

### III. Perceived Successes and Shortfalls of the Bayh-Dole Act

This chapter will deal with the perceived strengths and weaknesses of the BDA, as contemplated by academics and practitioners. Chapter IV will analyze these perceptions and assess the effect of the statute on university technology transfer.

#### A. *Perceived Successes of the Bayh-Dole Act*

##### 1. Single, Uniform Policy

Even those most critical of Bayh-Dole admit that the Act offers a single and uniform policy which government agencies and contractors must abide by.<sup>73</sup> In its legislative report commemorating the twenty-fifth anniversary of Bayh-Dole, Congress noted that Bayh-Dole successfully established a "single, uniform national policy designed to... encourage private industry to utilize government financed inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application."<sup>74</sup> This has allowed for more uniformity across agencies and less confusion between all associated entities, which can only benefit the technology transfer process.

- 73 However, these critics note that at least some provisions of Bayh-Dole allow for different agencies and contractors to behave in different manners. For example, Arti Rai and Rebecca Eisenberg explain that the "exceptional circumstances" from which agencies can depart from the typical "title to contractor" presumption are vague. By stating the agency can only exercise its power "infrequently," the standard is constraining the policy goal of "promoting widespread dissemination and use of research results" and thus allows for inconsistent actions across Government agencies. *See generally* Arti K. Rai and Rebecca S. Eisenberg, *The Public Domain: Bayh-Dole Reform and the Progress and Biomedicine*, 66 *LAW AND CONTEMP. PROBS.* 289 (2003). Critics also contend that the march-in rights provision can be construed differently across different agencies, despite the fact that no agency has fully used its march-in rights to date. *See* Duke News Release, *supra* note 69 (noting that the NIH has extreme flexibility to make a determination as to whether or not to march-in pursuant to the Bayh-Dole Act).
- 74 H.R. CON. RES. 319, 109th Cong. (2005), at 2, *reprinted in* H.R. REP. NO. 109-409 at 7. Congress issued this report and resolution ultimately to reaffirm that Bayh-Dole has "made substantial contributions to the advancement of scientific knowledge,... " and to ensure that Congress continues to uphold its commitment to the policies and objectives of the Act. *See id.* at 11-12.

## 2. Increase in Patents, Cooperative Ventures, and Commercial Products

One of the major issues inherent in successful technology transfer is that private industry requires that government funded inventions be patented to justify the expenditure of resources to develop an invention into commercial applicability.<sup>75</sup> Proponents of Bayh-Dole maintain that there has been a substantial increase in both the number of patents and cooperative ventures between universities and other companies pursuant to the Act. In 1980, fewer than 250 patents were issued to US universities annually; in 2003, there were 3933.<sup>76</sup>

Congress noted in their 2006 report that the Act has "resulted in new cooperative ventures and the emergence of sophisticated high-technology businesses, which provide a major catalyst for innovation and entrepreneurial activity."<sup>77</sup> Since 1980, it has been estimated that the licensing of inventions has added \$40 billion to the domestic economy and has been responsible for creating 260,000 new jobs.<sup>78</sup> These numbers are in stark contrast to the pre-Bayh-Dole scheme, where only a small percentage of the estimated 28,000-30,000 Government owned patents had been successfully licensed and exploited.<sup>79</sup>

## 3. The Emergence of the Biotechnology Field

Another perceived success of the Bayh-Dole Act is apparent from the emergence of the biotechnology field over the past quarter-century. Research indicates that the major share of university patents is related to biomedical research.<sup>80</sup> The Association of University Technology Managers (hereinafter AUTM) has found that 70%

75 See Michael S. Mireles, *Adoption of the Bayh-Dole Act in Developed Countries: Added Pressure for a Broad Research Exemption in the United States?*, 59 ME. L. REV. 259, 263 (2007). The requirement of a contractor electing rights to file a patent application helps achieve this goal. 35 U.S.C. § 202(c)(3) (2009).

76 See Bayh Dole at 25, *supra* note 30, at page 23. Also, a much higher percentage of patents are being successfully commercialized, and licensing has increased dramatically. Critics take issue with such direct comparison of the pre and post-Bayh-Dole numbers; their views regarding the numbers will be discussed later in this chapter, and an analysis of the true effect Bayh-Dole has had on the increase will be discussed in Chapter IV, *infra*.

77 See House Resolution, *supra* note 74, at 9. At least 4081 university start-up companies have been created since the Bayh-Dole Act's conception. See Bayh-Dole Act at 25, *supra* note 30, at 23; See Chester G. Moore, *Killing the Bayh-Dole Act's Golden Goose*, 8 TUL. L. J. TECH. & INTELL. PROP. 151, 155 (2006).

78 See Moore, *supra* note 77, at 156.

79 See Rebecca S. Eisenberg, *Symposium on Regulating Medical Innovation: Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1702 (1996). Eisenberg notes, however, that these numbers may be attributed to a "selection bias" of sorts and that many of these inventions were commercially irrelevant, period. See *id.* at 1703.

80 See Rai and Eisenberg, *supra* note 73, at 292.