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Late disclosures of federal funding in US patents

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ABSTRACT

Enacted primarily to encourage patents on federally funded inventions, an additional policy objective of the Bayh–Dole Act is to increase visibility around scientific discoveries made with US government support. The Bayh–Dole Act requires federal grantees to disclose subject inventions to funding agencies and declare government support in their patents. Prior research has shown, however, that hundreds of grantees have failed to declare federal funding in biomedical patents, and others have acknowledged government support several years late through certificates of corrections. Combining data from the National Institutes of Health and the Patent and Trademark Office, this study explores the extent to which grantees have declared government support late through certificates of corrections and likely reasons why this occurred. Over 3000 patents covering federally funded inventions have been corrected to acknowledge government support late, most in recent years. Many of these corrections appear to have been driven by high-profile controversies, changes in the Bayh–Dole regulations, and civil society advocacy. These findings call for policies to encourage timely compliance with invention reporting requirements and to increase the visibility of late acknowledgements of US government funding.

KEYWORDS: accountability, Bayh–Dole, patents, pharmaceuticals, NIH

I. BAYH–DOLE OBLIGATIONS TO DECLARE FEDERAL FUNDING IN PATENTS CLAIMING SUBJECT INVENTIONS

The Bayh–Dole Act of 1980 is one of the most important pieces of legislation in the history of US innovation policy. Before 1980, federal agencies had inconsistent policies on whether grantees could patent inventions arising from federally supported research and

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development projects.[1] Grantees were either prevented from taking title over federally funded inventions or were required to meet cumbersome procedures to patent them.[2] Bayh–Dole harmonized federal policy by generally allowing grantees to 'retain title' and seek patents over funded inventions. Although the benefits of this policy are still debated,[3] the stated objectives include promoting the 'utilization of inventions arising from federally supported research' and 'collaboration between commercial concerns and nonprofit organizations, including universities'.[4] Other stated objectives in the Act include ensuring that the US government 'obtains sufficient rights in federally supported inventions' and protecting 'the public against nonuse or unreasonable use of inventions'.[5]

Nevertheless, the Bayh–Dole Act did not confer unchecked discretion upon federal grantees to patent inventions arising from government funding.[6] To retain title, the Act requires grantees to follow various requirements and timelines. Once university administrators learn of a federally supported invention, they have two months to notify funding agencies[7] and two years to decide whether to retain the title.[8] If the grantees retain title, they are required to provide reports describing how the inventions are being utilized.[9] If grantees seek patent protection, their patent applications must include a government interest statement in their specifications declaring federal support.

Government interest statements are standardized clauses, which are placed at the beginning of the patent document. The general requirement to embed government interest statements is codified in 35 U.S.C. § 202(c)(6).[10] Under 37 C.F.R. § 401.14; grantees are required to use a standardized format acknowledging the receipt of federal support and confirming that the government has certain rights in the resulting inventions.[11] According to the standard format provided in 37 C.F.R. § 401.14, federal

1 Bhaven N. Sampat, *Patenting and U.S. Academic Research in the 20th Century: The World Before and After Bayh-Dole*, 35 Res. Pol'y 772 (2006).

2 *Id.*

3 See, eg Daniel J. Hemel & Lisa Larrimore Ouellette, *Bayh–Dole Beyond Borders*, 4 J.L. & Biosciences 282 (2017), at 286–91 (discussing the 'uneasy case for Bayh-Dole patents').

4 35 U.S. Code § 200.

5 *Id.*

6 Arti K. Rai & Bhaven N. Sampat, *Accountability in Patenting of Federally Funded Research*, 30 Nature Biotech. 953 (2012), at 954 (generally discussing the invention reporting requirements in the Bay–Dole Act).

7 37 C.F.R. § 401.14 (stating that '[t]he contractor will disclose each subject invention to the Federal agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters').

8 *Id.* (stating that '[t]he contractor will elect in writing whether or not to retain title to any such invention by notifying the Federal agency within two years of disclosure to the Federal agency').

9 35 U.S.C. 202(c)(5) permits federal agencies to require 'periodic reporting on utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees'; *see also Nat'l Inst. of Standards & Tech., iEdison Utilization Guidance Document,* https://www.nist.gov/document/iedison-utilization-guidance-document *(2023)* (stating that 'all subject inventions reported in iEdison to which title has been elected will require annual utilization reporting').

10 35 U.S.C. § 202(c)(6) (requiring contractors to include a statement in their patent applications and issued patents acknowledging that 'the invention was made with Government support and that the Government has certain rights in the invention'). 37 C.F.R. § 1.77(b)(3) also requires grantees to acknowledge US government rights.

11 37 C.F.R. § 401.14(f)(4) ('The contractor agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement,

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awardees are also required to name the funding agencies and list funding contracts or grants.[12] Federal agencies bind grantees to using this standard format through funding agreements.[13] Awardees must declare government support following this format when filing a US application and ensure that compliant funding disclosures appear in patents issued thereon.

Declaring government support in federally funded patents serves various policy and legal objectives. Patents that properly declare federal funding can be easily found through text searches using U.S. Patent and Trademark Office (USPTO) databases. Government interest statements can thus increase visibility around the role of federal funding toward technology development. Since 37 C.F.R. § 401.14 requires awardees to include federal contract and grant identifiers, adequately made government interest statements could be used to trace federal contributions to biomedical innovation. Recent empirical studies have explored these potential uses of government interest statements.[14] These types of analyses can guide future federal research investments[15] and inform other government policies, such as drug price negotiations under the Inflation Reduction Act.[16]

Additionally, proper acknowledgements can help agencies monitor compliance with other policies governing federally supported inventions within and beyond the Bayh–Dole Act. Under the Bayh–Dole Act[17] and regulations,[18] awardees are required to submit periodic reports on the utilization of subject inventions, including information about development status, date of first commercial sale, gross royalties received, and any other additional data reasonably specified.[19] Moreover, Bayh–Dole requires that exclusive licensees agree to manufacture products embodying federally funded

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"This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention."').

12 *Id.*

13 37 C.F.R. § 401.3 (requiring funding agreements to use the standard patent clause found in 37 C.F.R. § 401.14).

14 See, eg Danielle Li, Pierre Azoulay & Bhaven N. Sampat, *The Applied Value of Public Investments in Biomedical Research*, 356 Science 78 (2017), https://doi.org/10.1126/science.aal0010; Gaétan de Rassenfosse, Adam Jaffe & Emilio Raiteri, *The Procurement of Innovation by the U.S. Government*, 14 Plos One e0218927 (2019), https://doi.org/10.1371/journal.pone.0218927.

15 U.S. Gov't Accountability Off., *National Institutes of Health: Better Data Will Improve Understanding of Federal Contributions to Drug Development*, GAO-23-105656 (2023), at 1, https://www.gao.gov/products/gao-23-105656 (assessing compliance with various disclosure requirements, including listing of NIH grants in patents, and noting that these data provide evidence 'to make decisions related to biomedical innovation and future R&D investments').

16 *Id.* at 1–2 (explaining that the Department of Health and Human Service could leverage the federal grant and contracts data available through government interest statements to assess R&D costs and prior federal support).

17 35 U.S.C. 202(c)(5) (requiring that each funding agreement with contractors or awardees provide federal agencies with the right 'to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees').

18 37 CFR 401.14(h) (stating that annual utilization reports 'shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor [. . .]'). Grantees must submit utilization reports annually. Nat'l Inst. of Standards & Tech., *Creating a Utilization Report*, NIST (Nov. 12, 2024), https://www.nist.gov/iedison/iedison-organization-user-guide/utilization-reports/creating-utilization-report.

19 *Id.*

inventions substantially in the USA, unless infeasible.[20] Beyond the Bayh–Dole Act, some federal agencies have specific policies governing certain industries or technologies. For instance, current National Institutes of Health (NIH) policies state an explicit preference for non-exclusive licensing of federally funded patents covering research tools.[21] Each of these policies require some levels of oversight to promote compliance. Readily available acknowledgements of government support can help federal agencies track patents subject to these requirements and promote compliance.

Timely disclosures can also help agencies operationalize the use of 'march-in' rights to address high drug prices,[22] a policy option that has drawn increasing attention in recent years.[23] If any of four statutory bases for march-in rights are met,[24] the federal government can require awardees to grant licenses on patents covered by the Bayh–Dole Act to third parties. While the threat of using march-in rights has in some cases led to price reductions,[25] agencies have never fully exercised this authority to speed up generic entry and its overall impact on competition would depend on the use of complementary policies to address nonpublic patents.[26] Nonetheless, proper disclosures can help agencies and other stakeholders better determine which inventions could be subject to march-in rights. Timely disclosures may be especially relevant when the patents supported with government funding provide only a few years of exclusive rights after drug approval and the timeframe during which a compulsory license would have any impact on generic entry is narrow.

Bayh–Dole regulations require grantees to execute 'all instruments necessary' to confirm that the government has certain rights through the world on subject inventions.[27] One of the steps grantees take to fulfill this requirement is executing 'confirmatory licenses', which are recorded in a publicly searchable USPTO repository.[28] Publicly available confirmatory licenses can complement government interest statements as an identifier of federally funded inventions, especially if one of these two records

20 35 U.S.C. § 204

21 Nat'l Insts. of Health, *Research Tools Policy, NIH Data Sharing Policies*, https://sharing.nih.gov/other-sharing-policies/research-tools-policy (accessed Aug. 5, 2024) (stating that the use of exclusive licenses for research tools 'should generally be avoided' and, if an exclusive license is granted, they should include public interest safeguards).

22 35 U.S. Code § 203. Through government interest statements, agencies can also more easily determine which patent rights are subject to the worldwide 'royalty-free' license by or for the government provided in 35 USC 202(c)(4).

23 Jerry Avorn & Aaron S. Kesselheim, *March-In Guidance for Publicly Funded Drugs: A Necessary Safety Net for Patients*, Health Affairs Forefront (Feb. 20, 2024), https://www.healthaffairs.org/do/10.1377/forefront.20240214.592820/full/ (accessed May 28, 2025).

24 Emily G. Blevins & Kevin J. Hickey, *Pricing and March-In Rights Under the Bayh-Dole Act*, Cong. Rsch. Serv., IF12582, Version 3 (updated Dec. 3, 2024), https://www.congress.gov/crs-product/IF12582.

25 Several March-In and Royalty-Free Rights Cases Under the Bayh-Dole Act, *Knowledge Ecology Int'l*, https://www.keionline.org/cl/march-in-royalty-free (accessed Apr. 22, 2025).

26 Knowledge Ecology International, *KEI Comment to NIST on Bayh-Dole Rights and Cases of Mixed Patent Landscapes*, KEI (Feb. 6, 2024), https://www.keionline.org/39391 (calling for the use of complementary policies to address non-public patents) (accessed May 28, 2025); Lisa Larrimore Ouellette & Bhaven N. Sampat, *Using Bayh-Dole Act March-In Rights to Lower U.S. Drug Prices*, 5 JAMA Health Forum e243775 (2024) (finding that in only fourteen drugs listed in the October 2023 Orange Book all patents are subject to march-in rights, but 41 drugs have at least one patent) (accessed May 28, 2025).

27 37 CFR 401.14(f)(1).

28 Alan C. Marco et al., *The USPTO Patent Assignment Dataset: Descriptions and Analysis*, U.S. Pat. & Trademark Off., Econ. Working Paper No. 2015-2 (July 1, 2015), https://ssrn.com/abstract=2849634, at 8–9.

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is incomplete.[29] However, interagency guidance requires confirmatory licenses only on 'parent' applications and these then 'flow down' to subsequent filings claiming the same priority, except for continuations in part.[30] Additionally, confirmatory licenses are separate legal documents independent from the patent text and published in different USPTO databases. Users of patent information may therefore need to undertake onerous research to verify which inventions are covered by a confirmatory license. In contrast, government interest statements are required within the text of all patents subject to the Bayh–Dole Act and can be easily identified if available.

Failures to comply with Bayh–Dole invention disclosure requirements can cause irreparable harm to government agencies and the public. Late reporting to funding agencies could deprive them from taking time-sensitive decisions during the early stages of patent prosecution. This can have a greater impact when an awardee declines title on a federally supported invention but also fails to promptly notify funding agencies, which could prevent the government from securing any patent rights.[31] Omissions of government interest statements in patents can also distort narratives about the relative role played by federal funding in the development of certain technologies or specific products and lead to misguided decisions about public research expenditures.[32] Underreporting of government funding in patents can also limit public scrutiny over drug companies and prevent or delay calls for greater access to biomedical products embodying federally supported inventions.[33]

Noncompliance with Bayh–Dole requirements to disclose funded inventions to federal agencies and embed government interest statements can have significant consequences for grantees too. The Bayh–Dole Act[34] and regulations[35] give agencies authority to take patent ownership as a remedy against failures to comply with invention disclosure requirements.[36] Other actions that government agencies can take to remedy lack of compliance relate to the potential loss of federal funding. The current NIH

29 For a recent comprehensive effort to complement government interest statements with recorded confirmatory licenses, *see:* Daniel P. Gross & Bhaven N. Sampat, *The Government Patent Register: A New Resource for Measuring U.S. Government-Funded Patenting*, Nat'l Bureau of Econ. Research, Working Paper No. 32136 (2024).

30 Nat'l Inst. of Standards & Tech., *Confirmatory Licenses*, NIST.gov, https://www.nist.gov/video/confirmatory-licenses (accessed Dec. 9, 2024), at 1:40 (noting that confirmatory license submitted via iEdison for a non-provisional application 'flows down' to 'other patents that claim priority to that non-provisional application').

31 83 Fed. Reg. 15,954 (April 13, 2018) (indicating that a failure 'to timely disclose or elect title to a subject invention [. . .]' can deny the federal government 'any rights in the funded invention, through no fault of the funding agency').

