

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.<sup>89</sup>

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.<sup>90</sup> 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.<sup>91</sup> 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."<sup>92</sup> 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.<sup>93</sup> 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.<sup>94</sup> 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.

limit "the financial returns from patent licensing."<sup>95</sup> Additionally, licensing becomes difficult because of valuation problems in early stage inventions that universities are forced to try and commercialize under Bayh-Dole.<sup>96</sup>

### 3. Misallocated Research Priorities

A major criticism of Bayh-Dole is that it "distorts research priorities" by "redirecting resources away from basic research to more commercially viable lines of inquiry."<sup>97</sup> Scholars note that the nature and direction of academic research may be compromised due to universities and researchers' conflicting economic incentives.<sup>98</sup> The ultimate concern is that Bayh-Dole will lead to research and development with for-profit motives, and this conflicts with the policies outlined in the Act.<sup>99</sup>

A recent federal court decision may have indirectly criticized Bayh-Dole on these grounds. In *Myriad*, a court rules against multiple biotechnological patents, stating that they were "purifications of a product of nature" and thus do not possess the requisite utility.<sup>100</sup> Though this decision has recently been reversed by the Federal Circuit, commentators note that *Myriad* "represents an almost caricature-like example of the pitfalls of... technology transfer," as the purpose of the patent was to gain a valuable market commodity, and not to contribute to broader medical research.<sup>101</sup>

95 See Mowery et al., *supra* note 5, at 84. The general assertion is that Bayh-Dole's over-incentivizing universities to patent inventions will cause problems in the long run, as the costs incurred in managing the patents will indirectly lead to a higher price in any licensing contract. This would lead to sunk costs and become a disincentive for industries to want to become engaged in technology transfer.

96 See Clovia Hamilton, *University Technology Transfer and Economic Development: Proposed Cooperative Economic Development Agreements Under the Bayh-Dole Act*, 36 J. MARSHALL L. REV. 397, 406 (2003). The requirement to patent and the duty to commercialize also lead to "a number of low-value exchanges and agreements that have a low potential of truly yielding anything of commercial value." *Id.*

97 See Bayh-Dole at 25, *supra* note 30, at 31. This article continues by rationalizing that the "federal government's funding priorities have also always favored practical applications," in an attempt to demerit the critique of the act.

98 See Hamilton, *supra* note 96 at 406.

99 See Kathryn R. James, *The Myriad decision: Judicial criticism of the Bayh-Dole Act and its progeny?*, ABA Health eSource Vol 6-10 (June 2010), at page 3.

100 See Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al., 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *rev'd in part*, 2011 U.S. App. Lexis 15649 (Fed. Cir. 2011).

101 James, *supra* note 99, at 3. Commentators note that the *Myriad* patents were filed to obtain exclusive control over uses of a particular gene for profit. This maneuver arguably did not contribute to the "public good" and was provoked solely by economic motives. See *id.*