No. 09-1159

In the Supreme Court of the United States

BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, PETITIONER

v.

ROCHE MOLECULAR SYSTEMS, INC., ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER

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QUESTION PRESENTED

The University and Small Business Patent Procedures Act of 1980, 35 U.S.C. 200 *et seq.*, commonly known as the Bayh-Dole Act, establishes a framework for determining ownership interests in federally funded inventions. Under the Act, college and university, nonprofit, and small business federal contractors may "elect to retain title" to any invention conceived or reduced to practice in their performance of federally funded research. 35 U.S.C. 202(a). "If [the] contractor does not elect to retain title" to such an invention, the federal government may grant the inventor rights in the invention. 35 U.S.C. 202(d). The question presented is as follows:

Whether an inventor who is employed by a contractor that elects to retain rights in an invention may defeat the contractor's right to retain title under the Bayh-Dole Act by contractually assigning his putative rights in the invention to a third party.

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INTEREST OF THE UNITED STATES

This case concerns the disposition of rights in federally funded inventions under the University and Small Business Patent Procedures Act of 1980, 35 U.S.C. 200 *et seq.*, commonly known as the Bayh-Dole Act. The United States spends billions of dollars per year on science and technology research at colleges and universities, other nonprofit organizations, and small businesses, and it therefore has a substantial interest in the resolution of this case. At the invitation of the Court, the United States filed a brief as amicus curiae at the petition stage of this case.

STATEMENT

1. The United States has long supported scientific and technological research by providing monetary grants to colleges and universities, other nonprofit organizations, and small businesses. Since 1980, the ownership of inventions resulting from that research has been governed by the University and Small Business Patent Procedures Act of 1980, 35 U.S.C. 200 *et seq.*, commonly known as the Bayh-Dole Act.

The Act establishes a comprehensive framework for the disposition of rights in federally funded inventions, specifically defining the rights of the research institutions, individual researchers, and the United States. Because the balance of interests set out in the Act is best understood in light of the history of ownership of federally funded inventions, this brief first sets out that history and then describes the provisions of the Act at issue here.

2. Before 1980, no uniform source of law governed ownership of inventions that resulted from federally funded research. Instead, a "melange of 26 different agency policies" determined who would own such inventions. H.R. Rep. No. 1307, 96th Cong., 2d Sess. Pt. 1, at 3 (1980) (*House Report*). Over time, two main approaches emerged: a "title" approach, under which title to a federally funded invention vested in the federal government by statute; and a "license" approach, under which the government allowed the recipient of federal funds to retain primary ownership rights in an invention, on the condition that it grant the government a license to use the invention.

For some federal agencies, statutes provided that title to patents on federally funded inventions automatically vested in the federal government unless the agency waived its rights. See, *e.g.*, 42 U.S.C. 2182, 5908(a) (1976) (Department of Energy); 42 U.S.C. 2457(a) (1976) (National Aeronautics and Space Administration). By vesting title in the United States, those statutes superseded the inventor's common-law rights in his invention and his statutory patent rights. See *Arachnid, Inc.* v. *Merit Indus., Inc.*, 939 F.2d 1574, 1578 (Fed. Cir. 1991) (describing inventor's common-law and statutory rights). An inventor working on a federally funded project subject to those statutes therefore was not free to assign rights in his invention to third parties. Such an inventor had "no right to assign" because "when the invention was conceived by [the inventor], title to that invention immediately vested in the United States" by "operation of law." *FilmTec Corp.* v. *Hydranautics*, 982 F.2d 1546, 1550, 1553-1554 (Fed. Cir. 1992), cert. denied, 510 U.S. 824 (1993).

In contrast to agencies operating under vesting statutes, other agencies addressed ownership of patents for federally funded inventions by entering into agreements with individual research institutions that allowed those institutions to retain rights in such inventions. The National Science Foundation (NSF) and the Department of Health, Education and Welfare (HEW), for example, operated under Institutional Patent Agreement (IPA) programs adopted in the 1960s and 1970s. See David C. Mowery et al., *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act in the United States* 45 (2004). IPAs gave universities and nonprofit organizations with established technology-transfer programs a first option to own federally funded inventions. See S. Rep. No. 480, 96th Cong., 1st Sess. 21 (1979) (*Senate Report*). In return, those institutions typically were required to report the invention to the government, grant the government a royalty-free license, refrain from charging excessive royalties to other licensees, use royalty income for the support of education or research, refrain from assigning rights except in limited circumstances, and take effective steps to commercialize the inventions. See, *e.g.*, Federal Council for Sci. & Tech., *Report on Government Patent Policy* 330-339 (HEW IPA), 340-353 (NSF IPA) (1976) (*Patent Policy Report*).

Experience with the vesting statutes and the IPA programs revealed that both had shortcomings. Under the vesting statutes, the government often lacked the resources to develop and commercialize patent rights obtained through federally funded research. Gov't Accountability Office, GAO-09-742, *Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions* 2 (2009) (*GAO Report*); *House Report* 1-2. As a result, only about five percent of federally funded inventions were being marketed commercially at the time the Bayh-Dole Act was enacted. See 126 Cong. Rec. 8739 (1980) (statement of Sen. Dole); *GAO Report* 2.

IPAs had a different but equally significant deficiency. The statutes governing several agencies, such as the NSF, prohibited the agencies from entering into contracts "inconsistent with any provision of law affecting the issuance or use of patents." 42 U.S.C. 1871(a) (1976). As a result, IPAs could not allocate ownership rights in federally funded inventions by their own force, but instead depended upon the university or nonprofit organization obtaining an assignment of rights from the researcher. See, *e.g.*, *Patent Policy Report* 330-331, 342. An institution's failure to obtain an effective assignment of rights from the researcher thus could compromise the allocation of rights and obligations under the IPA. See, *e.g.*, *Government Patent Policy Act of 1980: Hearing on H.R. 5715 Before the Subcomm. on Science, Research and Technology of the H. Comm. on Science and Technology*, 96th Cong., 2d Sess. 80 (1980).

3. Congress enacted the Bayh-Dole Act to address those shortcomings. The Act establishes a uniform framework for the disposition of rights in federally funded inventions. That framework was designed to "use the patent system to promote the utilization of inventions arising from federally supported research or development," while "ensur[ing] that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions." 35 U.S.C. 200. Congress sought to balance the interests of the research institution, the government, and the inventor in a manner that would best "promote collaboration between commercial concerns and nonprofit organizations, including universities," and that would encourage "future research and discovery." *Ibid.*

The Act prescribes rights in "subject invention[s]," which are defined as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement" between a contractor and a federal agency. 35 U.S.C. 201(e). A "contractor" is a "person, small business firm, or nonprofit organization that is a party to a funding agreement." 35 U.S.C. 201(c). The term "funding agreement" is broadly defined as "any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government." 35 U.S.C. 201(b).

The Act creates a presumption that title to federally funded inventions will vest in the contractor, as opposed to the government or the inventor. That presumption is set out in the section of the Act titled "Disposition of rights," which states that a contractor may "elect to retain title to any subject invention." 35 U.S.C. 202(a). To exercise title, the contractor must "disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters." 35 U.S.C. 202(c)(1). The Act then requires the contractor to elect to retain title to the invention "within a reasonable time after disclosure," 35 U.S.C. 202(a), defined as "two years * * * or such additional time as may be approved by the Federal agency," 35 U.S.C. 202(c)(2), and to file timely patent applications for the invention, 35 U.S.C. 202(c)(3). The government "may receive title to any subject invention" when the contractor does not timely disclose the invention, elect to retain title, or seek patent protection for the invention. 35 U.S.C. 202(c)(1)-(3).