32 GAO, *supra* note 15, at 27 ('When NIH awardees do not disclose the agency's support accurately and completely, or do not name NIH as the funding agency, the public and other interested parties cannot link patents to NIH funding and determine the extent of the agency's involvement in developing the patented technologies, including drugs').

33 James Love, *Novartis, Dana-Farber, Oregon Health & Science University Wait 18 Years to Disclose NIH Funding in Key Gleevec Patent*, Bill of Health Blog (Oct. 11, 2019) (arguing that a failure involving a patent related to Gleevec (imatinib) helped Novartis 'avoid demands' to make the inventions available to the public on reasonable terms).

34 35 U.S.C. § 202(c)(1).

35 37 CFR 401.14(d)(1).

36 Yet, the data discussed in Section VI of this study suggest that NIH has been reluctant to exercise this authority.

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grants policy states that the agency can disallow costs, withhold future awards, suspend grants, and terminate a grant as remedies.[37] These remedies can be exercised against grantees that fail to disclose inventions or embed government interest statements in their patents.[38]

Despite facing the potential loss of patent title and government funding, there is growing evidence documenting that federal grantees often fail to comply with the Bayh–Dole invention disclosure requirements. Evidence of systemic omissions dates to at least 30 years ago.[39] Since then, evidence of widespread failures has been documented by agencies,[40] academics,[41] and advocates.[42] More recently, advocates have spotlighted the practice of reporting federal funding late through certificates of corrections attached as an image file to the patent document. Some late disclosures of federal funding have been covered by national media and drawn criticism from elected officials.

One noteworthy example involves a patent related to the blockbuster drug Gleevec (imatinib), marketed by Novartis. That patent was corrected in 2019,[43] nearly two decades late and during a House Oversight Committee investigation on excessive pricing.[44] House Oversight Committee staff criticized Novartis for the omission stating the late disclosure 'furthered its public message that the company spends significant amounts on research and development'.[45] Similarly, in 2020, research advocates alleged that COVID-19 vaccine developer Moderna failed to report funding in patents related to mRNA inventions backed by the Defense Advanced Research Projects Agency (DARPA).[46] The allegations received media coverage,[47] drew criticism from elected officials,[48] and led to an investigation by DARPA.[49] Three months after the DARPA

37 Nat'l Insts. of Health, *NIH Grants Policy Statement: Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support* § 8.5.2 (rev. Apr. 2024).

38 Nat'l Insts. of Health, *NIH Grants Policy Statement: Inventions and Patents* § 8.2.4 (rev. Apr. 2024).

39 Memorandum from June Gibbs Brown, Inspector General of the Department of Health and Human Services to Philip Lee, the Assistant Secretary of Health. *Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute.* June 15, 1994.

40 See, eg U.S. Gov't Accountability Off., *Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision*, GAO/RCED-99-242 (1999), https://www.gao.gov.

41 See, eg Rai & Sampat, *supra* note 6.

42 James Love, *Errors in Patent Grants: More Common in Medical Patents*, Bill of Health Blog (Oct. 21, 2017).

43 Love, *supra* note 33.

44 U.S. House of Representatives, Committee on Oversight and Reform, *Drug Pricing Investigation: Novartis—Gleevec*, Staff Report (Oct. 2020), https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/Novartis%20Staff%20Report%2010-1-2020.pdf at 34 (accessed May 28, 2025).

45 *Id.*

46 Luis Gil Abinader, *2020:3 KEI Research Note: Moderna Failures to Disclose DARPA Funding in Patented Inventions*, KEI Research Note RN-2020:3 (Aug. 27, 2020), https://www.keionline.org/rn-2020-3 (accessed Aug. 5, 2024).

47 Christopher Rowland, *Moderna Failed to Disclose Federal Support in Vaccine Patents, Researchers Say*, Wash. Post (Aug. 28, 2020), https://www.washingtonpost.com/business/2020/08/28/moderna-vaccine-patents-darpa-funding/ (accessed May 28, 2025).

48 Senator Chris Van Hollen (@ChrisVanHollen), *Each year taxpayers invest billions in medical research. Corporations should not turn taxpayer-funded discoveries into a means of price-gouging consumers and patients. We must pass the We PAID Act, which would ensure a fair price after public investments.*, X (formerly Twitter) (Aug. 29, 2020, 5:42 PM), https://x.com/ChrisVanHollen/status/1299824815562526721 (accessed May 28, 2025).

49 Donato Paolo Mancini, *US Government's DARPA Probes Moderna's Vaccine Patents*, Fin. Times (Aug. 29, 2020), https://www.ft.com/content/2be1f87e-9e96-4e23-9cc5-33ba35e50586 (accessed May 28, 2025).

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inquiry was launched, Moderna declared federal funding in one of the patents that research advocates had previously identified.[50] The investigation may have also been one of the factors driving Moderna to pledge not to enforce COVID-19 patents against other vaccine manufacturers during the pandemic.[51]

While there is growing evidence documenting these failures, some key questions about compliance with Bayh–Dole reporting requirements deserve further attention.[52] Recent evidence show that dozens of late acknowledgements of federal funding have been made even on Orange Book patents,[53] but the magnitude of this problem in the larger sample of federally funded biomedical inventions is unknown. Research is also needed to better understand the magnitude of this problem among other important inventions besides Orange Book patents. Furthermore, the factors driving federal grantees to eventually acknowledge government funding are worthy of further analysis.[54]

Combining patent data from the NIH and the USPTO, this study explores the practice of declaring federal funding late through certificates of corrections. The main analysis focuses on a large sample of patent corrections over time to explore why NIH grantees eventually acknowledge government funding. This study finds that many corrections have been made in recent years and have likely been driven by high-profile controversies, changes in regulation, and civil society advocacy. This study also shows that several late acknowledgements have been made over patents involved in court disputes, corroborating previous findings of underreporting even among important patents.

This article includes nine short sections. Section II describes the data sources used for this study. Section III builds upon previous research on failures to embed government interest statements in the patent specifications and provides new data on how many corrections have been issued to date. Section IV investigates whether late disclosures have been made on important patents beyond the Orange Book, and Section V explores what information grantees submit to the USPTO when correcting

50 James Love & Claire Cassedy, *Sanctions for Non Disclosure, as Set Out in Article 6 of the WIPO Basic Proposal on Intellectual Property, Genetic Resources and Traditional Knowledge, Should Include Possible Revocation of a Patent*, Joint PIJIP/TLS Rsch. Paper Series, Paper No. 127 (2024), https://digitalcommons.wcl.american.edu/research/127, at 5 (accessed May 28, 2025) (explaining that one of the patents assigned to Moderna was corrected in November 2020, 'some three months after KEI asked DARPA to investigate Moderna').

51 Jorge Contreras, *Deconstructing Moderna's COVID-19 Patent Pledge*, Bill of Health (Oct. 21, 2020), https://blog.petrieflom.law.harvard.edu/2020/10/21/moderna-covid19-patent-pledge (accessed May 28, 2025) (suggesting that 'Moderna's recent pledge could help to alleviate government pressure on the company' in light of the investigation by DARPA).

52 Bhaven N. Sampat, *The Government and Pharmaceutical Innovation: Looking Back and Looking Ahead*, 49 J.L. Med. & Ethics 10 (2021) (explaining that it is 'unclear how large the magnitude of this problem [the practice of disclosing federal support late through patent certificates of corrections] is').

53 Ouellette & Sampat, *supra* note 26.

54 Knowledge Ecology International, Government Funding of COVID Drugs and Vaccines - Global Congress Q&A, YouTube (Oct. 7, 2020), https://youtu.be/Ct3F_ZqPukI?si=xeloytZiVonly2AV&t=168, at 2:47 (accessed May 28, 2025) (Bhaven Sampat asking what motivates federal grantees to eventually declare government support years later through corrections); Maya Durvasula, Lisa Larrimore Ouellette & Heidi Williams, *Private and Public Investments in Biomedical Research*, 111 AEA Papers & Proc. 341 (2021), at 343 (highlighting, in reference to existing research gaps around compliance with Bayh-Dole invention reporting requirements, that 'a natural question is whether additions of public research disclosures via certificates of correction reflect – at least in some cases – strategic behavior on the part of applicants').

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patents. Section VI investigates whether the NIH has taken ownership of patents from grantees citing failure to disclose grounds. The main empirical contribution of this study is developed in Section VII, which provides a chronological analysis of patent corrections made by NIH grantees to declare federal support since the Bayh–Dole Act was enacted and examines major drivers that have likely spurred a large share of these late acknowledgements. Section VIII makes recommendations for improving enforcement of Bayh–Dole reporting requirements, and Section IX contains conclusions.

II. DATA COLLECTION AND LIMITATIONS

II.A. Data Collection

Following the approach described by Arti Rai and Bhaven Sampat,[55] this study began compiling all patents in RePORTER as of December 2023. RePORTER is an open dataset released by NIH that contains information about patents linked to intramural and extramural awards, drawn from the invention reporting platform called iEdison.[56] RePORTER had 38,130 patents issued between 1980 and 2020, each associated with at least one contract, grant, or intramural activity identifier. RePORTER identifiers were then reviewed to determine which of the 38,130 patents in the initial sample were linked to extramural awards and, therefore, presumably subject to Bayh–Dole invention disclosure requirements.[57] Approximately two percent (799) of the 38,130 patents in RePORTER were exclusively linked to intramural activities, and the rest (37,331) was associated with at least one extramural identifier. Like in prior studies,[58] PatentViews[59] was used to identify which patents listed in RePORTER had government interest statements in their specifications. Combining data from PatentViews and RePORTER is useful for determining which patents subject to Bayh–Dole reporting requirements properly acknowledged federal support when the USPTO issued them (Table 1).

The USPTO periodically publishes a comprehensive list of patents with certificates of corrections[60] but without distinguishing whether they correct failures to declare government support or other omissions. Crossing that list with RePORTER and PatentViews data yielded 3984 patents without government interest statements in their specifications but with corrections issued for any reason. Because USPTO data do not describe the corrections or classify them by type, the image files of these 3984 patents were manually reviewed to distinguish between corrections that declared

55 Rai & Sampat, *supra* note 6.

56 Nat'l Insts. of Health, *Research Portfolio Online Reporting Tools (RePORT)*, https://report.nih.gov/ (accessed Aug. 5, 2024).

57 NIH projects with activity codes that start with the letter 'z' are supported by intramural awards. This study considers patents as 'extramural' if they had at least one RePORTER project with any activity code other than a 'z' type. For details on 'z' activity codes, *see* U.S. Dep't of Health & Hum. Servs., NIH Exporter Data Dictionary, *NIH Research Portfolio Online Reporting Tools (RePORT)*, https://report.nih.gov/exporter-data-dictionary (accessed Dec. 5, 2024) (explaining that NIH uses three-character activity codes 'to differentiate the wide variety of research-related programs NIH supports' and awards beginning with the letter 'z' refer to intramural projects).

58 See, eg Ouellette & Sampat, *supra* note 26.

59 Andrew A. Toole, Christina Jones & Sarvothaman Madhavan, *PatentsView: An Open Data Platform to Advance Science and Technology Policy*, U.S. Patent & Trademark Off., Econ. Working Paper No. 2021-1 (2021).

60 U.S. Patent & Trademark Office, *Certificates of Correction*, https://www.uspto.gov/patents/search/authority-files/certificates-correction (accessed Aug. 10, 2024).

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Table 1. Summary of data sources and specific uses for this study

Source	Specific data from each source used in this study
RePORTER	Data file including patents supported with federal research awards and reported to the NIH through the interagency iEdison platform
PatentViews	Data file linking patents to government interest statements if an applicant made the federal funding disclosure by issuance date
Correction Authority File	Data file with a comprehensive list of patents with certificates of corrections issued by the USPTO to amend any type of omission
Patent Center	Image files with full patent texts, including the content of issued certificates of corrections, and image files of correction requests
PatEx	Data file with USPTO event codes, including 'denials' of requests for corrections, and linking patents to their 'parents' or 'child'
Patent Assignment Dataset	Data file linking patents to transactions recorded at the USPTO that convey assignments of rights, including the names of 'assignees'
Government Patent Register	Crosswalk made by Daniel Gross and Bhaven Sampat identifying assignments to federal agencies in the Patent Assignment Dataset
Patent Litigation Dataset	Data file made by David Schwartz, Ted Sichelman, and Richard Miller with a hand-coded list linking patents to district court cases

federal support from other certificates that corrected different errors. This manual review identified 3090 patents listed on RePORTER that were issued without government interest statements but eventually disclosed federal funding through corrections made between 1980 and 2023. The date when the USPTO issued a correction declaring funding was recorded for each patent.[61] If a patent was corrected multiple times, the date of the earliest correction declaring federal funding was recorded.

Litigation data are useful for exploring whether some underreporting of federal funding has involved important patents. This study used a hand-coded list of patents[62]

61 Certificates of correction are typically issued within a few weeks of being requested. Capturing the dates when grantees requested a correction would be a better approximation for the time when grantees took the first steps to disclose federal funding, but those requests (and their dates) are often unavailable, especially among earlier patents.

62 David L. Schwartz, Ted M. Sichelman & Richard Miller, *USPTO Patent Number and Case Code File Dataset Documentation* (USPTO Econ. Working Paper No. 2019-05, Nw. L. & Econ. Research Paper No. 19-12, San Diego Legal Studies Paper No. 20-435, Dec. 1, 2019), https://ssrn.com/abstract=3507607 (accessed May 28, 2025).

