manufacturing obligations, but included remedies to protect the public interest in national security, public health, and safety).

90. David S. Bloch, *Alternatives to March-in Rights*, 18 VAND. J. ENT. & TECH. L. 247, 262 (2016).

91. Kuyath, *supra* note 53, at 18.

92. GAO-16-209, *supra* note 87, at 6.

93. Kuyath, *supra* note 53, at 71; see 37 C.F.R. § 401.14 (1987) (listing elements of standard patent rights clauses for government contracting); see also 48 C.F.R. 52.227–11 (2007) (these FAR subsections indicate contractor's obligation, including disclosure of each subject invention within two months after inventor(s) written disclosure). For an explanation of standard patent right clauses, see also 37 C.F.R. § 401.14 (1987).

94. However, agency OTA is unlikely to substantially undermine the Bayh-Dole Act's statutory grant of substantive march-in rights. *Validity of restrictive covenants made ancillary to contracts of employment including financial disincentive provisions; Employee's agreements to assign future inventions*, 6 WILLISTON ON CONTRACTS § 13:17 (4th ed.) (2023) (“[F]unding agreement[s] entered into between the federal agency and the contractor obviously cannot impair the government's rights.”).

95. See generally 42 U.S.C.A. § 282(n) (For example, this provision gives the Director of NIH other than transaction authority to engage in unique research).

suitable for short-duration, smaller-scale projects, or one-off prototype development but not for larger late-stage R&D in which the government's interest in deterring harmful IP monopolies is at its peak.

III. LESSONS FROM DARPA PPP MODELS AND GOVERNMENT-FUNDED VENTURE CAPITAL

Having laid the requisite Bayh-Dole, DFARS, and OTA background in Parts I and II, Part III explores other avenues and novel approaches for increasing innovation acquisition. The following section provides a general overview of PPPs and their role in balancing private-sector innovation with the government's grant of IP rights and market exclusivities. Section A assesses considerations and lessons from DARPA PPP models. Section B considers DoD efforts to stir national defense innovation by directly attracting and supplying private venture capital to emerging technology.

A. *Public-Private Partnerships for Rapid Innovation Acquisition*

Some legal scholars propose PPPs as a means to combat abusive monopolies and to promote innovation by “de-linking” an innovator's R&D costs from a product's price—the idea is that government agencies should reward innovators directly rather than using indirect market exclusivities.⁹⁶ Phebe Hong, Aaron Kesselheim, and Ameet Sarpatwari recommend PPPs as a delinking solution allowing the private sector to recoup R&D investments while reducing reliance on market exclusivities to earn profits.⁹⁷ Hong, Kesselheim, and Sarpatwari propose several PPPs spanning government, industry, and civil society to delink pharmaceutical and biologics research and product development from market exclusivities.⁹⁸ They highlight the Innovative Medicines Initiative (IMI) as a prominent example of a multi-consortia European precompetitive PPP, which coordinates projects for basic research for drug development.⁹⁹ While admitting difficulties in comparative assessments of PPP outcomes, Hong, Kesselheim, and Sarpatwari acknowledge PPP's advantages for expanding access to foundational research.¹⁰⁰ Rather than relying on sole-sourced federal funding relationships, PPP partners would have better-distributed bargaining power to negotiate for an equitable distribution of foreground IP rights that arise from the PPP's research or product development efforts.¹⁰¹

96. Phebe Hong, Aaron S. Kesselheim, & Ameet Sarpatwari, *Transformative Models to Promote Prescription Drug Innovation and Access: A Landscape Analysis*, 19 YALE J. HEALTH POL'Y, L. & ETHICS 56, 60-61 (2020).

97. *See id.* at 61.

98. *See id.* at 86.

99. *See id.*

100. *See id.* at 89 (“Comparative outcome assessments for PPPs are difficult to conduct as PPPs differ widely in purpose, number of participants, and financial budgets. Furthermore, appropriate outcome indicators are not well-established in the literature.”).

101. *See generally id.* at 88 (“In partnership-focused frameworks, rights to new knowledge and technology arising from PPPs (‘foreground intellectual property’) are carefully negotiated among the various partners.”).

However, in the realm of national security innovation, PPPs are nothing new. Since the launch of Sputnik and the dawn of the space race, defense agencies like DARPA have utilized PPPs to collaborate with private entities and universities to respond to R&D gaps affecting national security. PPPs involve long-term contracts between the private sector and the government to provide public assets.¹⁰² Throughout DARPA's sixty-five-year history, it developed several PPP models to attract private-sector partners and quickly leverage DIB innovation at varying stages of R&D. For instance, the "open access" PPP model is most relevant for pre-competitive early, basic research environments that make IP valuation difficult.¹⁰³ DARPA's "shared limited to all partners only" PPP model allows IP licensing terms to be limited to specific uses, such as further scholarly research. "Exclusive IP" PPP models are for late-stage, proprietary research that is highly valuable to private sector competitiveness.¹⁰⁴ The exclusive IP model is advantageous because it provides DoD, and other funding agencies, R&D support services, access to unique infrastructure and equipment, and the flexibility to attract greater private sector participation.¹⁰⁵