The contractor's title to a federally funded invention is subject to several additional conditions. If the contractor is a nonprofit organization, it must obtain federal agency approval before assigning rights in a subject invention, 35 U.S.C. 202(c)(7)(A); must "share royalties with the inventor," 35 U.S.C. 202(c)(7)(B); and must utilize the remaining royalties or income to further "scientific research or education," 35 U.S.C. 202(c)(7)(C). The contractor must also ensure that any assignee that is granted the "exclusive right to use or sell any subject invention" agrees that any products made using the subject invention will be "manufactured substantially in the United States," unless the government waives that condition. 35 U.S.C. 204.

Although the Act presumptively vests title in the contractor, the government retains several important rights. The government is entitled to an irrevocable, paid-up license from the contractor to practice a federally funded invention. 35 U.S.C. 202(c)(4). Further, the government may keep title or otherwise restrict a contractor's title when particularly sensitive governmental interests are at stake, such as when a contractor is controlled by a foreign government or the research relates to foreign intelligence, nuclear propulsion, or nuclear weapons programs. 35 U.S.C. 202(a)(i)-(iv). The government also retains "march-in" rights to subject inventions, meaning that it may step in to license the invention in certain circumstances, such as when a contractor fails to take steps to achieve practical application of the invention, or when public health or safety requires it. 35 U.S.C. 203.

If a contractor does not elect to retain title to a subject invention, the federal agency "may consider"—"and after consultation with the contractor grant"—"requests for retention of rights by the inventor." 35 U.S.C. 202(d). The inventor's rights remain "subject to the provisions of this Act and regulations promulgated hereunder." *Ibid.*; see 37 C.F.R. 401.9. Thus, the inventor may receive title to the invention only when the contractor chooses not to retain title (or fails to comply with the applicable statutory prerequisites) and the government affirmatively authorizes the inventor to take title.

By its terms, the Bayh-Dole Act "take[s] precedence over any other Act which would require a disposition of rights in subject inventions of small business firms or nonprofit organizations contractors in a manner that is inconsistent with" the disposition of rights in the Act. 35 U.S.C. 210(a). Thus, unlike the pre-1980 experience with IPAs, when the ability of agencies like the NSF to control the allocation of rights in federally funded inventions was dependent on the contractor's obtaining an assignment of rights from the individual researcher, the Bayh-Dole Act explicitly gives precedence to the Act's own "[d]isposition of rights." 35 U.S.C. 202.

4. This case concerns the ownership of three patents for monitoring the effectiveness of treatments for human immunodeficiency virus (HIV). The patented process was developed by research scientists at the Leland Stanford Junior University (Stanford) using federal funds. One of those scientists, Dr. Mark Holodniy, performed research both at Stanford and at Cetus Corporation (Cetus). Holodniy executed agreements with both Stanford and Cetus regarding rights in his inventions, and a dispute subsequently arose about the ownership of the patents at issue here.

In the early to mid-1980s, Cetus developed polymerase chain reaction (PCR) technology, a technique for making billions of copies of specific sequences of DNA from a small number of starting molecules. Pet. App. 32a. In 1988, Cetus and Stanford began to collaborate on the use of PCR in HIV/AIDS research. *Ibid.* Later that year, Holodniy began to conduct research at Stanford's Center for AIDS Research. *Id.* at 34a-35a. Holodniy signed a "Copyright and Patent Agreement" with Stanford, *id.* at 118a-121a, in which he acknowledged that federal grants and contracts impose obligations on him with respect to federally funded inventions, *id.* at 118a; agreed to provide "a written disclosure" of any invention conceived or reduced to practice under a contract or grant, *id.* at 118a-119a; and "agree[d] to assign or confirm in writing to Stanford * * * that right, title and interest in * * * such inventions," *id.* at 119a.

In February 1989, Holodniy began to make regular visits to Cetus to learn about PCR and to develop a PCR-based test for HIV. Pet. App. 4a. At Cetus, Holodniy signed a "Visitor's Confidentiality Agreement," *id*. at 35a-36a, 122a-124a, in which he "assign[ed] to CETUS, [his] right, title, and interest in" any inventions conceived or reduced to practice "as a consequence of [his] access to CETUS' facilities or information," *id*. at 123a. Holodniy's research with Cetus produced an assay (procedure) for using PCR to measure the amount of HIV nucleic acids in blood samples from people infected with HIV. *Id*. at 5a, 37a. Holodniy published his findings with Cetus co-authors. *Ibid*.

Holodniy then returned to Stanford and conducted clinical studies to determine whether the assay could be used to judge the efficacy of anti-HIV drugs. Pet. App. 5a, 39a. That research demonstrated that PCR can be used to track the HIV RNA in a patient's bloodstream to assess the effectiveness of anti-HIV drugs the patient is taking. *Ibid*. Holodniy published this discovery with several Stanford and Cetus co-authors. *Id*. at 5a, 38a-40a. The research underlying the discovery was funded in part by the federal government through an agreement with Stanford. *Id*. at 5a, 109a, 114a-115a.

Beginning in 1992, Stanford submitted a series of patent applications for this method of monitoring the effectiveness of anti-HIV treatment, which resulted in the issuance of the three patents at issue. Pet. App.

107a-109a. Holodniy and other scientists are named as co-inventors of these patents, and Stanford is identified as the patent assignee. *Id.* at 4a, 125a, 127a, 129a, 131a; see *id.* at 41a (district court explains that Holodniy and other scientists "executed an assignment purporting to convey their interests in" the patents to Stanford and Stanford recorded the assignments with the Patent and Trademark Office). Each patent specified that the "invention was made with Government support" and that "[t]he Government has certain rights in th[e] invention." *Id.* at 5a-6a, 126a, 128a, 132a; see 35 U.S.C. 202(c)(6) (requiring such specifications). Stanford then disclosed the inventions to the federal government and confirmed to the government the grant of irrevocable, paid-up licenses to the inventions. Pet. App. 5a. In 1995, Stanford formally elected to retain title to the inventions under the Bayh-Dole Act. *Id.* at 5a-6a, 115a-116a.

5. Ten years later, petitioner filed suit, alleging that respondents (who had purchased Cetus's PCR business) were marketing HIV detection kits that infringed its patents. Pet. App. 5a-6a, 31a. Respondents counterclaimed, contending, *inter alia*, that they possessed ownership interests in the patents because of Holodniy's agreement with Cetus. *Id.* at 6a-7a, 122a-124a.

The district court rejected respondents' claim of ownership on several grounds. As relevant here, the court held that Holodniy's assignment to Cetus was ineffective to convey an interest in the patents because, under the Bayh-Dole Act, he lacked any such interest to convey. Pet. App. 61a-62a. The court explained that when "the individual inventor is not a contracting party," "the Bayh-Dole Act provides that the individual inventor may obtain title only after the government and the contracting party have declined to do so." *Id.* at 61a (citing 35 U.S.C. 202(d)). Because "Stanford exercised its right and obtained title in the patents" under the Bayh-Dole Act, the court concluded, Holodniy "had no interest to assign to Cetus." *Id.* at 62a.

In a later proceeding, the district court held that the patents were invalid for obviousness. See *Board of Trs. of Leland Stanford Junior Univ.* v. *Roche Molecular Sys., Inc.*, 563 F. Supp. 2d 1016, 1039-1049 (N.D. Cal. 2008). Petitioner appealed that decision, and respondents cross-appealed on the ownership issue. Pet. App. 2a-3a.