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from the USPTO litigation dataset[63] to identify court cases involving patents in the main sample. Another question explored in this study relates to the information that NIH grantees submit to the USPTO when requesting a certificate of correction. To investigate what information grantees provide in these requests, this study used the online USPTO database Patent Center to review a sample of 300 patents that corrected a failure to declare federal support. Additionally, the main dataset was crossed with the patent examination research dataset (PatEx) to explore how the USPTO implements the certificates of corrections procedures.[64] PatEx was used to find RePORTER patents that had received USPTO responses reflecting 'memos'[65] or 'denials'[66] of their requests for a certificate of correction.

II.B. Limitations

While RePORTER provides information on patents linked to NIH funding, access to most of the remaining data in iEdison is constrained to a narrow number of government officials.[67] This significantly limits academic and policy research on NIH invention reporting, including to address some of the questions explored in this study. Most importantly, secrecy around the dates when inventions are disclosed to NIH prevents research on gaps or lags between iEdison reporting and certificates of corrections. However, at least in recent iterations, iEdison appears to automatically prompt grantees that report an invention to submit evidence showing that their applications and patents have compliant government interest statements.[68] Until they resolve this issue, grantees may be unable to renew or close out NIH awards.[69] Therefore, it seems likely that in most cases there are short lags between invention disclosures filed via iEdison and funding acknowledgements made at the USPTO—except when grantees deliberately omit federal support and refuse to cooperate with the NIH. If both disclosures generally coincide, then the dates when corrections are issued serve as a rough approximation for the dates when grantees report their inventions to the NIH.

63 Andrew A. Toole, Richard Miller & Ted M. Sichelman, *Technical Documentation for Patent Litigation Docket Reports Data, 1963–2020* (USPTO Econ. Working Paper No. 2024–1, Mar. 2024), https://ssrn.com/abstract=4780166 (accessed May 28, 2025).

64 Stuart J.H. Graham, Alan C. Marco & Richard Miller, *The USPTO Patent Examination Research Dataset: A Window on the Process of Patent Examination* (Nov. 30, 2015), https://ssrn.com/abstract=2702637 (accessed May 28, 2025); Richard Miller, *Technical Documentation for the 2019 Patent Examination Research Dataset (PatEx) Release* (USPTO Econ. Working Paper No. 2020–4, Aug. 2020), https://ssrn.com/abstract=3675671 (accessed May 28, 2025).

65 PatEx events with the code 'COCM', which has 'certificate of correction memo'.

66 PatEx events with the code 'CDEN', which has 'post issue communication - certificate of correction denied'.

67 Ameet Sarpatwari, Aaron S. Kesselheim & Robert Cook-Deegan, *The Bayh-Dole Act at 40: Accomplishments, Challenges, and Possible Reforms*, 47 J. Health Pol. Pol'y & L. 879 (2022) (explaining that the use of iEdison 'is constrained to only to a narrow range of government officials').

68 GAO, *supra* note 15, at 26 (explaining that 'NIH awardees who submitted [incomplete or incorrect government interest statements] receive automated iEdison notifications to correct the statements by filing a certificate of correction with USPTO and submitting evidence of doing so to iEdison'); *Also see* Nat'l Inst. of Standards & Tech., Uploading a Government Support Clause Document, https://www.nist.gov/iedison/iedison-organization-user-guide/uploading-government-support-clause-document (accessed Aug. 10, 2024).

69 Nat'l Insts. of Health, *NIH Grants Policy Statement: Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support* § 8.5.2 (rev. Apr. 2024).

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The USPTO began to publish pending applications and generally allow public scrutiny of procedural documents in November 2000, with the implementation of the American Inventors Protection Act of 1999.[70] Most requests for certificates of corrections made by NIH grantees since then are available for public scrutiny through USPTO databases, and some are described in this study. Four of the requests described in Section V of this study state that the applicant became aware of the missing disclosures following a notification from iEdison. This suggests that reviewing correction requests may have some useful insight into why grantees correct their patents. In contrast, patent applications filed before November 2000 are not generally available for public scrutiny in USPTO online databases. That includes requests for certificates of corrections to declare federal support. Because of this, some earlier requests that potentially have useful insight into the motivations that led those grantees to address their failures to declare government funding cannot be scrutinized.

Lastly, RePORTER is an incomplete measurement of all the patents linked to NIH funding because some grantees never disclose their inventions through iEdison.[71] Since RePORTER is incomplete, this study likely underestimates the extent to which NIH grantees fail to comply with Bayh–Dole reporting requirements. Similarly, private companies and product developers working with late-stage research might be failing to declare federal funding relatively more often, but most inventions associated with NIH funding and therefore available in RePORTER originate from academic institutions. Further exploring failures among companies and product developers would probably require accompanying RePORTER with invention reporting data from other agencies, like the Biomedical Advanced Research and Development Authority (BARDA), which is unavailable.

However, precisely because RePORTER is based on the iEdison invention reporting platform, RePORTER data are well suited for researching patents that are confidently subject to Bayh–Dole requirements. There are other methods for identifying inventions arising from public funding that are probably more comprehensive than using RePORTER, such as linking patent with papers that describe the same technology—often referred to as patent–paper 'pairs'.[72] Nevertheless, linking patent–paper pairs is an inherently subjective process and therefore less useful for determining with certainty whether a lack of government interest statement reflects a 'failure to disclose federal funding' or instead an invention that falls outside of the Bayh–Dole reporting requirements.[73]

70 Bhaven N. Sampat & Mark A. Lemley, *Examining Patent Examination*, 2010 Stan. Tech. L. Rev. 1. 2010.

71 Nat'l Inst. of Health, *Frequently Asked Questions*, https://report.nih.gov/faqs (accessed Aug. 10, 2024). ('Patent information in RePORTER is incomplete. The patents in RePORTER come from the iEdison database. Not all recipients of NIH funding are compliant with the iEdison reporting requirements, particularly after their NIH support has ended'.).

72 Sampat, *supra* note 52, at 14 ('While this is inherently a subjective process, one promising approach to do this at scale, would be to match patents to "paired" papers using natural language processing and other computational techniques').

73 Despite those limitations, government agencies should still pair patents with papers to identify inventions possibly arising from federal funding and monitor Bayh–Dole reporting compliance. Section VIII discusses this recommendation.

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III. HOW FREQUENT AND LENGTHY ARE FAILURES TO ACKNOWLEDGE GOVERNMENT FUNDING IN PATENTS?

Approximately 17 percent (6490) of all patents in RePORTER associated with extramural awards (37,331) lack government interest statements in their specifications. Eight percent (3085) of extramural patents in RePORTER declared federal support through certificates of corrections. This means that approximately 47 percent of the extramural patents in RePORTER issued without government interest statements were later corrected to declare federal support. Around nine percent (3405) of all extramural RePORTER patents lack federal funding acknowledgments in their specifications or through certificates of corrections as of the end of 2023. Two percent (799) of all RePORTER patents (38,130) appear to have originated solely from NIH intramural projects.[74] Most of those patents (660) lack government interest statements in their specifications or late disclosures made through certificates of corrections as of 2023, but this is likely because they are governed by invention reporting procedures separate from the Bayh–Dole requirements.[75]

Figure 1 describes the share of patents in RePORTER with government interest statements in their specifications. This graph shows that the share of patents with extramural awards and government interest statements in their specifications has increased over time. Yet almost 10 percent of patents issued in 2020 and linked to extramural awards lack acknowledgements in their specifications. This only includes inventions that have already been reported, which means that the share of patents in RePORTER with late acknowledgements is likely to increase over time as more become compliant. In 2012, Arti Rai and Bhaven Sampat showed that slightly less than 10 percent of RePORTER patents issued in 2007 declared federal support in their specifications.[76] Over a decade later, the findings described in Figure 1 suggest roughly the same levels of compliance with Bayh–Dole requirements to declare federal funding in the specifications among patents in RePORTER.

Collapsing the sample of 3405 extramural patents without any disclosures into unique families provides further insights.[77] Continuity data from PatEx indicates that these 3405 patents belong to 2783 unique families with a total of 6073 patents. Crossing all 6073 patents with PatentViews shows that around 23 percent (636) of these families have at least one patent (whether 'parent' or 'child') with a government interest statement. This indicates that an important share of patents without proper disclosures can be linked to federal funding through acknowledgements made by other members of the same family. The takeaway from this finding is twofold. As others have recently proposed,[78] continuity data appear to be a promising avenue for complementing incomplete disclosures and finding additional patents linked to federal funding. These

74 That is, all federal awards linked to those 799 patents begin with the letter 'z', denoting intramural projects.

75 Eg United States Public Health Service, PHS Policy for Reporting Employee Inventions, Ch. 201, *Technology Transfer Policy Manual* (June 17, 2010), https://www.techtransfer.nih.gov/policy/phs-technology-transfer-policies (accessed May 28, 2025).

76 Rai & Sampat, *supra* note 6.

77 For various technical definitions of 'patent families', including terms like 'parent' and 'child', generally *see* Catalina Martinez, *Insight into Different Types of Patent Families*, OECD Sci., Tech. & Indus. Working Papers, No. 2010/02, OECD Pub., Paris (2010), https://doi.org/10.1787/5kml97dr6ptl-en.

78 Durvasula, Ouellette & Williams, *supra* note 54 (discussing federal funding among Orange Book patents and finding 15 patents linked to a government interest statement made through a disclosure in a parent application).

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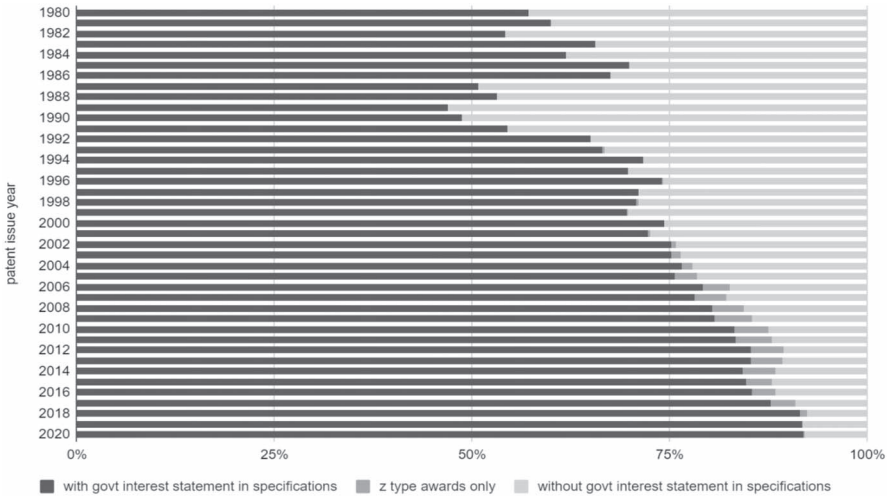


Figure 1. Share of RePORTER patents (38,130) with government interest statements in their specifications at the time of patent issuance, by year when patent was issued.

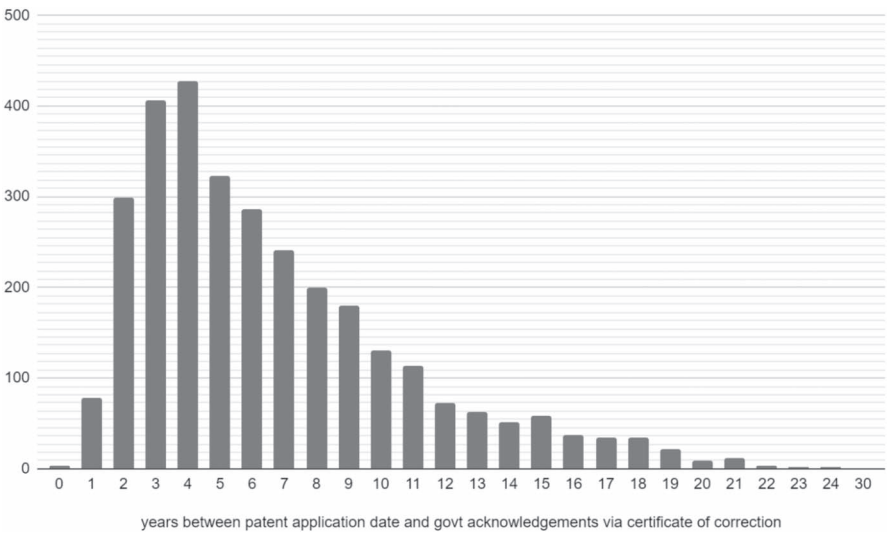


Figure 2. Distribution of all 1980–2020 RePORTER patents with certificates of corrections, by the number of years between patent application date and correction date.

findings also suggest that significant underreporting has occurred even for patents that should be on the NIH's radar due to separate acknowledgments made by other members of the same patent family.

Priority dates are useful to approximate when the obligation to report an invention to NIH began.[79] It is unclear whether correction dates are good proxies for when grantees

79 OECD, *OECD Patent Statistics Manual* (OECD Publishing 2009), https://doi.org/10.1787/9789264056442-en, at 61 (accessed May 28, 2025) (generally discussing the use of priority dates in statistical analyses and explaining that they are 'the earliest and therefore can be considered as the closest to the invention date').