Despite the allure, some R&D programs are not amenable to certain PPP models. Although PPP models can leverage flexible contracting, including OT agreements, deciding which PPP model to pursue requires carefully weighing the costs and benefits of forgoing traditional Bayh-Dole and DFARS patenting schemes and considering long-term R&D objectives.¹⁰⁶ For instance, in 2016, the Biomedical Advanced Research and Development Authority (BARDA) partnered with the U.S. Army to develop a Zika vaccine.¹⁰⁷ BARDA's PPP model for vaccine development received much criticism due to a lack of contractual price control safeguards protecting the public.¹⁰⁸ Acknowledging the PPP exclusive licensing issue, Jamie Love, Knowledge Ecology International director, mentioned defining, implementing, and enforcing affordable prices or setting price controls for potential vaccines was not feasible for the Army—especially since vaccine commercialization efforts would have required significant investment and faced a high risk of failure.¹⁰⁹ Although the Sanofi exclusive license transfer never came to fruition, the lack of safeguards highlighted a major chink in the American innovation ecosystem's armor.¹¹⁰

Despite past blunders, PPPs remain a powerful tool fostering research, development, and technology commercialization and maturation. While PPP models, similar to the IMI championed by Hong, are advantageous for technical data sharing and equitable patent licensing distribution, delinked PPPs are not a universal solution, especially for late-stage R&D. Moreover, completely delinking market

102. *Id.* at 85.

103. PPP LESSONS LEARNED, *supra* note 24, at 28.

104. *Id.*

105. *Id.*

106. *See id.* at 29.

107. *See* Eric Sagonowsky, *U.S. Army Can't Add a Pricing Safeguard to Sanofi's Zika Vaccine License, Official Says*, FIERCEPHARMA (Apr. 25, 2017, 9:34 AM), <https://perma.cc/GF8R-WVER>.

108. *See* Hong, Kesselheim, & Sarpatwari, *supra* note 96, at 94; *see also* Sagonowsky, *supra* note 107.

109. Sagonowsky, *supra* note 107.

110. *See id.*

exclusivities through PPPs might not be practical given the long-recognized need to incentivize national defense R&D through direct investment and internal compensation.¹¹¹ However, PPPs can be customized to achieve other agency-specific goals like rapid innovation.

B. Government Funded Venture Capital

Despite the successful track record of DARPA PPP models, the changing threat landscape and stiff competition surrounding emerging technology require new acquisition approaches to procure innovation faster. James Lewis astutely notes that the national security community's reluctance to expand the use of existing authority, such as OTA, stems from fears of weakened government oversight and IP control.¹¹² Instead of tried and tested PPPs, Lewis points to agency-funded venture capital as an imperfect but novel approach to increase technology acquisition.¹¹³ He suggests that allowing the DoD to have more discretionary funding to invest and own equity in start-ups could enable the DoD to partner with private sector investors and nontraditional contractors.¹¹⁴ Lewis's proposal is not entirely unprecedented. In-Q-Tel, a Central Intelligence Agency (CIA) created venture capital firm founded in 1999, provides an atypical example of an equity-acquiring approach for innovation acquisition.¹¹⁵ In-Q-Tel is government-funded but privately operated without direction from the CIA, its sponsoring agency. As a result of its autonomy, In-Q-Tel can invest in innovation, retain title to inventions, and share in startup revenue, while still granting the CIA government purpose rights to any subject inventions.¹¹⁶

Over the last two decades, other federal agencies also copied the CIA's government-sponsored venture capital model. For instance, in 2006, NASA joined Red Planet Capital, Inc., a nonprofit, to establish a strategic venture capital fund to gain more exposure to emerging technology and attract private sector innovators and investors.¹¹⁷ Likewise, in December 2022, Secretary of Defense Lloyd Austin announced the creation of the DoD's Office of Strategic Capital to shore innovation gaps and "add a new tool to the Department's investment toolbox."¹¹⁸ Thus, the national security and intelligence community's trend toward backing investment firms as innovation incubators may be a model worth amplifying throughout other federal agencies. Agencies regularly engaged in research and

111. FARLEY & ISAAC, *supra* note 58, at 48-49.

112. LEWIS, *supra* note 1, at 9.

113. *Id.* at 2.

114. *Id.*

115. *See id.* at 8-9; *see also The Beginning*, IN-Q-TEL, <https://perma.cc/X54H-FVAV> (providing a brief summary of In-Q-Tel's founding.).

116. *See* LEWIS, *supra* note 1, at 8-9 (concluding that giving agencies authority and funding to hold equity in start-ups allows agencies to act as angel investors, thereby compensating for agency risk aversion).

117. Press Release, David E. Steitz & Peter Banks, *NASA Forms Partnership With Red Planet Capital, Inc.*, NASA (Sept. 20, 2006), <https://perma.cc/234F-3F4Z>.