6. The court of appeals affirmed in part, vacated in part, and remanded. Pet. App. 1a-28a. As relevant here, the court held that petitioner had obtained no ownership interests in the patents from Holodniy because Holodniy had assigned his patent rights to Cetus, leaving nothing for him to assign to Stanford. *Id.* at 27a-28a. The court regarded the contract between Holodniy and Stanford, in which Holodniy "agree[d] to assign or confirm in writing" any invention he conceived or reduced to practice while at Stanford, as merely a promise to assign his rights "to Stanford at an undetermined time." *Id.* at 13a. By contrast, the court viewed Holodniy's agreement with Cetus—in which Holodniy stated that he "will assign *and do[es] hereby assign* to CETUS" his interest in inventions conceived as a consequence of his access to Cetus facilities and information—as "effect[ing] a present assignment" to Cetus of his future inventions. *Id.* at 14a (emphasis added). The court concluded that "Cetus's legal title vested first" and that Holodniy therefore had no rights to assign to Stanford with respect to the pertinent invention. *Ibid.*

The court of appeals rejected petitioner's contention that the Bayh-Dole Act gave Stanford title to the patents. Pet. App. 18a-21a. In the court's view, the Bayh-Dole Act was relevant only to determine what residual rights Stanford and the government might have after effectuating the assignments in the Holodniy-Stanford and Holodniy-Cetus agreements. *Id.* at 19a-20a; see *id.* at 21a. The court stated that "Stanford was entitled to claim whatever rights were still available after the Government declined to exercise its option [to take title to the patents], including the rights of [Holodniy's co-inventors on the patents]." *Id.* at 19a. But the court determined that Stanford could not claim title to the patents because Holodniy "still possessed rights at the time he signed the [agreement] with Cetus"; he assigned those rights to Cetus in the agreement; and the Act did not "automatically void the patent rights that Cetus received from Holodniy." *Id.* at 19a, 21a.

The court of appeals concluded that petitioner lacked standing to pursue the infringement claim because it did not own Holodniy's interest in the patents and, under Federal Circuit precedent, all co-owners must join as plaintiffs in an infringement suit. Pet. App. 27a. Based on that determination, the court vacated the district court's judgment that the patents were invalid. *Id.* at 27a-28a.

SUMMARY OF ARGUMENT

The Bayh-Dole Act permits a college or university, nonprofit organization, or small business contractor to retain patent rights in an invention conceived of or reduced to practice using federal funds. An individual inventor employed by the contractor may not defeat the contractor's presumptive title by assigning his putative rights to a third party.

A. The Act establishes a comprehensive framework for the "[d]isposition of rights" in federally funded inventions. 35 U.S.C. 202. That framework gives a contractor first priority by allowing it to "elect to retain title" to any subject invention. 35 U.S.C. 202(a). The federal government occupies the next position in the hierarchy: it has the right to a paid-up license and the ability to grant licenses as necessary to ensure commercialization, and it may take title to the invention if the contractor declines to exercise its rights or if important national interests require it. 35 U.S.C. 202(a) and (c)(1)-(4), 203. The inventor has lowest priority: he may retain title only if the contractor forfeits its rights and the government affirmatively authorizes him to retain title. 35 U.S.C. 202(d).

The court of appeals erred in allowing an individual inventor to circumvent through private contract the Bayh-Dole Act's framework for allocating ownership of federally funded inventions. Stanford complied with all of the requirements to obtain title under the Act, yet the court determined that Holodniy had compromised Stanford's rights by assigning ownership of the inventions to Cetus. That was error because Holodniy had no ownership rights in the subject inventions to assign to Cetus. And nothing in the Bayh-Dole Act suggests that a contractor must obtain an assignment of rights from an inventor to retain clear title under the Act.

B. The Act's history confirms that it is intended to grant contractors presumptive ownership of federally funded inventions by operation of law. Before 1980, title to federally funded inventions generally vested in the government by statute or could be retained by contractors by contract. In enacting the Act, Congress chose to allocate primary ownership rights to contractors in order to best encourage commercialization of useful inventions. Both supporters and opponents of the Act understood that it gave first priority to contractors so long as they followed the steps set out in the Act. The legislative history confirms that an individual inventor can obtain (and thus can assign) ownership rights in a federally funded invention only if the contractor declines to exercise its rights under the Act and the government authorizes the inventor to take title.

C. The court of appeals' decision frustrates the Act's important purposes. By allowing an inventor conducting federally funded research to override the Act's allocation of rights, the decision below undermines the uniformity and certainty of title that is necessary for effective commercialization. Moreover, the court of appeals' rule frustrates the government's ability to protect the taxpayers' multi-billion-dollar investments in research and development by allowing an inventor to transfer ownership of an invention to a third party that is not subject to the government's licensing and march-in rights. Finally, the decision below allows an inventor to nullify the provisions of the Act that require royalties to be dedicated to further research and development and products using the invention to be made in the United States, further reducing the Act's intended benefit to the public.

ARGUMENT

AN INDIVIDUAL INVENTOR MAY NOT DEFEAT A CONTRACTOR'S ELECTION OF TITLE UNDER THE BAYH-DOLE ACT BY ASSIGNING HIS PUTATIVE RIGHTS IN AN INVENTION TO A THIRD PARTY

The Bayh-Dole Act establishes a comprehensive framework for allocating rights in federally funded inventions. Under that framework, a contractor has presumptive title to a subject invention so long as the contractor complies with enumerated statutory prerequisites. The court of appeals' decision allows an individual inventor to defeat the contractor's title by assigning rights to a third party outside the framework of the Act. That holding cannot be reconciled with the Act's text, history, and purposes.

A. The Bayh-Dole Act Establishes A Comprehensive Framework For The Disposition Of Rights In Federally Funded Inventions

1. By its plain terms, the Act sets out a framework for the "[d]isposition of rights" in federally funded inventions. 35 U.S.C. 202(a). The Act establishes a statutory hierarchy of rights among contractors, the government, and inventors, and it specifically defines the circumstances under which each may take title to a federally funded invention.

First priority in this statutory scheme belongs to the contractor. The Act states that a contractor "may * * * elect to retain title to any subject invention." 35 U.S.C. 202(a). That statement—the first allocation of rights contained in the Act—makes clear that title to a subject invention presumptively vests in the research institution where the invention was developed using federal funds. See, *e.g.*, *Senate Report* 31 (the "normal rule" under the Act is that "small business firms and nonprofit organizations are to have the right to elect to retain worldwide ownership of their inventions"). If the contractor wishes to own and develop the invention, all it must do is "elect" to retain title and comply with the further conditions for exercising title set out in the Act, *i.e.*, the obligations to disclose the invention, to make an election of title, and to seek patent protection in a timely manner. 35 U.S.C. 202(c)(1)-(3). The Act does not condition the contractor's title to an invention on an assignment of rights from an inventor, but instead grants the contractor presumptive title to the invention by operation of law.

The Act further provides that the government retains important rights in federally funded inventions owned by the contractor and may, in some circumstances, take title to a subject invention. When the contractor elects to retain title to an invention, the government has the right to "a nonexclusive, nontransferable, irrevocable, paid-up license" to practice the invention, 35 U.S.C. 202(c)(4), and has the authority to require the contractor, its assignee, or an exclusive licensee to license the invention in order to achieve practical application of it, 35 U.S.C. 203. In addition, the government may take title to an invention if the contractor does not notify the government of the invention, does not elect to retain title to the invention, or does not seek patent protection for the invention in a timely manner. 35 U.S.C. 202(c)(1)-(3). In certain circumstances, such as when the research to be performed implicates particularly sensitive government interests, the government may provide in the funding agreement with the contractor that title to any resulting inventions will vest in the government. 35 U.S.C. 202(a). But the contractor's decision to retain title controls unless the government has retained title through a funding agreement or the contractor fails to exercise its rights in the manner and within the time specified in the Act.

The Act also confers limited rights on individual inventors of subject inventions. A nonprofit contractor that retains title under the Act must "share royalties with the inventor." 35 U.S.C. 202(c)(7)(B). The Act further provides that, if a contractor declines to retain title (or fails to exercise its rights under the Act), the government funding agency "may consider and after consultation with the contractor grant requests for retention of rights by the inventor." 35 U.S.C. 202(d). In that circumstance, the inventor obtains title to the invention "subject to the provisions of th[e] Act and regulations promulgated [t]hereunder." *Ibid.*; see 37 C.F.R. 401.9. Thus, with respect to ownership of patent rights in federally funded inventions, the inventor's rights are subordinate to those of both the contractor and the federal government. See, *e.g.*, *Platzer* v. *Sloan-Kettering Inst. for Cancer Research*, 787 F. Supp. 360, 364-365 (S.D.N.Y.) (concluding that "the intended beneficiaries of the Bayh-Dole Act are the [research] institutions themselves and the government," not the inventors), aff'd, 983 F.2d 1086 (Fed. Cir. 1992) (unpublished; per curiam), cert. denied, 507 U.S. 1006 (1993).