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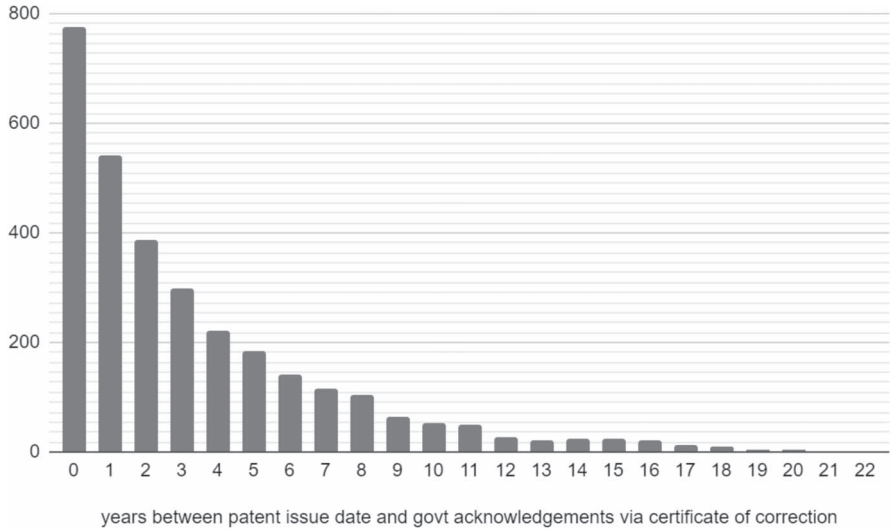


Figure 3. Distribution of all 1980–2020 RePORTER patents with certificates of corrections, by the number of years between patent issuance date and correction date.

made an iEdison submission. Assuming that they are, the delays from invention until a report to the NIH was made could be roughly estimated based on the average lags between priority and correction. Considering the 3090 patents with late disclosures, the corresponding corrections were on average issued around nine years from their earliest priority dates. Similarly, these 3090 patents were corrected approximately seven years from their application filing dates. This suggests that average lags between invention and iEdison submission among patents that declared federal funding through corrections have been significant. Contrary to the Bayh–Dole policy objectives, the NIH is presumably unaware of numerous patent filings—either entire families or some members—claiming federally supported inventions long after prosecution began. Moreover, among the patents with late funding disclosures, the corrections were on average made approximately three years after patent issuance. This shows that many patents have spent several years in force without fully complying with disclosure requirements. To be sure, even if a grantee declares government funding shortly after securing a patent, a brief delay can cause significant harm to federal agencies and taxpayers.[80]

80 For instance, a brief failure to disclose that was corrected shortly after the USPTO granted a patent may prevent funding agencies from determining whether an invention falls within an 'exceptional circumstances' as provided in 35 U.S. Code § 202(a). For a general discussion about 'exceptional circumstances', *see* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 Law & Contemp. Probs. 289 (2003). Also *see* Campbell Plastics Eng'g & Mfg., Inc. v. Brownlee, 389 F.3d 1243, 1249 (Fed. Cir. 2004) (citing arguments by the US government stating that 'indeed it has suffered harm from Campbell Plastics's failure to meet the notification requirements, *inter alia*, by putting the patent rights of the United States in foreign countries in jeopardy').

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Forty-four certificates of corrections were issued after the corresponding patents lapsed for failure to pay maintenance fees.[81] An additional 52 corrections were issued over expired patents.[82] While these are only a small fraction of the full RePORTER sample, the fact that a handful of patents were corrected after they lapsed or expired is surprising. These cases are also useful to draw insights into what motivates grantees to correct failures. Intellectual property right holders normally allow their patents to lapse when the cost of paying administrative fees exceeds their expected gains from maintaining patent rights.[83] Therefore, at least with regard to the certificates of corrections issued after the patents lapsed, the risk of economic harm as a result of losing patent title seems insufficient to explain why those grantees eventually declared federal funding. Section VII continues this discussion by exploring possible additional drivers of late acknowledgments.

IV. HAVE LATE DISCLOSURES AND FULL OMISSIONS OF FEDERAL FUNDING INVOLVED IMPORTANT PATENTS?

Lisa Ouellette and Bhaven Sampat have shown that more than 30 patents in the Orange Book have reported government interest statements only via certificates of corrections.[84] These failures include a patent related to the blockbuster drug Gleevec (imatinib), corrected a couple of years before expiring[85] and during a House Oversight Committee investigation on excessive pricing.[86] Other blockbuster drugs with patents that have declared government support several years late through corrections include Lyrica (pregabalin) and Prozac (fluoxetine hydrochloride).[87] These findings show that underreporting has involved several important patents linked to biomedical products. This section expands upon previous empirical findings by showing that underreporting of government support has also occurred among several patents involved in high-stakes litigation.

Table 2 describes all 417 district court cases relating to extramural patents in RePORTER. These court cases relate to 296 unique patents, reflecting that some of them have been invoked in multiple disputes. Compliance rates among these 296 litigated patents generally track the larger sample, with approximately 11 percent (32) lacking any government interest statements and around 10 percent (29) declaring federal support late through certificates of corrections. Within the sample that made

81 Eg U.S. patent 6,387,907 assigned to the University of Pennsylvania, lapsed in 2010 for failure to pay fees according to USPTO records. Nearly a decade later, this patent was corrected in 2019 to declare federal funding.

82 Eg U.S. patent 6,001,985 assigned to the University of Alabama at Birmingham's Research Foundation. This patent seems to have expired in 2015 but declared federal support through a certificate of correction issued in 2020.

83 Gaetan De Rassenfosse & Bruno van Pottelsberghe de la Potterie, *The Role of Fees in Patent Systems: Theory and Evidence*, 27 J. Econ. Surv. 696 (2013); Gaétan De Rassenfosse & Adam B. Jaffe, *Are Patent Fees Effective at Weeding Out Low-Quality Patents?*, 27 J. Econ. & Mgmt. Strategy 134 (2018).

84 Ouellette & Sampat, *supra* note 26.

85 Love, *supra* note 33.

86 H. Comm. on Oversight & Reform, *supra* note 44, at 34 (citing February 2019 correspondence from Novartis stating that no patents for Gleevec's active ingredients, methods of use, or indication were developed with federally sponsored research; and a subsequent November 2019 letter from Novartis notifying the U.S. House Committee on Oversight and Reform that one Gleevec patent had been corrected in July 2019 to declare government support).

87 Ouellette & Sampat, *supra* note 26.

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Table 2. District court cases involving extramural patents listed in RePORTER, 2003–20

Cause of action	GOVT at grant	≥1 GOVT at grant	GOVT via CoC	No GOVT by 2023	Total
Infringement (ANDA filers)	46	11	2	2	61
Infringement (NDA filers)	2	–	–	–	2
Infringement (drug patents)	16	–	1	7	24
Infringement (other patents)	118	53	15	45	231
Declaratory judgment	21	17	2	13	53
Breach of licensing contract	4	–	1	3	8
Civil action under 35 USC 146	1	–	2	–	3
Correction of inventorship	11	2	–	1	14
False patent marking	5	1	1	1	8
Interference proceeding	1	–	2	–	3
Term adjustment determination	9	–	1	–	10
Total	234	84	27	72	417

disclosures via corrections and have been litigated, the acknowledgements declaring federal support on average were made about six years after those patents were issued. Fourteen litigated patents have been corrected after their first district court complaint was filed.[88]

Four of the litigated patents without proper disclosures are in the Orange Book and therefore have been captured in previous empirical analyses.[89] Among the subset of litigated patents outside of the Orange Book, various ones have been involved in high-stakes controversies. One example relates to six molecular diagnostic patents that name Myriad Genetics founder Mark Skolnick as an inventor,[90] which were supported with intramural funding[91] and more than $6 million in NIH awards to the University of Utah.[92] Several of these patents were involved in the Supreme Court decision *Myriad,* which ruled that isolated naturally occurring DNA sequences cannot be patented.[93]

88 See, eg U.S. patents 5,545,522 and 5,716,785, exclusively licensed by Stanford University to LBS Technologies and asserted in an infringement claim against Incyte Corporation in 2007. LBS Techs., Inc. v. Incyte Corp., No. 2:07-cv-01297, (E.D. Pa. filed Mar. 30, 2007) (complaint). These two patents were corrected in August 2011 and February 2012, more than 14 years after their USPTO issue date.

89 U.S. patents 5,563,175 (Lyrica), 6,028,071 (Folotyn), 8,445,507 (Erleada), and 8,486,907 (Exondys 51).

90 U.S. patents 5,624,819, 5,710,001, 5,747,282, 5,753,441, 5,989,815, 6,162,897.

91 Jorge L. Contreras, *Will NIH Learn from Myriad when Settling Its mRNA Inventorship Dispute with Moderna?, Bill of Health* (Jan. 6, 2022), https://petrieflom.law.harvard.edu/2022/01/06/nih-moderna-mrna-covid-vaccine-patent/ (explaining that intramural NIH scientists Roger Wiseman and Andrew Futreal 'contributed DNA sequences from cancer-affected families to the effort').

92 Grant P01CA048711 awarding $6,030,913 from 1990 to 1994. This grant names Mark Skolnick at the University of Utah as the principal investigator. The award supported six Skolnick patents, according to RePORTER.

93 Jorge L. Contreras, The Genome Defense: Inside the Epic Legal Battle to Determine Who Owns Your DNA (Algonquin Books 2021).

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One of these patents acknowledged government support in its specifications,[94] and another was corrected.[95] The remaining Myriad patents lack federal funding acknowledgements.

'Cotransformation,' a method discovered by Columbia University scientists that has been widely used in the development and manufacture of biopharmaceuticals, provides another example of litigated patents without full disclosures. Although this method was conceived before the Bayh–Dole Act was enacted,[96] the NIH letter authorizing Columbia to elect title required that the university acknowledge government support in all applications filed thereon.[97] The NIH also required Columbia to request corrections for patent applications filed without government interest statements.[98] Over the course of 20 years, Columbia secured four key patents related to cotransformation but only two declared government support.[99] However, the RePORTER database indicates that all four emerged from extramural awards.[100] Columbia received over $400 million in fees and royalties from more than 30 companies licensing cotransformation patents.[101]

Underreporting of federal funding has also occurred among frequently litigated patents. A noteworthy example involves three imaging algorithm patents obtained by University of California neuroscientist Carl Cotman,[102] who has been backed by more than $100 million in NIH funding.[103] None of these three patents acknowledged federal support in their specifications, but the 'parent' has a confirmatory license and appears in RePORTER linked to extramural grants. In 2018, Carl Cotman assigned all three imaging algorithm patents to Rondevoo Technologies. Rondevoo is a non-practicing entity owned through Red Dragon Innovations[104] by intellectual property

94 U.S. patent 5,989,815.

95 U.S. patent 5,624,819.

96 Alessandra Colaianni & Robert Cook-Deegan, *Columbia University's Axel Patents: Technology Transfer and Implications for the Bayh-Dole Act*, 87 Milbank Q. 683 (2009).

97 Letter from Charles Miller, Assistant Secretary of Health and Human Services, to Paul A. Marks, Vice President for Health Services at Columbia University (Feb. 24, 1981), https://dukespace.lib.duke.edu/items/84f5215f-556f-4906-b609-5c126c31a875, at 6 (rejecting Columbia's request to exclusively license cotransformation technology and requiring interest statements in applications filed thereon acknowledging that the 'invention described herein was made in the course of work under a grant or award from the Department of Health and Human Services').

98 *Id.*

99 U.S. patents 4,399,216 and 4,634,665 (with proper government interest statements) and U.S. patents 5,179,017 and 6,455,275 (without government interest statements in the specifications or made through certificates of corrections).

100 Grant P01CA023767 awarding at least $19,806,766 to Columbia and naming Richard Axel as one of the principal investigators across several years. RePORTER links this grant with all four cotransformation patents.

101 Wyeth v. The Trustees of Columbia University in the City of New York, No. 1:03-cv-11570 (D. Mass. filed Nov. 24, 2003). Answer to complaint, at 2 ('Columbia further admits and alleges it has received at least $400 million in payments from its licenses'); Biotechs Sue Columbia Over Fourth Axel Patent, 21 Nature Biotechnology 9 (2003).

102 U.S. patents 7,088,854, 7,254,266, and 8,687,879.

103 A search for NIH grants naming Carl Cotman as a principal investigator in RePORTER shows a total of $106,871,936 in funding from 1985 to 2022. More than $35 million were funded during the years 1985–2002.

104 Rondevoo Techs., LLC v. DRVision Techs., LLC, No. 19-cv-1912 (W.D. Wash. Nov. 26, 2019) (disclosure stating that Rondevoo is owned by Red Dragon Innovations, whose members include Dan Cotman and Pai Yeh).

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lawyer Daniel Cotman,[105] who appears to be the son of the University of California neuroscientist.[106]

Shortly after, Rondevoo began a patent assertion campaign filing more than two dozen complaints against alleged infringers including companies using artificial intelligence to diagnose breast cancer,[107] prostate cancer,[108] lung cancer,[109] and other medical applications like orthopedics.[110] Rondevoo also asserted the Cotman patents against companies using artificial intelligence to analyze medical images for drug discovery and clinical trials.[111] Most of these cases settled within months, a typical outcome in patent infringement lawsuits initiated by non-practicing entities. A few others were dismissed without prejudice because Rondevoo failed to follow local rules.[112]

V. WHAT INFORMATION DO NIH GRANTEES SUBMIT TO USPTO WHEN REQUESTING CORRECTIONS?

Patentees can request the USPTO to correct issued patents that feature applicants' 'mistakes' by following the requirements set out in 35 U.S.C. § 255. To be eligible for a correction specifically based on a 'mistake' made by the applicant, the error must be clerical, typographical, or minor in character. Corrections that 'would constitute new matter or would require re-examination' are ineligible under 35 U.S.C. § 255. Additionally, pursuant to 35 U.S.C. § 255 patentees need to show that 'such mistake occurred in good faith'. Considering that patentees are required to show that their mistake occurred in 'good faith', this section explores what information NIH grantees typically submit when seeking to acknowledge government funding late through certificates of corrections and whether the USPTO ever asks them to provide additional supporting documents.[113]

NIH grantees normally acknowledge in their requests for correction that the failure to declare funding was their fault,[114] a requirement in 35 U.S.C. § 255. Sometimes

105 Peter Holslin, *Is a Patent Troll About to Kill the High-Tech Dildo Industry?* Vice (Aug. 3, 2015), https://www.vice.com/en/article/nn9emq/a-patent-troll-is-trying-to-stop-dildo-innovations-803.

