recently dealt with the latter issue, and this will be discussed in Chapters V, *infra*.[60]

C. Government Rights

1. Non-Exclusive License

The funding federal agency gains, at a minimum, a nonexclusive license to practice for or on behalf of the United States and subject invention throughout the world.[61] This provision has been criticized by some as being too narrow in international scope, and by others as too broad with respect to available uses.[62] Additionally, the license refers to the subject invention itself and not to the rights in patents covering such inventions.[63] Thus, a government license on a patentable product that was derived from a federally funded invention may not cover the use of all claims, and in effect may make full use of the patentable product impossible.

2. March-in Rights

One of the most contentious provisions of Bayh-Dole is the allowance for a government agency to "march in" and perform actions on an invention if the action is necessary because of any one of four enumerated situations. The funding agency can, under explicit circumstances, require the contractor to grant licenses or even to grant the licenses itself.[64] The effect of the march-in provision is to ensure that the government still has the ability to ensure an invention is achieving the policy

60 The Supreme Court noted in *Stanford v. Roche* that this (or any other) provision of Bayh-Dole does not reorder the "well-established" hierarchy of patent rights: absent an assignment of his rights, the title to the invention is initially vested in the inventor himself. *See* Stanford, *supra* note 10.

61 *See* 35 U.S.C. § 202(c)(4) (2009). The license is further irrevocable, nonexclusive, and paid up. *See* Nash and Rawicz, *supra* note 36, at 310.

62 *See* Nash and Rawicz, *supra* note 36, at 311. "Some argue that this license is too broad in that it applies to all federal agencies for all uses and not just for the funding agency's use; others view this license as too narrow, as this license should be available to international health organizations... so that developing countries may be able to obtain the drugs at acceptable costs.".

63 *See id.* at 313.

64 The most relevant of these circumstances are the lack of the contractor taking steps to achieve practical application of the subject invention and to alleviate health or safety needs. *See* 35 U.S.C. § 203 (2009); *See* Nash and Rawicz, *supra* note 36, at 330.

purpose of, among others, "promoting the commercialization and public available of inventions made in the United States by United States industry and labor."[65]

To encourage the government to use its march-in right, an adversely affected party can file a petition, detailing the specific reasons that would justify the government agency to march-in (and typically grant a license to the affected party).[66] While a number of petitions have been filed in the past quarter-century, the government has consistently refused to grant the petitions and.[67] Despite the government's lack of utilization of its march-in rights, it contends that the provision is effective since it provides leverage to promote commercialization of federally funded inventions.[68] Many other scholars and some government agencies disagree with respect to the effectiveness of the provision.[69] A detailed analysis of the effect of this provision will be discussed in Chapter IV, *infra*.

D. Implied Duty to Commercialize

While it is not explicitly stated in the statute, an analysis of the above provisions denotes an implied duty to commercialize levied on the contractor. First, the goal is explicitly mentioned in Bayh-Dole's policy objectives.[70] Secondly, the option to retain title to a subject invention triggers various requirements and responsibili-

65 35 U.S.C. § 200 (2009).

66 For an example petition, *See* Joseph M. Carik et al., "PETITION TO USE AUTHORITY UNDER THE BAYH-DOLE ACT TO PROMOTE ACCESS TO FABRYZYME (AGALSIDASE BETA), AN INVENTION SUPPORTED BY AND LICENSED BY THE NATIONAL INSTITUTES OF HEALTH UNDER GRANT NO. DK-34045, *available at* http://www.genomicslawreport.com/wp-content/uploads/2011/01/Fabrazyme-Bayh-Dole-Petition.pdf. This petition was subsequently denied. *See* John Conley, Government Refused to March-In Under Bayh-Dole – Again, Genomics Law Report, January 8, 2011, *available at* http://www.genomicslawreport.com/index.php/2011/01/18/government-refuses-to-march-in-under-bayh-dole-again/.

67 As of January 2011, the National Institute of Health has never granted a march-in petition under the public health provision or any other provision of § 203. *See* Conley, *supra* note 66.

68 *See* GAO Rep. No. 09-742, at 10-11, *reprinted at* http://www.gao.gov/htext/d09742.html, *hereinafter* GAO Report. The Government Accountability Office performed a study with respect to the effectiveness of the march-in provision and published its findings in 2009.

69 *See id.* at 11; *See generally* News Release, Duke University, Patent policy flaws complicate commercialization of federally funded university discoveries (December 11, 2002) *available at* http://www.eurekaalert.org/pub_releases/2002-12/du-ppfl120602.php.

70 *See* 35 U.S.C. § 200 (2009). A policy goal is to promote the commercialization and public availability of inventions.