2. In this case, Stanford retained title to the inventions at issue by complying with the Bayh-Dole Act. The court of appeals did not question Stanford's contention that the inventions at issue are "subject inventions" within the meaning of the Act. To the contrary, the court stated that the results of research conducted by Holodniy and other researchers at Stanford "formed the basis for the patents-in-suit," Pet. App. 5a, and it held that Holodniy's prior assignment to Cetus would control "[e]ven if Holodniy conceived and reduced to practice [the invention] after departing Cetus," *id.* at 15a. And the record makes clear that the pertinent research at Stanford was funded in part by two federal grants for AIDS research. *Id.* at 109a, 114a-115a.

Accordingly, when the inventions were made, title presumptively vested in Stanford by operation of law. 35 U.S.C. 202(a). Stanford then took the steps required to exercise its title: it disclosed the inventions to the government and provided to the government paid-up licenses to practice the inventions, Pet. App. 5a-6a, 114a-116a; see 35 U.S.C. 202(c)(1) and (4); submitted patent applications for the inventions, Pet. App. 5a, 108a-109a; see 35 U.S.C. 202(c)(3); and provided to the government a formal written election to retain title to the inventions, Pet. App. 5a-6a, 115a-116a; see 35 U.S.C. 202(a) and (c)(2). Indeed, neither the court of appeals nor respondent has disputed that Stanford took the necessary steps under the Act in order to exercise title to the inventions.

3. The court of appeals erred by failing to enforce the "[d]isposition of rights" (35 U.S.C. 202) in the inventions mandated by the Bayh-Dole Act, and by instead treating Stanford's rights in the inventions as depending upon Holodniy's assignment of title. That approach was incorrect because the Act allows a contractor to retain title by operation of law, 35 U.S.C. 202(a), and the inventor may gain title to the invention only when the contractor forfeits its right to title, 35 U.S.C. 202(d). Here, Holodniy possessed a contingent interest in any patentable "subject invention" that he might create with the assistance of federal funds, one that would mature only if the contractor waived or failed to exercise its rights under the Act and the government then authorized Holodniy to retain title. Although nothing in the Bayh-Dole Act precluded Holodniy from assigning that contingent interest to Cetus, Holodniy could not assign to Cetus any higher priority in the federally funded inventions than Holodniy himself would have possessed. Be-

cause Stanford elected to retain title under the Act, Holodniy's prior assignment did not have the effect of conveying to Cetus an ownership interest that Holodniy could not have asserted.[1]

The court of appeals framed the question presented as whether Stanford's "election of title under Bayh-Dole had the power to void any prior, otherwise valid assignments of patent rights." Pet. App. 19a. Stanford's entitlement to retain title to the patented inventions, however, does not depend on the view that the Bayh-Dole Act "void[ed]" Holodniy's assignment of rights to Cetus. Holodniy assigned to Cetus *his own* "right, title, and interest in" any inventions conceived or reduced to practice "as a consequence of [his] access to CETUS' facilities or information," *id.* at 123a; but the parties to that agreement surely understood that the scope of Holodniy's rights in any later-developed inventions would be determined under applicable law. If Holodniy's eventual contributions to the research that produced the patented inventions had not justified treating him as a co-inventor, for example, Cetus would have acquired no rights in those inventions because Holodniy would have had no such rights to assign. Similarly here, the Bayh-Dole Act did not "void" Holodniy's assignment to Cetus of all his rights in the relevant inventions; it simply limited, to the contingent interests described above, the rights that Holodniy could potentially assign.

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[1] The Act requires a nonprofit organization that retains title to a federally funded invention to share any royalties with the inventor, 35 U.S.C. 202(c)(7)(B), and nothing in the Act would have precluded Holodniy from assigning to Cetus all or part of his contingent interest in such royalties. Neither the parties nor the courts below have suggested, however, that any such royalties are in dispute.

By placing the disposition of rights in a federally funded invention in the hands of the inventor, the court of appeals turned the Bayh-Dole Act's hierarchy on its head. In the court's view, title to a federally funded invention belongs in the first instance not to the contractor, but to the inventor. The court determined that Holodniy possessed rights in the inventions that he had assigned to Cetus, Pet. App. 19a, and that Stanford's and the government's rights were subordinate to Holodniy's assignment, *id.* at 13a-18a. The court considered the government's rights second, stating that "when the Bayh-Dole Act's provisions are violated, 'the government can choose to take action * * * [but] title remains with the named inventors or their assignees.'" *Id.* at 18a-19a (quoting *Central Admixture Pharmacy Servs., Inc.* v. *Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1352-1353 (Fed. Cir.), cert. denied, 552 U.S. 1038 (2007)). The court put the contractor's rights last, stating that Stanford could only "claim whatever rights were still available after the Government declined to exercise its option." *Ibid.*

As a result, the court held that an inventor like Holodniy may preclude a university or other nonprofit contractor from obtaining its statutory ownership interests in a federally funded invention simply by making a present assignment of rights to a third party. That holding nullifies the university or other nonprofit contractor's statutory right to elect to retain title, as well as its corresponding statutory obligations to commercialize the invention, grant the government a license, and devote the proceeds to research and education.

4. The Bayh-Dole Act allows a contractor to obtain clear title to an invention by operation of law, without seeking any assignment by an inventor. The Act states

that the contractor may "elect to retain title" in a subject invention, 35 U.S.C. 202(a), and it describes that election as the contractor's "acquir[ing] title under this chapter," 35 U.S.C. 203(a), and "receiv[ing] title to a[] subject invention," 35 U.S.C. 204. The Act specifies the steps the contractor must take to exercise title under the Act (35 U.S.C. 202(c)(1)-(3)), and those steps do not include the acquisition of an assignment of rights from the inventor. Regulations implementing the Bayh-Dole Act confirm that, when a contractor complies with the statutory requirements, it "retain[s] the entire right, title, and interest throughout the world to each subject invention." 37 C.F.R. 401.3(a); see 37 C.F.R. 401.14(a) (clause (b)).

Contrary to the court of appeals' understanding (Pet. App. 19a), title to a "subject invention" within the meaning of the Bayh-Dole Act does not initially vest in the inventor. To be sure, under the Patent Act, the right to obtain a patent on an invention generally belongs to the inventor, who may assign that right. See 35 U.S.C. 101, 115, 116, 152. By its terms, however, the Bayh-Dole Act "take[s] precedence over any other Act" governing the disposition of rights in subject inventions. 35 U.S.C. 210(a). Thus, even assuming that Holodniy's assignment of rights to respondent would otherwise have prevailed over his assignment of rights to petitioner, the priority rules in the Bayh-Dole Act are controlling here.[2]

[2] Respondent suggests (Supp. Cert. Br. 12) that the Bayh-Dole Act does not displace an inventor's rights under the Patent Act because Section 210 does not specifically mention the Patent Act. But the Bayh-Dole Act states that it takes precedence over "*any* other Act" that would require a contrary disposition of rights, "including *but not necessarily limited to*" the 21 listed statutes. 35 U.S.C. 210(a) (emphasis added). Because "statutory language suggesting exclusive-

The Act's specification of the circumstances in which an inventor may retain title to a subject invention confirms that the inventor does not have the initial right to title under the Act. An inventor may retain rights in a subject invention only if "a contractor does not elect to retain title" and the government grants the inventor's request for retention of rights after consulting with the contractor. 35 U.S.C. 202(d); see 37 C.F.R. 401.9 (inventor's ability to retain title is subject to federal approval). The Act does not identify any other circumstance in which an inventor can obtain title, and it does not allow an inventor to trump the rights of a contractor. See, *e.g.*, *Fenn* v. *Yale Univ.*, 393 F. Supp. 2d 133, 139 (D. Conn. 2004) (inventor could not retain rights under Act where university intended to exercise right to retain title and informed the government of that intention), aff'd, 184 Fed. Appx. 21 (2d Cir. 2006) (unpublished opinion).