106 Dan Cotman, *Cotman IP Law Group*, https://web.archive.org/web/20231128224645/https://www.cotmanip.com/legal-team/dan-cotman (accessed Aug. 5, 2024). ('My dad, who is a world-renowned neuroscientist in the field of Alzheimer's Disease research, taught me to embrace the unknown').

107 Rondevoo Techs., LLC v. Paige.AI, Inc., No. 1:20-cv-00591 (D. Del. filed Apr. 29, 2020).

108 *Id.*

109 Rondevoo Techs. LLC v. VoxelCloud, Inc., No. 2:19-cv-06736 (C.D. Cal. filed Aug. 2, 2019).

110 Rondevoo Techs., LLC v. RSIP Vision, Inc., No. 5:20-cv-03003 (N.D. Cal. filed Apr. 30, 2020).

111 Rondevoo Techs., LLC v. ScienceSoft USA Corp., No. 4:19-cv-00691 (E.D. Tex. filed Sept. 24, 2019).

112 David Hricik, *Failure to Identify Related Cases on Civil Coversheet: A Throwback*, Patently-O (May 11, 2020), https://patentlyo.com/hricik/2020/05/identify-coversheet-throwback.html (accessed May 28, 2025).

113 This analysis seems important given that some courts have found that third parties do not have the right to judicial review of certificates of corrections issued by the USPTO. Hallmark Cards, Inc. v. Lehman, 959 F. Supp. 539, 542 (D.D.C. 1997), at 543 ('In the instant action, the Congressional framework precludes the right of third parties to file a civil action in the ease of the issuance of a Certificate of Correction; the third party's recourse for the alleged errors made by the PTO is to raise the issue as a defense in an infringement suit').

114 Eg see applicant's letters requesting corrections on U.S. patents 10,617,678, 10,450,613, 9,956,042, or 9,828,637.

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grantees indicate that their failure was a 'minor' error,[115] 'clerical' error,[116] 'inadvertent' in nature,[117] or made in 'good faith'[118] but typically without explaining what caused that mistake or how they detected it. Other grantees have said that they 'recently' became aware of the need to declare federal funding.[119] In one apparently exceptional case, four requests relating to patents owned by Washington University explain that the grantee 'believed that no government support paragraph was needed' when the applications were filed.[120] 'Subsequently', Washington University 'learned that the paragraph is required to place it in proper form for the iEdison federal reporting system'.[121] Stated differently, these four correction requests were motivated by a prompt from the iEdison reporting platform. It is difficult to estimate how many more corrections have been prompted by iEdison based solely on the information submitted to the USPTO because few requests provide the same levels of insights as Washington University did in these instances, but exploring this seems relevant for future work.

USPTO typically grants requests to acknowledge government support through certificates of corrections without requiring patentees to submit any additional information or documentation. According to the PatEx dataset, only 13 RePORTER patents filed from 2002 to 2020 faced a negative USPTO response or request for further actions before issuing a certificate of correction to declare federal funding. Most of these responses or requests from USPTO were based on failures to meet minor procedural requirements, such as paying the corresponding fees.[122] In a rare case, the USPTO initially denied a request related to a patent assigned to the Texas Tech University System, indicating that the patentee failed to explain 'the root cause of error'.[123] The USPTO issued a certificate six months later after Texas Tech simply stated that the government interest statement had been 'inadvertently' omitted from the application.[124] This suggests that NIH grantees typically succeed when attempting to correct their patents and USPTO rarely asks for further information.

Allowing grantees to declare federal support late serves the Bayh–Dole policy objectives better than denying correction requests. Late disclosures enable greater public scrutiny and increase certainty about the application of other Bayh–Dole safeguards. However, generally allowing grantees to declare federal support late decreases the incentives for diligently avoiding mistakes during patent prosecution. For grantees,

115 Eg see applicant's letters requesting corrections on U.S. patents 6,494,834, 6,766,184, 6,987,105, or 7,261,881.

116 Eg see applicant's letters requesting corrections on U.S. patents 7,988,971, 8,846,098, or 9,757,339.

117 Eg see applicant's letters requesting corrections on U.S. patents 6,979,728, 7,549,743, 9,211,358, or 10,314,284.

118 Eg see applicant's letters requesting corrections on U.S. patents 8,329,175, 8,912,336, 9,451,904, or 10,750,977.

119 Eg see applicant's letters requesting corrections on U.S. patents 7,304,149, 7,583,992, 8,188,232, and 9,045,562.

120 Applicant's letter explaining the request to correct U.S. patent 8,546,541, Feb. 21, 2017 (filed Apr. 17, 2017).

121 *Id.*

122 This is according to a hand review of USPTO transactions flagged by PatEx as 'COCM' or 'CDEN'. In a few of these events, however, the full image or text of the transactions flagged as COCM or CDEN are unavailable in public databases, which prevents further research to determine why USPTO appears to have objected to a correction request.

123 USPTO response from March 8, 2019, denying a request to correct U.S. patent 9,555,108.

124 Applicant's letter from August 27, 2019, explaining the request to correct U.S. patent 9,555,108.

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investing resources to avoid omissions that can normally be cured after their patents are issued might even be irrational. Additionally, the USPTO's acceptance of most requests for correction without requiring detailed information about root causes or how patentees eventually detected them enables strategic behavior. This indicates the need for a stricter approach. The key question is whether and how USPTO can adopt a stricter enforcement of 35 U.S.C. § 255 while preserving Bayh–Dole objectives of increasing visibility around federally funded inventions. One option is requiring applicants to file a separate USPTO form for correcting errors involving government interest statements. Section VIII discusses this recommendation further.

VI. HAS NIH EVER TAKEN THE TITLE OF A PATENT FROM A GRANTEE THAT FAILED TO DISCLOSE FUNDING?

NIH has on various occasions shown reluctance to take ownership of inventions from grantees who fail to comply with Bayh–Dole reporting requirements.[125] When NIH detects possible reporting gaps, the agency apparently gives grantees several opportunities to cure them. The NIH appears to view taking patent ownership as a last-resort remedy, which should be used only when grantees refuse to address invention reporting failures (see Box 1). Few failures have been subject to court scrutiny,[126] and none appear to involve inventions funded by NIH. This suggests that NIH has either rarely or never taken ownership of an invention from a grantee that failed to comply with reporting requirements. Nevertheless, it is still relevant to explore this issue empirically.

Box 1. NIH generally prefers correcting failures over taking title of non-compliant patents

NIH officials have repeatedly described the agency's enforcement policy in failures to disclose cases, indicating a strong preference for correcting existing gaps over taking title of non-compliant patents. The agency sees taking title as a last resort. For instance, explaining the 'consequences of missing the reporting deadlines', NIH Assistant Extramural Inventions Policy Officer Mary Frances Deutsch said during a webinar that: 'the first thing you've got to do is acknowledge there is an issue, tell us about it, and get up to speed. Under Bayh-Dole – we don't want to take your technology, okay, but we do want you to be compliant with the regulations or the strings that came attached to that reward. So, if you have a subject invention that hasn't been disclosed, get it in there. Folks do what we call "back reporting," and sometimes a lot—more than what we'd like to see. But our main objective is to get it reported so that we can accurately reflect the outcomes of your research. The invention reporting is a key outcome of that federal investment'.

125 Love & Cassedy, *supra* note 50, at 3 (explaining that from 2017 to 2021, 'KEI sent a series of letters and petitions concerning failures to disclose to three U.S. federal agencies, the NIH, BARDA, and DARPA'. Nevertheless, '[i]n none of these cases did the U.S. government take title to a patent').

126 Andrew Goldman, *Bayh-Dole Obligations to Disclose Federal Funding in Patented Inventions*, KEI Briefing Note 2018:1 (rev. Mar. 16, 2018); For an earlier review, also see: Scott D. Locke, *Patent Litigation over Federally Funded Inventions and the Consequences of Failing to Comply with Bayh-Dole*, 8 Va. J.L. & Tech. 1 (2003).

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Similarly, referring to a question about what happens if a grantee 'never resolves' an error from iEdison showing an invention reporting gap, NIH Assistant Extramural Inventions Policy Officer Scott Cooper said during an interview: '[y]eah, there are some consequences if it's not resolved, but we do offer the grantee many opportunities to correct mistakes if they have them. We send notification messages to them. We send multiple alerts. We're available via phone and e-mail to assist our grantees in helping them become compliant, so if, for example, the disclosure is not resolved or it's not accepted and we do reject it, then we would work with the grantee to help them determine why it was not accepted and assist them in becoming compliant'.

Sources: NIH Grants, Invention Reporting Under Bayh-Dole, YouTube (Nov. 17, 2021), https://youtu.be/-wBeYK2j92c?si=yTXaUY55LrfU4KOS&t=2360 at 39:20 (accessed Aug. 5, 2024);

Podcast – Invention Reporting and Patent Protections for Grantees, NIH Extramural Nexus (July 20, 2020), https://nexus.od.nih.gov/all/2020/07/20/new-all-about-grants-podcast-invention-reporting-and-patent-protections-for-grantees/ (accessed Aug. 5, 2024).

Campbell is useful for understanding the procedures federal agencies probably follow when they take ownership of inventions under failure to disclose grounds.[127] In 1992, the Army entered into a contract with Campbell Plastics to develop components for an aircrew protective mask. The contract incorporated Federal Acquisition Regulation (FAR) clause 52.227-11 requiring disclosure to the Army of any inventions within two months of conception or reduction to practice.[128] During the contract period, Campbell developed an invention related to 'sonic welding' and included a government interest statement on the corresponding patent issued in 1997.[129] However, Campbell failed to timely report the subject invention to Army staff using the required DD Form 882.[130]

Citing noncompliance with FAR clause 52.227-11, the Army contracting officer issued a decision in 2000 concluding that Campbell Plastics had 'forfeited title to the subject invention'.[131] The Army recorded its decision as an assignment at the USPTO, attaching a letter to Richard Campbell explaining that his company 'forfeited title' for failing to comply with FAR clause 52.227-11.[132] The Army recorded this assignment in 2001, describing it as the 'contracting officer's final decision letter'. Campbell Plastics appealed the decision arguing that the company disclosed the invention to the Army and acknowledged federal support in the corresponding patent, even though it failed to

127 Campbell Plastics Eng'g & Mfg., Inc. v. Brownlee, 389 F.3d 1243, 1249 (Fed. Cir. 2004).

128 48 C.F.R. § 52.227-11 (1989).

129 U.S. Patent 5,895,537.

130 Instead, Campbell Plastics provided the Army with reports and drawings that failed to meet the contractual disclosure requirements.

131 In Re Appeal of Campbell Plastics Eng'g & Mfg. Inc., ASBCA No. 53319, 03–1 B.C.A. (CCH) ¶ 32206 (Mar. 18, 2003) (stating that 'the contracting officer issued a final decision concluding that Campbell had "forfeited title to the subject invention, now U.S. Pat. No. 5,895,537, to the U.S. Army for failure to comply with FAR clause 52.227-11"').

132 Assignment of U.S. patent 5,895,537, Reel/Frame 011828/0396, executed Dec. 15, 2000, and recorded May 15, 2001, available at United States Patent and Trademark Office, https://assignment.uspto.gov (accessed April 12, 2025).

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submit the DD Form 882.[133] In 2003, the Armed Services Board of Contract Appeals denied the appeal finding that the actions taken by Campbell Plastics were insufficient to meet the contract requirements.[134] In 2004, the Federal Circuit affirmed the decision to take patent title.[135]

While the decision to take title in *Campbell* focused on the failure to disclose the invention using DD Form 882, the procedures used by the Army probably illustrate the steps other agencies take in similar cases. If the NIH or other agencies take ownership of inventions from grantees that fail to acknowledge federal funding in the patent specifications, their decisions are probably recorded as an assignment at the USPTO as in the *Campbell* case. If this is correct, then publicly available USPTO assignment data could be useful for exploring whether NIH has ever taken ownership of a patent on failure to disclose grounds. USPTO assignment data might even capture enforcement actions that were recorded but then administratively overturned without reaching the courts.

Combining USPTO data[136] with an entity classification crosswalk made by Daniel Gross and Bhaven Sampat[137] is useful for identifying patent assignments where a federal agency appears as the 'assignee'. Using that approach, this study found 133,631 patent assignments executed from 1980 to 2023 where a federal agency appears as the 'assignee'. This includes the conveyance in U.S. patent 5,895,537, assigned to the Army from Campbell. The 'conveyance text' of all 27,698 assignments not coded by USPTO as 'govern' or 'employee' were then manually reviewed to determine whether any of them describe a decision to take ownership on failure to disclose grounds. None of the assignments reviewed appear to convey an NIH decision to take the title of an invention on failure to disclose grounds. The only assignment conveying a decision to take ownership seems to be the Army record in *Campbell*, which is neither an invention funded by NIH nor a failure to declare federal support in the patent. These findings are consistent with evidence suggesting that NIH has declined to take ownership of patents in various apparent failures to disclose cases documented by advocates and the last resort policy agency staff have described.

133 Brief for Appellant, Campbell Plastics Eng'g & Mfg., Inc. v. Brownlee, No. 03-1512 (Fed. Cir. Oct. 31, 2003) ('Throughout development, Campbell Plastics continually disclosed all features of the subject invention, though not on a "DD Form 882." Well prior to the filing of the application, the Army had an enabling disclosure of the invention. Moreover, the application was filed acknowledging and reserving a paid-up license to the Government in the invention'.).

