

II. Statutory Provisions of the Bayh-Dole Act

A. Introductory Provisions

1. Policy and Scope of the Act

The BDA's enumerated policy objectives are codified in 35 U.S.C. § 200.⁴¹ Despite the objective of encouraging private industry to utilize government funded inventions and bring them to commercial applicability, the BDA does not specifically affect the patentability of an invention.⁴² Patents are subject to the patentability requirements of 35 U.S.C. §§ 101, 102, 103 and 112.⁴³ The Federal Circuit rejected an argument that government funded inventions should be subject to lesser requirements, stating that "The Bayh-Dole Act was intended to enable universities to profit from their federally-funded research. It was not intended to relax the statutory requirements for patentability."⁴⁴

It is further notable that the scope of the BDA has been recently interpreted not to affect the general patent policy that title to the invention vests in the actual inventor. The Supreme Court recently adjudged a case that proposed that the BDA effectively reordered the "hierarchy," and that title automatically vests in the universities for federally funded inventions. The court rejected this argument and determined that ownership vests in the inventor, regardless of whether or not an invention is federally funded.⁴⁵

41 The statute states: "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." 35 U.S.C. § 200 (2009).

42 See Nash and Rawicz, *supra* note 36, at 246.

43 These statutes are the general rules relating to patentability, notably § 101 governing patentable subject matter and utility, § 102 governing novelty, § 103 governing nonobviousness, and § 112 governing enablement, written description, and best mode. See 35 U.S.C. §§ 101-103, 112 (2008).

44 Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 929 (Fed. Cir. 2004).

45 See Stanford, *supra* note 10. A detailed discussion of this landmark case and its implications in the field of university technology transfer is discussed in Chapter V, *infra*.

2. Definitions

The Act seeks to further identify its scope by defining terms that ultimately govern when the Act should apply. Of note, the BDA applies only for funding by federal agencies for "the performance of experimental, developmental, or research work funded in whole or in part⁴⁶ by the federal government."⁴⁷

A subject invention⁴⁸ is any invention of the contractor "conceived or first actually reduced to practice in the performance of work under a funding agreement...."⁴⁹ The use and placement of the term "contractor" ensures that the reduction to practice relates to the contractor's invention, and that work of a contractor reducing someone else's invention to practice would not qualify as a "subject invention."⁵⁰

B. Disposition of Rights

The disposition of rights contemplated under Bayh-Dole is codified in 35 U.S.C. § 202. This specifically allows for the contractor to retain title from the government.⁵¹ For the contractor to achieve this, it must undertake several procedural steps, including a disclosure and an election.⁵²

1. The Disclosure and Election

§ 202(a) of the Act requires the contractor to make an affirmative election that it wishes to gain the title to a subject invention. Furthermore, the BDA imposes four exceptions that give the government the option to override the contractor's option

46 Thus, the project need not be entirely funded by government money. *See* Nash and Rawicz, *supra* note 36, at 255.

47 35 U.S.C. § 201(a-b) (2009). A federal agency is any executive agency as defined in 5 U.S.C. § 105 or the military departments under 5 U.S.C. § 102. A funding agreement is "any contract, grant or cooperative agreement entered into between any Federal agency....".

48 *See* 35 U.S.C. § 201(e) (2009) (subject invention); *See* 35 U.S.C. § 201(d)(2009) (invention).

49 35 U.S.C. § 201(e) (2009).

50 *See* Nash and Rawicz, *supra* note 36, at 258.

51 *See* 35 U.S.C. § 202 (2009).

52 *See* Nash and Rawicz, *supra* note 36, at 266.