That conclusion is reinforced by the Act's restrictions on inventors who *are* allowed to retain rights in subject inventions. The Act provides that, "[i]f a contractor does not elect to retain title to a subject invention" and the government "grant[s] [a] request[] for retention of rights by the inventor," the inventor takes title "subject to the provisions of [the Bayh-Dole] Act and regulations promulgated [t]hereunder." 35 U.S.C. 202(d). The applicable regulations in turn state that, when an inventor is allowed "to retain rights to a subject invention" pursuant to Section 202(d), the agency must impose upon the

ness is missing," *Chevron U.S.A. Inc.* v. *Echazabal*, 536 U.S. 73, 81 (2002), respondent's invocation of the *expressio unius* canon is inapt; and because Section 210 does not provide "a list of specific items followed by a general term," *Hall St. Assocs.* v. *Mattel, Inc.*, 552 U.S. 576, 586 (2008), the *ejusdem generis* canon is likewise inapposite.

inventor specified restrictions that apply to small business contractors. 37 C.F.R. 401.9.

The Act does not expressly limit the prerogatives of an inventor who obtains rights in a subject invention *other than* pursuant to Section 202(d). The natural inference from that omission is that inventors can obtain such rights only if the contractor declines to retain title and the government grants the inventor's request. By contrast, the court of appeals' decision suggests that inventors can exercise *greater* rights in subject inventions outside of the Bayh-Dole Act framework than they could exercise after satisfying the statutory prerequisites to retention of title. That approach would seriously undermine Congress's effort to ensure that federally funded inventions are used to advance the public interest.[3]

[3] Congress's authority to allocate inventors' rights in federally funded inventions is reinforced by long-standing practice regarding patentable inventions created by federal employees. A 1950 Executive Order, which remains in effect today, provides that "[t]he Government shall obtain the entire right, title and interest in and to all inventions made by any Government employee (1) during working hours, or (2) with a contribution by the Government of facilities, equipment, materials, funds, or information, or of time or services of other Government employees on official duty, or (3) which bear a direct relation to or are made in consequence of the official duties of the inventor." Exec. Order No. 10,096, 3 C.F.R. 292 (1949-1953 Comp.), amended by Exec. Order No. 10,695, 3 C.F.R. 355 (1954-1958 Comp.), and Exec. Order No. 10,930, 3 C.F.R. 456 (1959-1963 Comp.). Federal regulations implement that policy and provide detailed procedures for employees to retain title to inventions that were made outside the course of their federal work. See 37 C.F.R. Pt. 501. Just as the government may allocate rights in inventions made by its employees, see, *e.g.*, *Heinemann* v. *United States*, 796 F.2d 451, 455-456 (Fed. Cir. 1986), cert. denied, 480 U.S. 930 (1987), it may also allocate rights in inventions made by its contractors with federal funds.

B. The Bayh-Dole Act's History Confirms That An Inventor May Not Trump A Contractor's Election Of Rights By Private Contract

1. Before 1980, there was significant debate throughout the federal government about whether it would best serve the public interest to vest title to federally funded inventions in the government or to grant ownership to the research institutions where the inventions were made. Pet. Br. 2-10; see pp. 2-5, *supra*. In the Bayh-Dole Act, Congress granted primary rights in federally funded inventions to the research institutions, rather than to the government. The congressional deliberations evidenced an overriding concern that, although the government was spending significant sums on science and technology research, taxpayers were not gaining useful products in return. The Senate Report accompanying the Act noted the "inability of the Federal agencies to deliver new inventions and processes from their research and development programs to the marketplace where they can benefit the public," *Senate Report* 2, primarily due to resource constraints, *id.* at 19 (citing statistic that "the cost of taking a new invention from basic research through development and commercialization costs 10 times as much as did the basic research itself").

Although federal agencies that owned patents generally "ma[de] them available to private businesses for development and possible commercialization through nonexclusive licenses," that approach had proved inadequate to encourage private industry to take on the substantial costs of bringing a product to market. *Senate Report* 2; see *id.* at 18. As a result, "[h]undreds of valuable medical, energy, and other technological discoveries [we]re sitting unused under Government control," 126 Cong. Rec. at 8739 (statement of Sen. Bayh), and "the public [wa]s not receiving the full benefits of the research and development efforts that it [wa]s supporting," *Senate Report* 19.

Congress chose to allow universities and other contractors to retain title to those inventions because it viewed those entities as better positioned than the federal agencies to develop federally funded inventions. Extensive hearings had "clearly demonstrated that the universities and nonprofit organizations who are conducting this research effort are much more efficient in delivering these important discoveries to the marketplace than are the [federal] agencies." *Senate Report* 29. Congress therefore granted those contractors the exclusive ownership rights required for effective commercialization of the inventions, *id.* at 3, 18, 24, while giving the federal government a license to use the inventions, *id.* at 30. Congress further sought to "protect [the] public welfare" by giving the government march-in rights to license any federally funded invention that the relevant contractor was not adequately utilizing. *Id.* at 28.

2. The legislative record reflects a consensus that, under the statute as ultimately enacted, a contractor could obtain clear title to a federally funded invention by complying with the conditions set out in the Act. Section 202 of the Act "establishe[d] the basic framework for the disposition of rights in inventions made by small business firms and nonprofit organizations under funding agreements with the Federal Government." *Senate Report* 31. Under that framework, the "normal rule" is that "small business firms and nonprofit organizations are to have the right to elect to retain *worldwide ownership* of their inventions by making an election within a

reasonable time after they disclose the invention." *Ibid.* (emphasis added). See, *e.g.*, 126 Cong. Rec. at 8741 (statement of Sen. Nelson) (Act "establish[es] a presumption that universities and small businesses shall retain title to inventions they develop with government financial assistance"); *id.* at 2007 (statement of Sen. Weicker) (Act "grant[s] to the universities and small companies the right of first refusal for patents arising from their Federal grants or contracts"); *The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the Sen. Comm. on the Judiciary*, 96th Cong., 1st Sess. 40 (1979) (statement of Elmer Staats, Comptroller General of the United States) (statute embodies "a uniform Government-wide title-in-the-contractor policy"); *House Report* 5 (similar House bill "establishes a presumption that ownership of all patent rights in government funded research will vest in [the] contractor")[4]; see also *Statement on Signing H.R. 6933 Into Law*, 16 Weekly Comp. Pres. Doc. 2803, 2804 (Dec. 12, 1980) ("[T]his legislation enables small businesses and nonprofit organizations to obtain title to inventions made with Federal support.").

It was well understood that the Act would "automatically grant small businesses and nonprofits title to inventions arising from Government-supported research." *Senate Report* 36 (statement of Alice Rivlin, Director of the Congressional Budget Office). See, *e.g.*, *House Report* 12 (similar House bill "provides for the acquisition

[4] Although the *House Report* considered an earlier version of the bill, which provided that "[a] contractor that is a small business or a nonprofit organization will acquire title to its contract invention," 126 Cong. Rec. at 29,891, there is no suggestion in the legislative record that Members of Congress viewed that language as materially different from the language that ultimately was enacted.

of title to contract inventions by contractors which are either a small business or a nonprofit organization"). Even those Members of Congress who disagreed with the balance of interests struck in the Act understood that it "assigns *automatic title* to the contract invention where the contractor is a small business or nonprofit organization." *Id.* at 30 (views of Rep. Brooks) (emphasis added).