134 In Re Appeal of Campbell Plastics Eng'g & Mfg. Inc., ASBCA No. 53319, 03-1 B.C.A. (CCH) ¶ 32206 (Mar. 18, 2003) ('Campbell's argument that it disclosed the invention is unpersuasive. Its arguments are premised upon reports that it made as to the possible use of sonic welding and its effectiveness. We are not convinced the actions taken by Campbell [. . .] and relied on here as disclosures, are sufficient to meet the contract's requirements'.).

135 Campbell Plastics Eng'g & Mfg., Inc. v. Brownlee, 389 F.3d 1243, 1249 (Fed. Cir. 2004) ('Because Campbell Plastics's piecemeal submissions do not adequately disclose the subject invention under the parties' contract, the government may take title to the invention pursuant to FAR 52.227–11(d)').

136 Stuart J.H. Graham, Alan C. Marco & Amanda F. Myers, *Patent Transactions in the Marketplace: Lessons from the USPTO Patent Assignment Dataset*, 27 J. Econ. & Mgmt. Strategy 343 (2018).

137 Daniel P. Gross & Bhaven N. Sampat, *The Government Patent Register: A New Resource for Measuring U.S. Government-Funded Patenting*, Nat'l Bureau of Econ. Research, Working Paper No. 32136 (2024), https://www.nber.org/papers/w32136 (this study used the 'entity_classification' crosswalk file made by Professors Daniel Gross and Bhaven Sampat to identify USPTO patents assignments where a federal agencies is the 'assignee').

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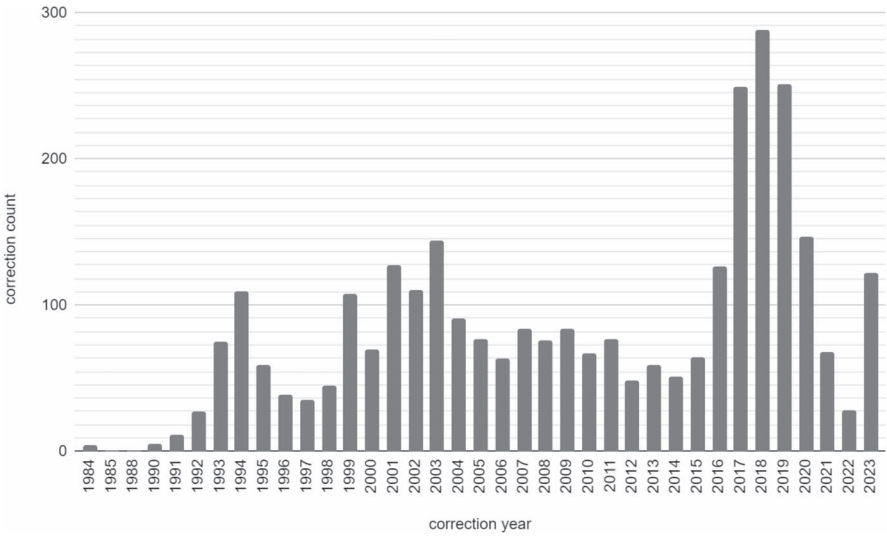


Figure 4. Certificates of corrections made to acknowledge federal support on patents without government interest statements, by year when the certificate of correction was issued.

VII. WHY DO GRANTEES EVENTUALLY DECLARE FEDERAL FUNDING THROUGH CERTIFICATES OF CORRECTIONS?

Considering the NIH's reluctance to take ownership of inventions under failure to disclose grounds, the risk of losing title alone seems insufficient to explain why grantees declare federal funding in their patents or retroactively correct failures. Other additional motivations appear to be driving grantees to comply with Bayh–Dole reporting requirements. Analyzing trends in certificates of corrections over time can help us understand what those motivations are. Studying correction trends over time can also provide insights into the magnitude of this problem. The first certificate of correction among patents in RePORTER was issued in 1984, four years after the Bayh–Dole Act was enacted. Since then, NIH grantees have made an average of 83 corrections annually to acknowledge federal support. Yet the number of corrections has spiked in certain years, as Figure 4 shows. These spikes in corrections have likely been driven by (1) high-profile controversies, (2) sporadic audits, (3) recent changes in Bayh–Dole regulations, and (4) civil society advocacy. The rest of this section discusses those possible drivers of patent corrections to declare federal funding.

VII.A. Scripps Controversy (1992–94)

In 1992, Swiss company Sandoz agreed to provide $300 million over 10 years to the Scripps Research Institute in exchange for the right of first refusal to develop their drug discoveries.[138] This deal was seen within the US government as a potential outsourcing of discoveries supported by taxpayers. Outraged by this agreement, then NIH Director Bernadine Healy described the deal as an 'aberration' and a 'dangerous exception' to

138 B.J. Spalding & Stephen Edgington, *Sandoz and Scripps Institute Join in $300-Million R&D Pact*, Nature Biotechnology, Jan. 1993, at 13, https://doi.org/10.1038/nbt0193-13.

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the standard arrangement with industry.[139] Other officials believed that the deal was potentially contrary to the Bayh–Dole Act.[140] Although the most contentious terms were later removed,[141] controversy around this deal sparked a broader inquiry into Bayh–Dole compliance at Scripps. In March 1993, Representative Ron Wyden (now Senator) requested the Department of Health and Human Services (HHS) to audit the extent to which Scripps was complying with Bayh–Dole reporting requirements.[142] In response, then HHS Inspector General June Gibbs Brown led an audit on Scripps from March 1993 to June 1994.[143]

Gibbs Brown found that at least 94 of the 125 patents they reviewed were developed with federal support, but Scripps had included government interest statements in only 51 of them.[144] The House Subcommittee on Regulation, Business Opportunities, and Technology then held a hearing in July 1994 to discuss the audit.[145] At the hearing, Ron Wyden said that Scripps was probably a 'microcosm of a much larger problem'.[146] Agreeing with Wyden, then HHS Assistant Inspector General Michael Hill explained that their 'cursory' review of patents assigned to 25 leading universities suggested that other grantees seemed to have omitted government support.[147]

Testifying on behalf of NIH, then Deputy Director for Extramural Research Wendy Baldwin indicated that their systems needed improvement and explained that the agency had just launched a new online invention reporting platform.[148] The new platform later became known as iEdison.[149] During the hearing, Scripps characterized their failures as 'inadvertent' and committed to correcting all patents with missing disclosures.[150] RePORTER data shows that Scripps corrected nearly 40 patents from 1993 to 1995 to declare federal support. The audit, congressional hearing, media coverage,[151] NIH's commitment to increase oversight, and the launch of iEdison likely prompted other grantees to correct additional patents with missing funding acknowledgements.

139 Christopher Anderson, *Scripps Backs Down on Controversial Sandoz Deal*, 260 Science 1872 (1993).

140 *Id.* (citing NIH's legal advisor stating that the agency 'is concerned that the agreement unduly restricts scientific research supported by the government, appears to be contrary to the letter and spirit of the Bayh-Dole Act').

141 *Id.* (citing Scripps' President Richard Lerner stating that the institute intended to 'take out of the agreement anything that NIH finds egregious', and reporting that six controversial provisions were either removed or amended).

142 Gibbs Brown Memorandum, *supra* note 39.

143 *Id.*

144 *Id.*

145 Underreporting Federal Involvement in New Technologies Developed at Scripps Research Institute: Hearing Before the Subcomm. on Regulation, Bus. Opportunities & Tech. of the H. Comm. on Small Bus., 103d Cong. 2 (1994) (Serial No. 103-93, printed by the U.S. Gov't Printing Office).

146 *Id* at 2.

147 *Id* at 7 ('We examined data on 25 universities with the most patents, involving over 4500. We found that only 1818 or 37 percent contained the Government rights clause, and if you recall, Mr Chairman, that is a similar percentage as the 51 that were identified by Scripps initially in April 1993'.).

148 *Id* at 17.

149 Tamsen Valoir, *The Government Purse Has Strings Attached*, Intellectual Property Today, Dec. 2006, at 33, https://www.iptoday.com/pdf/2006/12/Valoir-Dec2006.pdf (accessed May 28, 2025).

150 Underreporting Federal Involvement Hearing, *supra* note 145, at 20.

151 See, eg Teresa Riordan, *Patents: Keeping Track of Federally Aided Technology Is the Subject of a Congressional Hearing Today*, N.Y. Times (July 11, 1994), https://www.nytimes.com/1994/07/11/business/patents-keeping-track-federally-aided-technology-subject-congressional-hearing.html (accessed May 28, 2025).

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The Scripps controversy therefore helps explain the first spike in corrections from 1993 to 1995.

VII.B. GAO and HHS Oversight (1999)

Five years later, the Government Accountability Office (GAO) conducted another audit on Bayh–Dole compliance at the request of Senator Orrin Hatch. Based on a review of 2083 patents issued in 1997, the GAO found that government grantees were 'not complying with provisions on the disclosure, reporting, retention, and licensing of federally sponsored inventions'.[152] The GAO analysis also made reference to a draft report submitted in July 1999 by the HHS Inspector General to NIH, which found that 'compliance with Bayh–Dole requirements remained insufficient'.[153] These additional efforts probably explain the next spike in certificates of corrections around 1999. As with the audit conducted by the HHS Inspector General between 1993 and 1994, inquiries from GAO probably led some grantees to correct patents without acknowledgments of federal support.

VII.C. Changes in Regulations (2016–18)

Amendments to the Bayh–Dole regulations proposed by the National Institute of Standards and Technology (NIST) in 2016[154] and adopted in 2018[155] probably explain a share of the big surge in patent corrections around that period. Previous Bayh–Dole regulations gave federal agencies only 60 days to take ownership of a patent after discovering a failure to comply with reporting requirements.[156] Historically, this short timeframe served as a critical legal barrier preventing federal agencies from taking patent title.[157] The 2018 amendments extended this window, allowing agencies to take ownership at any time after discovering a gap in invention reporting compliance.

One stated motivation was that failing 'to timely disclose or elect title to a subject invention [. . .] can work to deny the Federal government any rights in the funded

152 GAO, *supra* note 40, at 2.

153 *Id* at 12.

154 Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 81 Fed. Reg. 78,090 (Nov. 7, 2016), https://www.federalregister.gov/d/2016-25325 ('Remove the 60-day agency time limitation after learning that a contractor has failed to disclose an invention or elect rights, in § 401.14(a)(d)(1), in order to improve due diligence and enhance the ability of agencies to work with contractors') (accessed May 28, 2025).

155 Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 83 Fed. Reg. 15,954 (April 13, 2018), https://www.federalregister.gov/d/2018-07532 ('A number of comments objected to the proposed revision to § 401.14(d)(1), which would remove the 60-day time limit within which a Federal agency must make written request to a contractor to convey title, after learning of the failure of the contractor to disclose an invention or elect title within the specified times. While NIST appreciates the concerns of commenters, the proposed revision will be maintained in the final rule'.) (accessed May 28, 2025).

156 37 C.F.R. § 401.14 (2024), https://www.ecfr.gov/compare/current/to/2018-04-12/title-37/chapter-IV/part-401/section-401.14 (compare the current regulations with the version before April 13, 2018, which stated that federal agencies 'may only request title within 60 days after learning of the failure of the contractor to disclose or elect within the specified times') (accessed May 28, 2025).

157 See, eg Underreporting Federal Involvement Hearing, *supra* note 145, at 14 (then HHS audit manager Dave Pryal noting that the 60-days deadline to take patent title from Scripps had lapsed and Ron Wyden suggesting that 'basically, the only thing that spares Scripps in this situation is that the federal government let the statute of limitations run out').

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invention, through no fault of the funding agency'.[158] It therefore appears that a key concern was discouraging failures that deprive agencies from securing *any* rights in federally supported inventions because grantees neither elected title nor reported the invention to funders within the required timeframe. By extending the window to request title, however, this amendment also signaled that agencies may have greater interest in enforcing reporting obligations even when grantees secured patent rights.

Although the new regulations generally apply to inventions governed by contracts or grants awarded after May 2018, federal agencies have discretion to prospectively require the new procedures on amended agreements.[159] Moreover, after the new regulations were adopted NIH held a series of workshops to discuss the amendments and encourage grantees to comply with Bayh–Dole invention reporting requirements.[160] During these workshops, NIH staff highlighted the possibility of correcting failures to disclose retroactively and apparently encouraged grantees to seek corrections even on expired patents.[161] Some universities that attended these workshops reportedly audited their entire patent portfolios and subsequently requested multiple certificates of corrections in batches.[162] One possible motivation for making corrections in bulk could have been demonstrating good faith, a tactic to persuade NIH staff against requesting patent ownership at any time after detecting a failure to report a subject invention as the new regulations now allow.

VII.D. Civil Society Advocacy (2017–21)

Advocacy efforts led by civil society organization Knowledge Ecology International (KEI) have driven additional certificates of corrections. Since 2017, researchers at KEI have documented and alerted agencies about dozens of patents linked to federal funding but without government interest statements.[163] These include patents

158 83 Fed. Reg. 15,954 (April 13, 2018).

159 83 Fed. Reg. 15,954 (April 13, 2018) (stating that 'if such existing funding agreement is thereafter amended, the funding agency may, in its discretion, make the amended funding agreement subject to the rule prospectively').

160 Eg NIH Office of Extramural Research, An In-Depth Look at Bayh-Dole and Reporting Requirements, 2018 NIH Regional Seminar on Program Funding and Grants Administration, iEdison Workshop (2018) http://ott.gmu.edu/wp-content/uploads/2019/03/IP_Workshop-An_In-Depth_Look_at_Bayh-Dole_For-OTT-Website.pdf (accessed May 28, 2025).

