

## 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.

of the inventions it recognizes are related to biotechnology.<sup>81</sup> Since the majority of these inventions are also publicly funded, Bayh-Dole has proved to be highly important in this field.<sup>82</sup>

Though one may be able to concede that Bayh-Dole did not explicitly create the biotechnology revolution, the incentives it provides are critical for promoting innovation in this field.<sup>83</sup> The biotechnology field necessarily carries high research and development costs,<sup>84</sup> which is well addressed by Bayh-Dole's policy objective of encouraging maximum participation of small business firms in research and development efforts, and in promoting collaboration between commercial entities and nonprofit organizations.<sup>85</sup> There are now close to 200,000 Americans employed in the biotech field, which is a number that can be at least partially attributed to the Bayh-Dole Act.<sup>86</sup>

### *B. Perceived Shortfalls of the Bayh-Dole Act*

#### 1. It Would Have Happened Anyway

One of the more popular critiques of the Bayh-Dole Act is the wealth of attention it receives is undeserved. Commentators note that university patents had been on the rise in the years prior to Bayh-Dole.<sup>87</sup> Thus, Bayh-Dole has been evaluated as an effect more than a cause of university patent successes.<sup>88</sup> Critics also contend

81 See Bayh-Dole at 25, *supra* note 30, at 24. The article further explains that biotechnology was a field that was "in its infancy" prior to Bayh-Dole.

82 See Rai and Eisenberg, *supra* note 73 at 292. Rai and Eisenberg later argue that Bayh-Dole limits the government's ability to oversee the use of intellectual property rights, in ultimately suggesting a modification of Bayh-Dole. *See id.* at 293-294. An analysis of proposed changes to Bayh-Dole with respect to march-in will follow in Chapter IV, *infra*.

83 See Bayh-Dole at 25, *supra* note 30, at 24.

84 See Esteban Burrone, *Patents at the Core: the Biotech Business*, World Intellectual Property Office, available at [http://www.wipo.int/sme/en/documents/patents\\_biotech.htm](http://www.wipo.int/sme/en/documents/patents_biotech.htm). Burrone notes that the facts that the biotech field are so research intensive and carry such high R&D costs for new products, coupled with the low cost of imitation by competitors, leads the industry to be highly patent dependent. *Id.*

85 See 35 U.S.C. § 200 (2009). Congress has further explicitly noted that Bayh-Dole has "stimulated... the development of the biotechnology and information communication industries" and notes that it is poised to play a role in nanotechnology, another area with very high research and development costs. *See House Resolution, supra* note 74, at 8.

86 See Mireles, *supra* note 75, at 264.

87 *See id.* at 265. A variable that may have led to a rise in university patenting includes the creation of the Federal Circuit as a court with exclusive jurisdiction on patent claims. *Id.* at 265.

88 *See* Mowery, *supra* note 5, at 97.