3. At no point before or during the debates on the Bayh-Dole Act did any widely-held view emerge that an individual inventor should retain ownership rights in a federally funded invention. In the decades before the Act's passage, the government either allowed research institutions to retain ownership of federally funded inventions or kept the inventions for itself. See pp. 2-5, *supra*. Neither of those approaches allowed individual inventors to retain title to federally funded inventions. In enacting the Bayh-Dole Act, Congress chose the former approach over the latter; it did not choose an unprecedented third option in which an individual inventor could assign away rights in a subject invention contrary to the wishes of both the contractor and government. Indeed, those Members of Congress who objected to the disposition of rights mandated by the Act did so because they believed that the government should have greater rights in subject inventions than contractors—not because they believed inventors should have ownership rights. See, *e.g.*, *House Report* 29 (views of Rep. Brooks) (asserting that "what the government acquires through the expenditure of its citizens' taxes, the government owns," and describing the statute as "a pure giveaway of rights that properly belong to the people"); 126 Cong. Rec. at 8738 (statement of Sen. Long) (statute

would give contractors "gifts of ownership of taxpayer-financed research").[5]

4. The legislative record does not suggest that a contractor's election of title would be effective only if the contractor obtained an assignment of rights from the inventor. Rather, the Committee Reports describe the inventor's ability to take title to a federally funded invention as contingent on the contractor's declining to take title. See, *e.g.*, *Senate Report* 33 (Section 202(d) "provides agencies with the authority to leave rights with individual inventors in cases when contractors do not elect rights"); *House Report* 16 (similar House bill "authorized a contractor's employee-inventor to receive some or all of the contractor's rights to a contract invention if the responsible agency and the contractor approve"). That omission is telling because, under the IPAs previously used by some agencies, the contractor was required to obtain such an assignment because the agencies themselves lacked statutory authority to allocate the inventor's rights. See pp. 3-5, *supra*. Congress did possess that authority, however, and it decided to "override conflicting statutes" so that its policy of granting ownership rights to a contractor would be "uniform." *Senate Report* 26.

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[5] Some Members of Congress suggested that the statute "does not go far enough" and that "all contractors, regardless of size or profit status," should be able "to acquire title to their inventions made under Federal contracts." 126 Cong. Rec. at 30,365 (statement of Sen. Schmitt); see also, *e.g.*, *id.* at 8745-8746 (statement of Sen. Cannon); 1993-1994 (statement of Sen. Stevenson). That view eventually was reflected in Executive Order No. 12,591, 3 C.F.R. 220 (1987 Comp.), which instructed federal agencies to apply portions of the Bayh-Dole Act to large contractors. See also *Memorandum on Gov't Patent Policy,* 1 Pub. Papers 248 (Feb. 18, 1983).

C. Allowing An Inventor To Transfer Ownership Of A Federally Funded Invention Outside The Bayh-Dole Act's Framework Frustrates Congress's Purposes

Congress enacted the Bayh-Dole Act to "promote the utilization of inventions arising from federally supported research or development"; to "ensure that the Government obtains sufficient rights" in federally funded inventions to protect taxpayers' investments; to encourage "future research and discovery"; and to benefit "United States industry and labor." 35 U.S.C. 200. The court of appeals' decision frustrates each of those important purposes.

1. The Act's primary purpose was to encourage commercialization by bringing uniformity and certainty to ownership of federally funded inventions. *Senate Report* 1-3. Since 1980, contractors have understood that, if they comply with the Act's requirements, they can obtain title to federally funded inventions subject to certain rights retained by the government. See *The Bayh-Dole Act—The Next 25 Years: Hearing Before the Subcomm. on Technology and Innovation of the H. Comm. on Science and Technology*, 110th Cong., 1st Sess. 4-5 (2007); Pet. App. 111a, 137a (reflecting Stanford's understanding).[6] That certainty of title has been

[6] See also, *e.g.*, Michael S. Mireles, Jr., *States As Innovation System Laboratories: California, Patents, and Stem Cell Technology*, 28 Cardozo L. Rev. 1133, 1143 (2006) ("The Act provides a presumption of ownership in the recipient of the grant funding."); Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 Minn. J. L. Sci. & Tech. 393, 403 (2006) (Act "allow[s] [contractors] to retain title to the inventions if they diligently file patent applications and promote commercial development of the inventions"); John H. Raubitschek, *Responsibilities Under the Bayh-Dole Act*, 87 J. Pat. & Trademark Off. Soc'y 311, 311

a driving factor behind the massive increase in patents by United States colleges and universities. See, *e.g.*, *Innovation's Golden Goose*, The Economist, Dec. 14, 2002, at 3 (calling the Act "the most inspired piece of legislation to be enacted in America over the past half-century" and documenting sharp rise in patents and jobs created); AAU Cert. Br. 2, 16-20; MIT Cert. Br. 7-10. Moreover, "the assurance of clear title to Government-funded inventions provided by the Act has led directly to increased patent licensing," which "has been a major factor in allowing increased business support and collaboration in university research." S. Rep. No. 662, 98th Cong., 2d Sess. 2 (1984). "Universities can negotiate with businesses and reach agreements over who will have what rights to inventions that come from joint efforts when the universities own the basic patents." *Ibid.*

The court of appeals' decision upsets the settled expectations of the nation's federally funded research institutions. Under the decision below, even when a contractor elects to retain title and complies with the requirements of the Act, an inventor may defeat that title by making an assignment to a third party, the terms or even existence of which may be unknown to the contractor at the time of the election and for years thereafter. The decision below thus creates serious uncertainty about contractors' title to patents, raising the cost of due diligence for contractors and potential licensees, and making it difficult and risky for contractors to give po-

(2005) (Act "gave universities and small businesses the right to own their inventions made with federal funds"); *Innovation's Golden Goose,* The Economist, Dec. 14, 2002, at 3 ("[The Act] transferred ownership of an invention or discovery from the government agency that had helped to pay for it to the academic institution that had carried out the actual research.").

tential licensees or investors warranties of good title to patents obtained through the Bayh-Dole Act framework.

Contractors and the government cannot limit the damage to the Bayh-Dole Act scheme by modifying their assignment clauses in future contracts. Changing future contracts will not change the allocation of rights for the massive number of past and present agreements relating to ongoing or completed research over the three decades since the Act took effect. See Pet. 17-18. And even with respect to future contracts between universities and individual researchers, a university that insisted upon a present assignment of rights from the researcher would still run the risk that the researcher had already executed a similarly worded assignment of rights to a third party, and that the earlier assignment would be found controlling.

2. The decision below also impairs the government's ability to protect taxpayers' substantial investment in scientific research and development. The federal government funds over half of all scientific and technical research conducted at colleges and universities in the United States, see *GAO Report* 1, which amounted to more than $31 billion in 2008, NSF, *NSF 10-311, Academic R&D Expenditures: FY 2008*, at 8 & tbl. 1 (2010). Additional billions of dollars of federal funds are provided each year to small businesses and nonprofit organizations.

Congress recognized that the federal government should have the authority to protect those substantial investments and ensure that taxpayers benefit from them. *Senate Report* 16 (recognizing the need to "receive the optimum return on the Federal Government's basic research expenditures since this is becoming by far the largest source of American basic research money"). Accordingly, the Bayh-Dole Act guarantees the government an irrevocable, paid-up license from the contractor to practice a federally funded invention. 35 U.S.C. 202(c)(4). The Act further provides that, if a contractor does not take sufficient action to achieve practical application of the invention, is not adequately satisfying a public health or safety need related to the invention, or has not ensured that assignees with exclusive rights manufacture products using the invention substantially in the United States, the agency may "march in" and require the contractor to grant licenses to third parties. 35 U.S.C. 203, 204. Those provisions give the government "leverage to promote commercialization of federally funded inventions." *GAO Report* 9-12. By allowing an inventor to assign rights in federally funded inventions free from the restrictions that bind the contractor, and that would similarly bind the inventor himself if he took title under the Bayh-Dole framework after the contractor declined to do so, the court of appeals' decision subverts Congress's effort to ensure that federal funding for research ultimately promotes the public interest. See pp. 20, 22-23, *supra*.