161 Eg NIH Funding, 2020 NIH Virtual Seminar on Program Funding and Grants Administration, YouTube (Nov. 10, 2020), https://youtu.be/l33SwBAzFRI?si=ILMN2-HMh75GNHuM&t=1582, at 26:25 (workshop slide indicating that the USPTO Electronic Patent Assignment System (EPAS) 'allows grantees to correct a government support clause statement free of charge to their organization/institute' and 'can be used for previously waived records, abandoned non provisional patent applications, and expired issued patents') (accessed May 28, 2025).

162 Oregon Health & Science University, Press statement distributed by email to journalists in response to reports indicating that the university failed to include a government interest statement in a patent related to Gleevec for nearly two decades (17 October 2019) (on file with author) (stating that '[i]n April of 2018 the National Institutes of Standards and Technology gave notice that final revisions to federal regulations for formatting "standard clauses" indicating federal funding support in patent filings would become effective in May of 2018. The government offered training on the new format in late 2018, and in 2019 Oregon Health & Science University (OHSU) began the process of reviewing its entire intellectual property portfolio for correction and filing updates. Updating the Gleevec patent to give notice of funding from the NIH was one of many patents updated in this process'.).

163 Failures to Disclose U.S. Government Bayh-Dole Rights in Patents, *Knowledge Ecology International* https://www.keionline.org/bayh-dole/failure-to-disclose (accessed Apr. 22, 2025)

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assigned to Moderna,[164] Regeneron,[165] University of Pennsylvania,[166] and University of Pittsburgh,[167] among others. In response to complaints made by KEI, some funders have initiated investigations into these apparent failures. Notably, in 2020, DARPA announced an investigation on patents assigned to Moderna after KEI alerted the agency of apparent failures to comply with invention reporting requirements.[168] The allegations made by KEI received considerable media coverage[169] and drew criticism from elected officials, including Senator Chris Van Hollen.[170] Three months after DARPA announced the investigation, one of the patents KEI researchers had previously identified was corrected to declare federal funding.[171]

Complaints made by KEI have probably motivated other certificates of corrections since 2017. University of Pennsylvania (79) and University of Pittsburgh (28) are among the academic institutions with the most corrections made during the 2017–21 period. Other institutions with a high number of corrections issued from 2017 to 2021 include Johns Hopkins University (115), Dana-Farber Cancer Institute (42), and Washington University (35). As Figure 5 shows, the number of corrections made by the University of Pennsylvania and the University of Pittsburgh spiked in 2019. These two universities had made only a handful of corrections on RePORTER patents before 2019. Various months prior to their respective spikes in corrections, KEI alerted NIH of apparent failures to disclose federal funding in patents assigned to each of these universities.[172]

If the NIH receives a complaint from 'third parties' about apparent failures to disclose, the agency 'contacts' the president of that university.[173] NIH typically does not publish information about its discussions with university leadership in connection with these allegations. Therefore, the exact scope of those discussions, the potential remedial action that NIH invokes, and the outcomes of these engagements between government officials and university leadership are unknown. Yet, it seems plausible

164 Luis Gil Abinader, 2020:3 KEI Research Note: Moderna Failures to Disclose DARPA Funding in Patented Inventions, KEI Research Note RN-2020:3 (Aug. 27, 2020), https://www.keionline.org/rn-2020-3 (accessed Aug. 5, 2024).

165 Luis Gil Abinader, KEI Research Note 2020:4, Regeneron Failed to Disclose BARDA Funding in Their REGN-COV2 Patent, KEI (Oct. 20, 2020), https://www.keionline.org/rn-2020-4 (accessed Aug. 5, 2024).

166 Claire Cassedy, University of Pittsburgh Failure to Disclose Federal Funding for Patents on Vizamyl, KEI (May 18, 2018), https://www.keionline.org/27691 (accessed Aug. 5, 2024).

167 *Id.*

168 Donato Paolo Mancini, *US Government's Darpa Probes Moderna's Vaccine Patents: Researchers Accuse Biotech Company of Failing to Disclose Federal Grants in Patents Which Also Cover Covid-19 Candidate*, Fin. Times (Aug. 29, 2020), https://www.ft.com/content/2be1f87e-9e96-4e23-9cc5-33ba35e50586.

169 Eg Christopher Rowland, *Moderna Failed to Disclose Federal Support in Vaccine Patents, Researchers Say*, Wash. Post (Aug. 28, 2020), https://www.washingtonpost.com/health/2020/08/28/moderna-vaccine-patents-government-support/ (accessed May 28, 2025).

170 Van Hollen, *supra* note 48.

171 Love & Cassedy, *supra* note 50.

172 Failures to Disclose U.S. Government Bayh-Dole Rights in Patents, *Knowledge Ecology Int'l*, *supra* note 163 (describing several complaints filed by KEI with NIH concerning patents assigned to the University of Pennsylvania, beginning in October 2017 and a May 2018 complaint regarding patents assigned to the University of Pittsburgh) .

173 NIH Funding, *supra* note 161, at 3:35 (explaining that, 'on occasions, a third party' has contacted the NIH 'concerning the lack of compliance from an NIH grantee' and 'in those cases, the NIH will contact either the president of the university or the CEO of the small business and discuss non-compliance issues').

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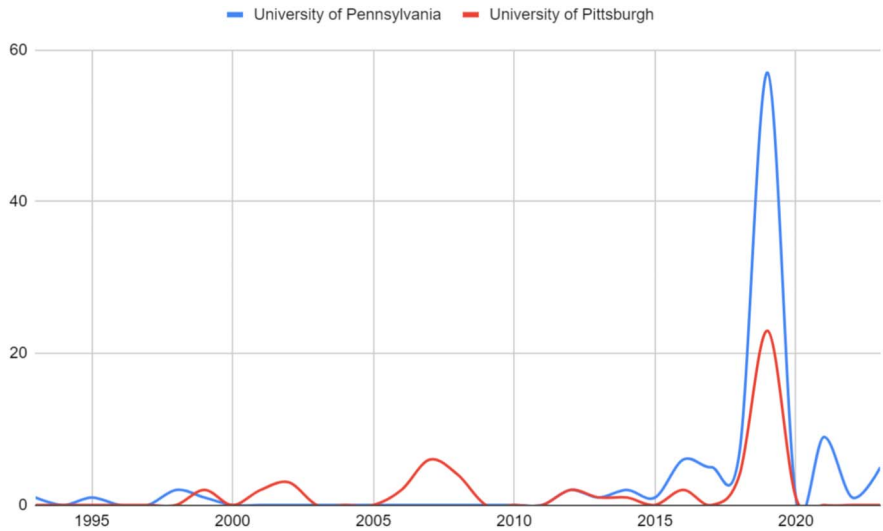


Figure 5. Total number of certificates of corrections made on RePORTER patents assigned to the University of Pennsylvania and the University of Pittsburgh, by year issued.

that at least some of the advocacy efforts led by KEI have resulted in institution-wide initiatives to increase compliance with Bayh–Dole reporting requirements beyond the specific patents identified by the civil society group.[174] This could explain why two universities at the center of failure to disclose complaints made by KEI began to correct dozens of patents in bulk a few months after the advocacy group alerted NIH about those apparent invention reporting gaps.

VIII. RETHINKING ENFORCEMENT OF THE BAYH–DOLE INVENTION REPORTING REQUIREMENTS

Compliance with Bayh–Dole invention reporting requirements by NIH grantees appears to be increasing. This study provides evidence indicating that in recent years, a larger share of patents supported with NIH extramural awards have timely embedded government interest statements in their specifications and the USPTO has issued an increasing number of corrections that address previous omissions. High-profile controversies, civil society advocacy, and changes in the Bayh–Dole regulations seem to have driven a significant number of corrections. Yet, these corrections have on average been made three years after patent issuance and in some cases over a decade after the application date. Some of the patents with long correction lags cover biomedical products and have been asserted in court against alleged infringers. These delays indicate that the NIH is likely unaware of many federally funded inventions for several years after they are patented, including some in the higher end of the value spectrum. This may prevent NIH from taking time-sensitive decisions, especially at the early stages of patent prosecution. Even when a correction is made, funding disclosures are

174 Rai & Sampat, *supra* note 6 (generally making a similar point, indicating that '[u]niversities that knew compliance was going to be monitored, not only by funding agencies but also by third-party firms, academics and public-interest groups would presumably be motivated to improve compliance').

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attached as image files to the patent document. Reviewing these files is an onerous task, which undermines the value of federal funding disclosures for users of patent data.

Future policy efforts could focus on incentivizing timely compliance and increasing the visibility of disclosures made late through certificates of corrections. This section discusses six measures that could help promote these two complementary policy objectives. One of these proposals would require Congress to enact new legislation. The remaining policy options could be implemented using existing legal authority. Although these policy recommendations are focused on reporting by NIH grantees, most of these measures are relevant and could be implemented by other agencies.

VIII.A. Actively Monitor Compliance

The NIH largely relies on information voluntarily reported by grantees to monitor compliance with Bayh–Dole funding acknowledgement requirements.[175] Audits to assess compliance appear to be rare and motivated by high-profile controversies like in the Scripps case. Although NIH sometimes contacts university leadership when it receives allegations from third parties about apparent failures to acknowledge federal funding in specific patents, these complaints likely only cover a small share of all omissions. Without active monitoring by NIH, many failures to acknowledge government support in patents probably go unnoticed for several years or are never corrected.

After detecting dozens of failures to acknowledge federal support by Scripps, then HHS Inspector General June Gibbs Brown recommended NIH to 'maintain information on patents awarded by the USPTO' to monitor compliance.[176] One approach that Gibbs Brown recommended was to 'review the USPTO patents of selected grantees and investigate those that show an unreasonably low percentage of their patents were developed with government funds'.[177] Then Assistant Secretary for Health Philip Randolph Lee disagreed with that recommendation arguing that actively monitoring patents assigned to grantees would be too much work for the NIH. Lee indicated that cross validating patents using USPTO data to identify failures to declare federal funding 'would result in an enormous burden that we believe would show little gain in compliance'.[178] In rejecting this recommendation, Philip Lee possibly underestimated

175 Gibbs Brown Memorandum, *supra* note 39, at 9 (stating that if a grantee does not disclose an invention or patent, 'NIH will have no way of determining grantee compliance with reporting requirements of the Act'); Underreporting Federal Involvement Hearing, *supra* note 145, at 2 (Representative Ron Wyden stating that invention reporting functions 'according to a voluntary honor code' and disclosure of federal funding 'appears to be entirely discretionary').

176 *Id.*

177 *Id.* ('We believe NIH should maintain information on patents awarded by the USPTO. The NIH could investigate those grantees which, based on a review of the data from the USPTO, appear to be underreporting inventions to NIH. For example, NIH might review the USPTO patents of selected grantees and investigate those that show an unreasonably low percentage of their patents were developed with Government funds'.).

178 Letter from Assistant Secretary for Health Philip R. Lee to the Inspector General about the draft report *Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute*. May 24, 1994. https://oig.hhs.gov/documents/audit/3302/A-15-93-00029-Complete%20Report.pdf, at 3 (arguing that implementing a 'cross-walk between data elements in the patent and in NIH databases' followed by 'a determination by NIH program staff that a close enough fit exists to suggest that the patent may have been developed under NIH support' would result in an 'enormous burden that we believe would show little gain in compliance') (accessed May 28, 2025).

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the value of timely federal funding disclosures for the NIH and the public as discussed in Section I. However, the assessment that actively monitoring USPTO patent databases to detect reporting gaps would have constituted an 'enormous burden' using the data tools available in 1994 was probably correct.

Thirty years later, digitalized patent information and modern data science techniques can now be leveraged by NIH to actively monitor compliance without incurring an 'enormous burden'. The agency already has extensive data on patents that include government interest statements in their specifications and details about the grants that led to those inventions. The NIH could use these data to 'train' an algorithm that computes textual similarity by feeding it information on patent and grant pairs already in the agency's internal records.[179] The NIH could also use additional data sources to train that algorithm, like academic papers acknowledging NIH grants. Linking with USPTO data, the NIH could then use this algorithm to identify published applications and patents without government interest clauses but textually similar to grant descriptions or papers in their internal records. Whenever an application or patent without government interest statements shows a probabilistic match with NIH grants or papers, the agency should begin a consultation with the corresponding grantees to determine whether those inventions fall under Bayh–Dole reporting obligations.

Closer monitoring is especially important for valuable patents, because the potential benefits of detecting failures could justify the higher oversight costs. Relatively greater oversight could be achieved either through modern data science techniques alone or in combination with manual reviews of sources such as the Orange Book and court disputes. Daily Orange Book updates are available online. The NIH could also track public repositories of patents with term extensions,[180] which often relate to drugs and medical devices. Tracking litigation data may require more effort. The USPTO collects data on litigated patents and releases new reports approximately every four years. As a first phase, the NIH could request early releases of patent litigation reports done by the USPTO. In the medium term, the NIH could create their own litigation observatory to detect possible failures to acknowledge government funding and other important trends among federally supported patents.

VIII.B. Make Corrections Text Searchable

Government interest statements that are properly embedded in the patent specifications are text searchable using USPTO databases. This helps users of patent data quickly identify inventions developed with federal support. In contrast, the USPTO publishes certificates of corrections as image files attached to the end of patent documents. These images are not text searchable, making patents with late acknowledgements of federal support difficult to find using available USPTO databases. Those corrections are therefore 'invisible' for many of the intended users of this patent data.[181]

179 For a similar proposal, *see* Bhaven Sampat, *Linking Drugs to Government Funding: An Idea*, https://www.youtube.com/watch?v=hGWuRABB5IM&ab_channel=KEIWashDC, YouTube (Oct. 7, 2020) (accessed May 28, 2025).

180 *See,* eg United States Patent and Trademark Office, Applications for Patent Term Extension and Patent Terms Extended Under 35 U.S.C. § 156, https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156 (accessed May 28, 2025).

