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

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.[83] The biotechnology field necessarily carries high research and development costs,[84] 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.[85] 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.[86]

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.[87] Thus, Bayh-Dole has been evaluated as an effect more than a cause of university patent successes.[88] 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. 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.

that the "celebratory analysis" in the popular press lacks hard evidence, as studies do not explain how the effects have been attributed to Bayh-Dole.[89]

Critics also take specific issue with the contention that Bayh-Dole spurred the biotechnology industry. Mowery et al. show that biomedical technology had increased significantly by the 1970s, and the *Chakrabarty* decision and shifts in intellectual property rights policy increased the economic value of these patents.[90] Thus, Bayh-Dole should be seen as only one of many variables leading to the biotechnology boom in the latter part of the twentieth century.

2. Undermining Research, Development, and Technology Transfer

Rai and Eisenberg argue that Bayh-Dole actually undermines the flow of biomedical research for several reasons.[91] First, "patents on upstream discoveries... [permit] owners to charge a premium for the use of discoveries that might otherwise be more cheaply available in a competitive market or in the public domain."[92] Essentially, Bayh-Dole's requirement on the contractor to patent the early stage invention will unreasonably raise the price for another entity to use the discovery and ultimately benefit the public.[93] Rai and Eisenberg also explain that upstream patenting could hinder subsequent research because a single entity will have monopoly control of basic research discoveries across a broad field.[94] Furthermore, the high costs of patent management may hinder technology transfer as the costs

89 *See id*. However, empirical studies and analysis have been performed on this topic, and will be analyzed in Chapter IV, *infra.*

90 *See id.* at 127-128. The *Chakrabaty* case was a Supreme Court decision widening the scope of patentable subject matter, especially with respect to genetically modified organisms. *See* Diamond v. Chakrabarty, 447 U.S. 303 (1979).

91 *See* Rai and Eisenberg, *supra* note 73. The major contentions in this article can be superimposed to relate to all fields of patenting, though those with higher R&D costs are more likely to be affected by the commentators' arguments.

92 *Id.* at 295.

93 However, critics to this argument state that without patents to permit pricing above the marginal cost, no one would be motivated to incur the R&D expenses to innovate to begin with. *See id.* at 296. It has also been posited that Bayh-Dole amounts to the public being required to "double-pay." Because the inventions are publicly funded, the public incurs a cost at the research phase. Then, because of the patent, the contractor is able charge a monopoly price, effectively charging the public again. *See* Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 Minn J.L. Sci. & Tech 393, 410-411 (2006).

94 *See* Rai and Eisenberg, *supra* note 73 , at 296. This is particularly important for patents on early-stage discoveries that open up new research fields as they would be quite broad and lead to monopolistic control over a large range of issues.