3. Allowing an inventor to transfer ownership of a federally funded invention to a third party would similarly frustrate Congress's efforts to foster scientific research and development in the United States and to benefit American workers. Congress required that nonprofit contractors use "the balance of any royalties or income earned * * * for the support of scientific research or education," 35 U.S.C. 202(c)(7)(C), not only to "assist * * * the university or nonprofit organization" in its further research efforts, but to bring "very real benefit[s] to the public." *Senate Report* 30. Congress also required that a contractor obtaining title under the

Act must ensure that any assignee granted the "exclusive right to use or sell any subject invention" agrees to manufacture any products using the subject invention "substantially in the United States" unless the government waives that condition, 35 U.S.C. 204. That preference for United States industry "is designed to maximize the probability that the jobs created through the commercialization of new products and technologies based on Government supported inventions will benefit American workers." *Senate Report* 34. Under the decision below, however, an inventor may evade those requirements by assigning rights in a federally funded invention to a third party outside of the Bayh-Dole Act framework. It is only through the comprehensive scheme set out in the Act that Congress's objectives can be realized.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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APPENDIX

1. 35 U.S.C. 200 provides:

Policy and objective

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

2. 35 U.S.C. 201 provides:

Definitions

As used in this chapter—

(a) The term "Federal agency" means any executive agency as defined in section 105 of title 5, and the military departments as defined by section 102 of title 5.

(b) The term "funding agreement" means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as herein defined.

(c) The term "contractor" means any person, small business firm, or nonprofit organization that is a party to a funding agreement.

(d) The term "invention" means any invention or discovery which is or may be patentable or otherwise protectable under this title or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 *et seq*.).

(e) The term "subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: *Provided,* That in the case of a variety of plant, the date of determination (as defined in section 41(d)[1] of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance.

(f) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is be-

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[1] See References in Text note below.

ing utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

(g) The term "made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(h) The term "small business firm" means a small business concern as defined at section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

(i) The term "nonprofit organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

3. 35 U.S.C. 202 provides:

Disposition of rights

(a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention: *Provided, however,* That a funding agreement may provide otherwise (i) when the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government, (ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter (iii) when it is determined by a Government authority which is authorized by statute or Executive order to conduct foreign intelligence or counter-intelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security of such activities or, (iv) when the funding agreement includes the operation of a Government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor's right to elect title to a subject invention are limited to inventions occurring under the above two programs of the Department of Energy. The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter.

(b)(1) The rights of the Government under subsection (a) shall not be exercised by a Federal agency unless it first determines that at least one of the conditions identified in clauses (i) through (iv) of subsection (a) exists. Except in the case of subsection (a)(iii), the agency shall file with the Secretary of Commerce, within thirty days after the award of the applicable funding agreement, a copy of such determination. In the case of a determination under subsection (a)(ii), the statement shall include an analysis justifying the determination. In the case of determinations applicable to funding agreements with small business firms, copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy, and recommend corrective actions.

(2) Whenever the Administrator of the Office of Federal Procurement Policy has determined that one or more Federal agencies are utilizing the authority of clause (i) or (ii) of subsection (a) of this section in a manner that is contrary to the policies and objectives of this chapter, the Administrator is authorized to issue regulations describing classes of situations in which agencies may not exercise the authorities of those clauses.

(3) At least once every 5 years, the Comptroller General shall transmit a report to the Committees on the Judiciary of the Senate and House of Representatives on the manner in which this chapter is being implemented by the agencies and on such other aspects of Government patent policies and practices with respect to federally funded inventions as the Comptroller General believes appropriate.

(4) If the contractor believes that a determination is contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency, the determination shall be subject to the[1] section 203(b).

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

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[1] So in original. The word "the" probably should not appear.

(1) That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time.

(2) That the contractor make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency) whether the contractor will retain title to a subject invention: *Provided,* That in any case where publication, on sale, or public use, has initiated the one year statutory period in which valid patent protection can still be obtained in the United States, the period for election may be shortened by the Federal agency to a date that is not more than sixty days prior to the end of the statutory period: *And provided further,* That the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times.

(3) That a contractor electing rights in a subject invention agrees to file a patent application prior to any statutory bar date that may occur under this title due to publication, on sale, or public use, and shall thereafter file corresponding patent applications in other countries in which it wishes to retain title within reasonable times, and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times.

(4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided,* That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production.

(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: *Provided,* That any such information as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.

(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Govern-

ment support and that the Government has certain rights in the invention.

(7) In the case of a nonprofit organization, (A) a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions (provided that such assignee shall be subject to the same provisions as the contractor); (B) a requirement that the contractor share royalties with the inventor; (C) except with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education; (D) a requirement that, except where it proves infeasible after a reasonable inquiry, in the licensing of subject inventions shall be given to small business firms; and (E) with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, requirements (i) that after payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, 100 percent of the balance of any royalties or income earned and retained by the contractor during any fiscal year up to an amount equal to 5 percent of the annual budget of the facility, shall be used by the contractor for scientific research, development, and education con-

sistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility; provided that if said balance exceeds 5 percent of the annual budget of the facility, that 75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent shall be used for the same purposes as described above in this clause (D); and (ii) that, to the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.

(8) The requirements of sections 203 and 204 of this chapter.

(d) If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.

(e) In any case when a Federal employee is a coinventor of any invention made with a nonprofit organization, a small business firm, or a non-Federal inventor, the Federal agency employing such coinventor may, for the purpose of consolidating rights in the invention and if it finds that it would expedite the development of the invention—

(1) license or assign whatever rights it may acquire in the subject invention to the nonprofit organization, small business firm, or non-Federal inventor in accordance with the provisions of this chapter; or

(2) acquire any rights in the subject invention from the nonprofit organization, small business firm, or non-Federal inventor, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction and no other transaction under this chapter is conditioned on such acquisition.

(f)(1) No funding agreement with a small business firm or nonprofit organization shall contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the head of the agency and a written justification has been signed by the head of the agency. Any such provision shall clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The head of the agency may not delegate the authority to approve provisions or sign justifications required by this paragraph.

(2) A Federal agency shall not require the licensing of third parties under any such provision unless the head of the agency determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve the practical application of the subject invention or work object. Any such determination shall be on the record after an opportunity for an agency hearing. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

4. 35 U.S.C. 203 provides:

March-in rights

(a) With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to

use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

(b) A determination pursuant to this section or section 202(b)(4) shall not be subject to the Contract Disputes Act (41 U.S.C. § 601 et seq.). An administrative appeals procedure shall be established by regulations promulgated in accordance with section 206. Additionally, any contractor, inventor, assignee, or exclusive licensee adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Court of Federal Claims, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand or modify, as appropriate, the determination of the Federal agency. In cases described in paragraphs (1) and (3) of subsection (a), the agency's determination shall be held in abeyance pending the exhaustion of appeals or petitions filed under the preceding sentence.

5. 35 U.S.C. 204 provides:

Preference for United States industry

Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

6. 35 U.S.C. 205 provides:

Confidentiality

Federal agencies are authorized to withhold from disclosure to the public information disclosing any invention in which the Federal Government owns or may own a right, title, or interest (including a nonexclusive license) for a reasonable time in order for a patent application to be filed. Furthermore, Federal agencies shall not be required to release copies of any document which is part of an application for patent filed with the United States Patent and Trademark Office or with any foreign patent office.