181 Durvasula, Ouellette & Williams, *supra* note 54, at 344.

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Working with the NIH and other agencies, the USPTO can address this gap retroactively. One approach the USPTO could take is to 'train' a textual similarity algorithm using a large dataset of certificates of corrections that acknowledge government support. The NIH can help the USPTO identify a large dataset of those certificates from patents listed in RePORTER but without government interest statements in their specifications, like this study and others have previously done. Other federal agencies could also provide data about certificates of corrections based on patents corrected by their own grantees. The USPTO can then use the textual similarity algorithm to scan all certificates of corrections in their archives and identify which of them specifically declare government support.[182] Once identified, the USPTO should then make these certificates text searchable in existing patent databases.

Moving forward, the USPTO should incorporate certificates of corrections with government interest statements immediately into their text-searchable indexes. This will require USPTO data systems to easily discern between requests for corrections that declare government support from requests that seek to address other errors. A textual similarity algorithm could again help the USPTO perform this task. Another approach the USPTO can take is requiring patentees to use a separate form when requesting corrections, specifically to declare federal support, as explained in detail below. The use of that specific form would notify the USPTO data systems that the corresponding certificate of correction contains a government interest statement that needs to be made text searchable.

VIII.C. Create Separate Correction Procedures

Although 35 U.S.C. § 255 allows corrections only for mistakes that 'occurred in good faith,'[183] the USPTO tends to correct failures to disclose federal funding without inquiring into the root causes. Allowing patentees to declare federal support late serves the Bayh–Dole policy objectives better than denying requests for certificates of correction. However, permitting patentees to easily correct existing omissions also decreases the incentives to diligently avoid errors during patent prosecution. The latter supports the adoption of a stricter enforcement of the requirements in 35 U.S.C. § 255. The challenging question is whether and how the USPTO can implement stricter enforcement of the requirements in 35 U.S.C. § 255 while preserving Bayh–Dole policy objectives.

Requiring patentees to use a separate USPTO form for requesting a certificate of correction, specifically involving failures to declare government support, could help implement stricter enforcement of the requirements in 35 U.S.C. § 255 while preserving Bayh–Dole objectives. Using a special 'late government interest statement' form would have two main policy goals. First, with the use of a late government interest statement form, the USPTO will be able to immediately identify patents that are newly declaring federal support. Quickly identifying these patents will help the USPTO's data systems immediately flag to public users that an applicant made a late federal funding acknowledgment. This event could be made text searchable in public USPTO databases immediately after the patentee files the special form. The USPTO could also consider

182 Sampat, *supra* note 52, at 18 (recommending a similar solution, suggesting that the USPTO or other federal agencies could 'OCR the CoC and extract any missing government interest statements').

183 35 U.S.C. 255.

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adding a copy of the special form to the patent image file, indicating that the correction request is still pending. Unlike other types of corrections that may illegally expand the scope of patent descriptions and claims, adding a statement to the image file while the form is still being processed by the USPTO is unlikely to draw disputes from third parties that would benefit from quicker transparency.

Late government interest statement forms would also allow the USPTO to inquire about failures to declare federal funding during patent prosecution, which would be consistent with 35 U.S.C. § 255. The USPTO could use this form to ask patentees a small set of questions about the 'good-faith' nature of their omissions. This inquiry could be based on predetermined and open-ended questions. The USPTO could work with NIH and other agencies to design this form. Since the completed form would be entered on the patent transactions record, answers would be available for public scrutiny. Examples of specific questions that the USPTO could ask patentees include when and how they learned about missing government support acknowledgments. The USPTO could also ask patentees to attest whether other federal agencies or a third party alerted them about the lack of a government interest statement, and when they first received notice of that omission. Long lags between the dates when a patentee received notice of an apparent failure to declare government support and their request for correction could lead to further inquiries by the USPTO or referrals to the corresponding funding agencies. The USPTO could automatize portions of this procedure, for instance, by requesting further information only for correction requests that show long delays.

Further inquiries or referrals to funding agencies could delay correction requests. Delaying corrections would not necessarily undermine the Bayh–Dole policy objectives, however. If the USPTO makes requests searchable immediately after they are filed, users of public patent data will be able to identify federally supported inventions while corrections are pending. Once a grantee formally requests a certificate of correction at the USPTO, uncertainties about government funding would dissipate because the form acknowledging federal support would be available for public scrutiny.

VIII.D. Increase Transparency around Enforcement

NIH has declined to take ownership of inventions in various failures to disclose cases documented by KEI researchers. However, some KEI complaints have led to late acknowledgments via corrections. It seems that some of those corrections have been motivated by engagements from NIH staff directly with university leadership. Moreover, some grantees have stated that iEdison prompted them to declare government funding in their patents and this motivated them to seek certificates of corrections. In these cases, the risk of losing NIH funding or challenges in renewing existing federal awards may have been a key motivation for correcting failures. This interpretation is consistent with NIH statements suggesting that compliance is lower among former grantees with expired awards.[184] Nevertheless, the extent to which NIH threatens

184 Nat'l Inst. of Health, *Frequently Asked Questions*, https://report.nih.gov/faqs (accessed Aug. 10, 2024). ('Not all recipients of NIH funding are compliant with the iEdison reporting requirements, particularly after their NIH support has ended').

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grantees with terminating funding, taking patent ownership, or using other remedies to force compliance remains unclear.

Greater transparency around NIH's enforcement actions is needed to better understand what drives grantees to correct federally funded patents. Particularly, NIH should explain: (1) what remedies the agency typically invokes in their discussions with university leadership; (2) what reasons grantees cite to explain their failures to acknowledge federal funding and what commitments each institution has made to ensure compliance with Bayh–Dole requirements; (3) whether NIH has ever taken ownership of an invention from a grantee under failure to disclose grounds and which specific patents have been involved; and (4) how frequently the agency suspends or terminates grants under failure to disclose grounds and which patents have triggered this remedial action.

A better understanding of the enforcement actions NIH takes, and their outcomes, will inform policy debates about which remedies federal agencies should exercise to promote compliance with Bayh–Dole reporting requirements. For instance, the threat of losing NIH funding may be enough incentive to correct relatively unimportant patents. However, the threat of losing NIH funding might be insufficient to deter strategic behavior around patents linked to profitable biomedical products. Similarly, terminating funding may become a less effective remedy once the relevant NIH award is about to expire or has already ended. Evidence suggesting that the threat of losing NIH funding is insufficient to induce corrections over profitable patents or that strategic behavior increases near the end of relevant awards, when the impact of terminating a grant may be lower, could serve to justify the greater use of stricter remedies. Greater transparency around how the NIH enforces reporting requirements could provide insights to explore these questions further and inform discussions about what types of remedies agencies should invoke to promote compliance.

VIII.E. Take Ownership of Patents as a Remedy

Amendments to Bayh–Dole regulations proposed by the NIST in 2016 and adopted in 2018 addressed a key legal barrier for harsher enforcement actions. Agencies can now request transfer of patent ownership at any time after detecting a failure to disclose, replacing the previous 60-day window. The greater risks that this extended timeframe represents possibly motivated many recent patent corrections and may be helping increase timely compliance with reporting requirements.

Despite these legal changes, however, the NIH's historical preference for working with grantees over taking ownership does not seem to have shifted. Based on recent public remarks, the NIH policy consists of giving various opportunities to cure failures and taking ownership only as a last resort when grantees refuse to collaborate. Consistent with this, the review of a large sample of patent assignments described in Section VI of this study did not find a recorded NIH decision to take ownership specifically motivated by a failure to timely acknowledge federal government support.

Working with grantees to cure failures may sometimes serve the public interest better than taking patent ownership. But if NIH never requests ownership as a remedy, regardless of facts in each case, in practice, grantees could avoid loss of rights simply

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by making corrections once the agency detects a failure to declare funding. Over time, reluctance to take ownership could undermine the credibility of the legal risks and incentives to comply created by the new Bayh–Dole regulations.

Historical preferences for correcting failures over taking ownership have probably created status quo bias at NIH and other federal agencies. Departing from long-standing government practices is generally difficult, and this may be an important challenge that federal officials considering taking ownership of a patent under failure to disclose grounds probably face. Because the use of this remedy has been uncommon, there are probably limited precedents, guidelines, and institutional experiences that government officials can rely upon to decide whether a particular grantee should lose ownership of patents that fail to declare federal funding. Absent a consistent and transparent framework, federal government officials may be incentivized to maintain current practices.

The NIH could therefore benefit from adopting an enforcement policy describing how the agency will address failures to disclose. This policy would clearly describe the circumstances under which the agency will take ownership of patents that failed to comply with Bayh–Dole invention reporting requirements. Expressed willingness to cure a failure or even the issuance of a certificate of correction should be insufficient to avoid the loss of title. Some factors that the NIH could weigh in favor of taking title can include: the (1) amount of government funding awarded over time; (2) precedents of failures to disclose at that institution and institutional measures previously adopted to ensure compliance; (3) information provided to the USPTO when requesting certificates of corrections; (4) profits generated from royalties and other licensing payments; (5) evidence indicating that the awardees violated other NIH policies, such as preference for the nonexclusive licensing of patents claiming research tools; and (6) assertion of patents against alleged infringers.

Weighing these and other factors can help the NIH determine when to take patent ownership from grantees that failed to comply with Bayh–Dole reporting requirements. The NIH would still retain discretion to decide whether to take ownership of specific patents, but the enforcement policy should be transparent and based on a framework consistent with the Bayh–Dole public interest safeguards. Regardless of other circumstances, however, taking patent ownership should be the default remedy when the NIH finds evidence of intentional conduct to conceal government funding.

VIII.F. Enact a Private Right of Action

Courts have found that the federal government must take affirmative action to take the title of inventions that fail to comply with reporting requirements.[185] Defendants in patent infringement cases or third parties can informally provide the government with evidence of apparent failures, but do not have rights to trigger a formal investigation, compel agencies to join ongoing litigation, nor force a final determination on whether taking ownership is appropriate. Even if an agency investigates an apparent failure, they

185 Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Sols., P.C., 482 F.3d 1347, 1353 (Fed. Cir. 2007) (stating that '[t]he government must take an affirmative action to establish its title and invoke forfeiture. The defendants here have no basis to challenge the government's discretion in not invoking forfeiture').

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have exclusive discretion to decide whether taking patent ownership is appropriate.[186] Given the ongoing lack of transparency around enforcement actions, it is unclear how long agencies take to address informal third-party complaints about failures to disclose or how thoroughly they corroborate the evidence received. Reluctance from federal agencies to take title or thoroughly investigate informal complaints about apparent failures may leave defendants in patent infringement cases and the public more generally unprotected from a lack of compliance with Bayh–Dole reporting requirements, through no fault of their own.[187]

Congress can help close this gap. In 2019, Senators Chris Van Hollen and Rick Scott introduced a bipartisan bill called the 'We PAID Act'[188] proposing policies to ' ensure that the prices of drugs developed using federally funded research [] are set at reasonable levels'.[189] Most relevantly for this analysis, the We PAID Act proposed two new procedures for canceling patents that failed to declare government support. One of the proposed pathways was bringing an action in a district court by a party that suffered an 'injury' from the failure to declare federal funding, which could be a private entity according to the proposed We PAID Act. It appears that the primary purpose of this proposal was allowing defendants in patent infringement lawsuits to bring an action against plaintiffs. Another pathway Van Hollen and Scott proposed was bringing a request to cancel as unpatentable through an Inter Partes Review (IPR) proceeding. The aim with this second option seems to have been to allow any person other than the patent holder to bring an IPR action.

Advocacy efforts by the KEI have driven additional corrections in recent years. However, current laws do not provide advocacy organizations or individuals with a formal pathway to lodge petitions over alleged failures to comply with invention reporting requirements.[190] Defendants in patent infringement cases do not have a formal avenue either. Enabling third parties to trigger formal proceedings with possible consequential remedies could help increase Bayh–Dole compliance. The two pathways proposed in the We PAID Act therefore seem worth further consideration.

IX. CONCLUSION

Compliance with Bayh–Dole invention reporting requirements appears to be increasing. but over 3000 patents have declared federal funding late through certificates of

186 Fenner Invs., Ltd v. Hewlett-Packard Co., No. 6:08-CV-273, 2010 WL 3275758, at 5 (E.D. Tex. Apr. 15, 2010).

187 Importantly, defendants in an infringement lawsuit and the public more generally would still be able to trigger march-in proceedings when any of the conditions in the Bayh–Dole Act are met, even on patents that lack government interest statements. However, a failure to disclose will likely increase the complexity of those proceedings.

188 The We Protect American Investment in Drugs (PAID) Act, S. 2387, 116th Cong. (2019).

189 Press Release, U.S. Senator Chris Van Hollen, Van Hollen, Scott Introduce Landmark Legislation to Address Skyrocketing Prescription Drug Costs (July 31, 2019), https://www.vanhollen.senate.gov/news/press-releases/van-hollen-scott-introduce-landmark-legislation-to-address-skyrocketing-prescription-drug-costs (accessed Aug. 5, 2024).

190 In fact, some apparent failures to disclose federal funding in patents identified by KEI researchers seem to have resulted in 'no action at all' from US government agencies. Love & Cassedy, *supra* note 50, at 4 ('In some cases the funding agency was able to persuade a company or university to file a correction with the U.S. patent office disclosing federal funding of the invention, and in other cases the agency took no action at all').

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corrections. This includes important patents covering drug products involved in court litigation. Policy efforts to ensure timely compliance and increase the visibility of late acknowledgments are thus warranted. While this analysis has focused on acknowledgments by NIH grantees, the recommendations may be relevant for other federal agencies too. Further research could focus on exploring which remedies the NIH has used against grantees that fail to disclose government funding in patents and how often.

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