118. *See* Press Release, *Secretary of Defense Establishes Office of Strategic Capital*, DEP'T OF DEF. (Dec. 2022), <https://perma.cc/P6H9-WYH5>; *see also* Ross Wilkers, *DOD Launches Investment Arm to Fuel Innovation*, WASH. TECH. (Dec. 2, 2022), <https://perma.cc/3XQY-ZKHU> (for more background on OSC and government-sponsored venture capital).

pre-competitive PPPs may benefit from similar equity-acquiring approaches for investment in high-risk research, with the potential for yielding high rewards.

IV. CONCLUSION

Many praise the Bayh-Dole Act for ushering in a wave of American innovation. However, the price of its uniform pro-contractor patent policy exacts a toll on government oversight. March-in provisions are the Bayh-Dole Act's self-suggested solution for government agencies to regain control of federally-funded IP; yet, its lack of use indicates deficiency. The precedent set by failed NIH march-in petitions is a warning that the Bayh-Dole Act is not living up to its lofty endeavor of protecting the public through ex post patent restriction safeguards. As a result, agencies like the DoD use elaborate contracting schemes that allow the DoD to circumvent Bayh-Dole shortcomings and attract private-sector partners using OTA.

Given such a vibrant array of contracting levers at its disposal for meeting its national security mission, acquiring IP rights, and safeguarding the public, this poses the question—*Why should the DoD go marching in?* March-in rights provide an avenue to combat harmful monopolies and abusive practices. Predatory profiteering can present whenever a contractor attempts to hold an important development program hostage and demands exorbitant prices from the government. Although 35 U.S.C. § 203 applies to patent rights, the Bayh-Dole Act could be reformed to allow agencies to exercise march-in rights on technical data associated with patentable subject inventions. Even so, the prospect of exercising Bayh-Dole march-in rights is akin to killing an ant with a sledgehammer. For the DoD, this crushing tactic would produce unwieldy side effects. The DoD preserves trust within the DIB by abstaining from the march-in rights nuclear option whenever disputes arise or negotiations sour. Exercising march-in rights would send an irreparable shockwave throughout the DIB, countering the DoD's goal of going faster to stay technologically competitive. The march-in rights ripple effect would also hamper all private-public partnering formed by multiple government agencies.

Parts II and III discussed several proposals beyond march-in rights authority to boost U.S. innovation and attract private-sector partners. Congress must direct efforts to harmonize the various FAR supplements into a uniform regulatory system to streamline and accelerate IP acquisition. Like the DoD, various federal agencies have specific acquisition supplements and contracting schemes mirroring DFARS. Today, if a contractor develops a subject invention for the DoD, the contractor must comply with separate FAR supplements if it delivers the same system to the Department of Homeland Security, the National Aeronautics and Space Administration, or the Department of Energy.¹¹⁹ Otherwise, one regulatory misstep could result in the contractor inadvertently relinquishing its IP and technical data rights. While an effort to harmonize supplemental, agency-specific

119. Eli Mazour, *If You Fix It, They Will Come: Drawing Lessons Learned from Patents for Dealing with Rights in Technical Data*, 38 PUB. CONT. L.J. 667, 683 (2009) (advocating for standardized technical data policy for all federal agencies to avoid private contractor risk of losing technical data due to intricacies of regulation unique to each agency).

acquisition is an enormous undertaking, Congress could grant more agencies OTA as a smaller step toward uniformity.

Extending OTA to more federal agencies is a step toward achieving Rai and Eisenberg's desire to give agencies more discretion in determining when IP rights are detrimental to the public interest and should be dedicated to the public domain. Although statutory reform is a far more elegant solution to reigning in private-sector patenting, OTA would give agencies more leeway to engage in R&D outside traditional Bayh-Dole and FAR requirements, without upending the Bayh-Dole Act's premise that contractors retain title to subject inventions. However, Congress would have to make case-by-case determinations before doling out expansive OTA powers. Congress should consider (1) the federal agency's mission as a purchaser and research funding agent and (2) the nature of the agency's private-sector partnerships before expanding OTA.

Furthermore, improvements to NIST's iEdison database would mitigate Rai and Eisenberg's concern about the trend toward a lack of data-sharing resulting from the Bayh-Dole Act. While a congressional requirement compelling fund recipients to disclose all failures and best efforts seems burdensome, the disclosures may help spur innovation and reduce economically inefficient duplicative research. Best effort reports could be integrated into iEdison progress and commercialization reports, with robust firewalls preventing private researchers from accessing competitor IP. DARPA's PPP models also produce a highly customizable collaboration framework that can promote data sharing and equitable license dissemination among PPP partners.

Finally, Part III discussed the DoD's novel venture capital approach to acquire critical emerging technologies rapidly. Government-backed venture capital investment is a financially risky alternative to traditional DoD private-sector engagement. However, the government-venture capital approach is consistent with the delinkage model Hong, Kesselheim, and Sarpatwari endorsed for reducing public exposure to harmful patent monopolies. Essentially, government-venture capital efforts delink conventional market-exclusivity rewards for private sector ingenuity and instead directly encourage R&D through angel investment. The risk of inaction in developing critical technologies amidst steep global competition outweighs the financial uncertainty. Thus, the DoD's venture capital approach to innovation acquisition might provide the necessary edge to accelerate R&D and help the United States remain internationally competitive.