7. 35 U.S.C. 206 provides:

Uniform clauses and regulations

The Secretary of Commerce may issue regulations which may be made applicable to Federal agencies implementing the provisions of sections 202 through 204 of this chapter and shall establish standard funding agreement provisions required under this chapter. The regulations and the standard funding agreement shall be subject to public comment before their issuance.

8. 35 U.S.C. 207 provides:

Domestic and foreign protection of federally owned inventions

(a) Each Federal agency is authorized to—

(1) apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest;

(2) grant nonexclusive, exclusive, or partially exclusive licenses under federally owned inventions, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of chapter 29 of this title as determined appropriate in the public interest;

(3) undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract, including acquiring rights for and administering royalties to the Federal Government in any invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction, to facilitate the licensing of a federally owned invention; and

(4) transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

(b) For the purpose of assuring the effective management of Government-owned inventions, the Secretary of Commerce is authorized to—

(1) assist Federal agency efforts to promote the licensing and utilization of Government-owned inventions;

(2) assist Federal agencies in seeking protection and maintaining inventions in foreign countries, including the payment of fees and costs connected therewith; and

(3) consult with and advise Federal agencies as to areas of science and technology research and development with potential for commercial utilization.

9. 35 U.S.C. 208 provides:

Regulations governing Federal licensing

The Secretary of Commerce is authorized to promulgate regulations specifying the terms and conditions upon which any federally owned invention, other than inventions owned by the Tennessee Valley Authority, may be licensed on a nonexclusive, partially exclusive, or exclusive basis.

10. 35 U.S.C. 209 provides:

Licensing federally owned inventions

(a) AUTHORITY.—A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under section 207(a)(2) only if—

(1) granting the license is a reasonable and necessary incentive to—

(A) call forth the investment capital and expenditures needed to bring the invention to practical application; or

(B) otherwise promote the invention's utilization by the public;

(2) the Federal agency finds that the public will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;

(3) the applicant makes a commitment to achieve practical application of the invention within a reasonable time, which time may be extended by the agency upon the applicant's request and the applicant's demonstration that the refusal of such extension would be unreasonable;

(4) granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws; and

(5) in the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.

(b) MANUFACTURE IN UNITED STATES.—A Federal agency shall normally grant a license under section 207(a)(2) to use or sell any federally owned invention in the United States only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

(c) SMALL BUSINESS.—First preference for the granting of any exclusive or partially exclusive licenses under section 207(a)(2) shall be given to small business firms having equal or greater likelihood as other applicants to bring the invention to practical application within a reasonable time.

(d) TERMS AND CONDITIONS.—Any licenses granted under section 207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions—

(1) retaining a nontransferrable, irrevocable, paid-up license for any Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States;

(2) requiring periodic reporting on utilization of the invention, and utilization efforts, by the licensee,

but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with, except that any such report shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5; and

(3) empowering the Federal agency to terminate the license in whole or in part if the agency determines that—

(A) the licensee is not executing its commitment to achieve practical application of the invention, including commitments contained in any plan submitted in support of its request for a license, and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken, or can be expected to take within a reasonable time, effective steps to achieve practical application of the invention;

(B) the licensee is in breach of an agreement described in subsection (b);

(C) termination is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license, and such requirements are not reasonably satisfied by the licensee; or

(D) the licensee has been found by a court of competent jurisdiction to have violated the Federal antitrust laws in connection with its performance under the license agreement.

(e) PUBLIC NOTICE.—No exclusive or partially exclusive license may be granted under section 207(a)(2) unless public notice of the intention to grant an exclusive or partially exclusive license on a federally owned invention has been provided in an appropriate manner at least 15 days before the license is granted, and the Federal agency has considered all comments received before the end of the comment period in response to that public notice. This subsection shall not apply to the licensing of inventions made under a cooperative research and development agreement entered into under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a).

(f) PLAN.—No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development or marketing of the invention, except that any such plan shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.

11. 35 U.S.C. 210 provides:

Precedence of chapter

(a) This chapter shall take precedence over any other Act which would require a disposition of rights in subject inventions of small business firms or nonprofit organizations contractors in a manner that is inconsistent with this chapter, including but not necessarily limited to the following:

(1) section 10(a) of the Act of June 29, 1935, as added by title I of the Act of August 14, 1946 (7 U.S.C. 427i(a); 60 Stat. 1085);

(2) section 205(a) of the Act of August 14, 1946 (7 U.S.C. 1624(a); 60 Stat. 1090);

(3) section 501(c) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951(c); 83 Stat. 742);

(4) section 30168(e) of title 49;

(5) section 12 of the National Science Foundation Act of 1950 (42 U.S.C. 1871(a);[1] 82 Stat. 360);

(6) section 152 of the Atomic Energy Act of 1954 (42 U.S.C. 2182; 68 Stat. 943);

(7) section 305 of the National Aeronautics and Space Act of 1958 (42 U.S.C. 2457);

(8) section 6 of the Coal Research and Development Act of 1960 (30 U.S.C. 666; 74 Stat. 337);

(9) section 4 of the Helium Act Amendments of 1960 (50 U.S.C. 167b; 74 Stat. 920);

(10) section 32 of the Arms Control and Disarmament Act of 1961 (22 U.S.C. 2572; 75 Stat. 634);

(11) section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5908; 88 Stat. 1878);

(12) section 5(d) of the Consumer Product Safety Act (15 U.S.C. 2054(d); 86 Stat. 1211);

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[1] See References in Text note below.

(13) section 3 of the Act of April 5, 1944 (30 U.S.C. 323; 58 Stat. 191);[1]

(14) section 8001(c)(3) of the Solid Waste Disposal Act (42 U.S.C. 6981(c); 90 Stat. 2829);

(15) section 219 of the Foreign Assistance Act of 1961 (22 U.S.C. 2179; 83 Stat. 806);

(16) section 427(b) of the Federal Mine Health and Safety Act of 1977 (30 U.S.C. 937(b); 86 Stat. 155);

(17) section 306(d) of the Surface Mining and Reclamation Act of 1977 (30 U.S.C. 1226(d); 91 Stat. 455);[1]

(18) section 21(d) of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2218(d); 88 Stat. 1548);

(19) section 6(b) of the Solar Photovoltaic Energy Research Development and Demonstration Act of 1978 (42 U.S.C. 5585(b); 92 Stat. 2516);

(20) section 12 of the Native Latex Commercialization and Economic Development Act of 1978 (7 U.S.C. 178j, 92 Stat. 2533); and

(21) section 408 of the Water Resources and Development Act of 1978 (42 U.S.C. 7879; 92 Stat. 1360).

The Act creating this chapter shall be construed to take precedence over any future Act unless that Act specifically cites this Act and provides that it shall take precedence over this Act.

[1] See References in text note below.

(b) Nothing in this chapter is intended to alter the effect of the laws cited in paragraph (a) of this section or any other laws with respect to the disposition of rights in inventions made in the performance of funding agreements with persons other than nonprofit organizations or small business firms.

(c) Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on February 18, 1983, agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such persons to retain ownership of inventions except that all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in section 202(c)(4) and section 203 of this title. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized.

(d) Nothing in this chapter shall be construed to require the disclosure of intelligence sources or methods or to otherwise affect the authority granted to the Director of Central Intelligence by statute or Executive order for the protection of intelligence sources or methods.

(e) The provisions of the Stevenson-Wydler Technology Innovation Act of 1980 shall take precedence over the provisions of this chapter to the extent that they permit or require a disposition of rights in subject inventions which is inconsistent with this chapter.

12. 37 C.F.R. 401.9 provides:

Retention of rights by contractor employee inventor.

Agencies which allow an employee/inventor of the contractor to retain rights to a subject invention made under a funding agreement with a small business firm or nonprofit organization contractor, as authorized by 35 U.S.C. 202(d), will impose upon the inventor at least those conditions that would apply to a small business firm contractor under paragraphs (d)(1) and (3); (f)(4); (h); (i); and (j) of the clause at § 401.14(a).