have less fear in utilizing their rights, and the transparency of the provision will ensure that technology transfer is not chilled.

B. Is Bayh-Dole's Shift in Presumption of Ownership Effective? A Review of Empirical Data

This section undertakes to determine whether or not the policies advocated by Bayh-Dole under § 200 have been accomplished pursuant to the general provisions disposing rights to a contractor under § 202. The effect of the ability for a contractor to retain ownership, and by extension, the Act as a whole, will be analyzed based upon three criteria:

1) Has Bayh-Dole led to an increase in patenting, and if so, are these patents "important," and is the increase beneficial to the public?
2) Has Bayh-Dole led to an increase in commercialization of inventions, and if so, has increased commercialism benefitted the marketplace?
3) Has Bayh-Dole advanced or retarded scientific progress, and what is the effect on the U.S. economy?

1. Bayh-Dole's Effect on Patenting

Some general conclusions with regards to the BDA's effect on patenting can be made using evidence of the number of patents in a university portfolio before and after Bayh-Dole. At first glance, the uptick in number of patents granted to U.S. research universities seems to be directly related to the time period of the Bayh-Dole Act's enactment (see Appendix A – Figure 1).[174] As seen from the figure, the number of patents stayed fairly steady and minimal until 1970, and increased slowly between 1970 and 1980. After the BDA's passage, the number of granted patents nearly doubled between 1980-1985, then increased more than twofold between 1985-1990, and again nearly doubled between 1990-1995. Proponents of the Act's success point to this easily quantifiable trend as *per se* evidence of Bayh-Dole's success.[175]

174 *See* David Roessner et al., *The Economic Impact of Licensed Commercialized Inventions Originating in University Research, 1996-200,* Final Report to the Biotechnology Industry Organization (September 3, 2009), *hereinafter* Economics Report, at page 15 (reproduced in Appendix A: Figure 1).

175 *See generally* Howard Bremer et al., *The Bayh-Dole Act and Revisionism Redux,* at page 6, Life Sciences Law & Industry, Vol. 3, No. 17 (September 11, 2009).

a) Importance and Generality

BDA detractors argue both that the increase in the number of patents is due to factors outside of Bayh-Dole, and also that it is not necessarily a benefit to technology transfer.[176] Specifically, two studies[177] attempt to show that even though Bayh-Dole led to an increase of the patents, they are not "important" and lack generality.[178] Henderson, Jaffe, and Trajtenberg undertook to prove this by determining the frequency with which patents were cited in subsequent research.[179]

To test the Henderson evidence, Mowery charts the amount of "citations"[180] based on patents in both biomedical and nonbiomedical inventions.[181] Mowery points to little increase in citation percentages post-Bayh-Dole, and concludes, to an extent, that the general increase in patents generally did not result in "better" inventions.[182] However, Mowery's research contradicted the Henderson findings as it did not show any decline of importance of patents post-Bayh-Dole based upon citation level.

To better reconcile these two studies, a practical method to determine whether or not Bayh-Dole is having a "useful" effect on technology transfer is to see how

176 *See* Mowery, *supra* note 5, at 126; *See* Chapter III-B-1, *supra*.

177 *See* Rebecca Henderson, Adam Jaffe, and Manuel Trajtenberg, *Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965-1988,* at page 123, (President and Fellows of Harvard College and the Massachusetts Institute of Technology, 1998), *available at* http://www.tau.ac.il/~manuel/pdfs/univeristies_as_a_source.pdf; *see* Mowery, *supra* note 5 , at 119.

178 *See* Henderson, Jaffe and Trajtenberg, supra note 178, at 122-23. Henderson's study defines "importance" by a statistical formula summing the number of instances reference to a patent is cited and reducing them by a discount factor. This is because "at least some of such future inventions will reference or cite the original invention in their patents, thereby making the number and character of citations received a valid indicator of the technological importance of an invention" *Id.* at 122. Furthermore, generality is characterized by an exponential summation function with citations as a variable, with the net effect of indicating the "basicness" of the research. *Id.* at 123. The researchers create this variable pursuant to their hypothesis that "patents that cover more ‘‘basic’’ research will be cited by work in a broader range of fields" *Id.*

179 *See id.* at 123. The findings of the researchers supported the hypothesis that the importance and generality of inventions declined post-Bayh-Dole in a fairly robust fashion. *Id.* at 124.

180 *See* Mowery, *supra* note 5, at 119. Mowery defines a "citation" as "the number of citations received by each patent following its issue" for six years. He notes that this is a good variable to measure importance of a patent, assuming "citations form an index of the influence over subsequent inventive activity of the cited patent." Mowery qualifies his analysis by stating that recent patents will be underrepresented, because many patents take 4-5 years for citations to peak. *Id.*

181 *See id.* at 113-125 (including tables 6.4, 6.5, and 6.6).

182 Mowery's statistics showed little effect (positive or negative) regarding the 'generality' and 'importance' of post Bayh-Dole patents compared to pre-Bayh-Dole. This finding invalidated his original hypothesis, based on the Henderson study, that importance and generality would decline in patents post-Bayh-Dole. *See id.* at 125-26, 148.

commercialization of patents has been shaped post-Bayh Dole. This will be presented in section IV-B-2, *infra.*

b) Rise in Biotechnological Patents

With regards to "important" inventions in the biotechnology fields, it is fairly clear that Bayh-Dole led to the creation of numerous FDA approved drugs. In the years immediately following 1980, the amount of drugs created with public funding increased immensely.[183]

Mowery attempts to discredit Bayh-Dole as the driving factor for the rise in these important biotechnological inventions. By noting the same level of increase in biomedical patents versus nonbiomedical patents after the BDA, Mowery attempts to formulate the argument that Bayh-Dole was not the driving factor of the biotech revolution, and, by proxy, of the increase in patents in general.[184]

In response to the critics, one can hypothesize that the uptick in biotechnology and patenting in general was, in part, fostered by Bayh-Dole. While it is clear that the percentage of biotechnical inventions did rise before the act, several factors related to Bayh-Dole instigated this rise. The IPA system enacted in 1968 enabled universities to manage their own inventions made with NIH (and later NSF) support.[185] Thus, though critics[186] point to the rise in biotech before 1980 as a reason that Bayh-Dole was an effect rather than a cause of increased patenting, this argument fails to consider the effects of Bayh-Dole provisions before the actual passing of the Act.

Similarly, patenting of biotechnological inventions increased because of the shift in incentives offered by Bayh-Dole. While critics contend that Bayh-Dole did not contribute to the rise in biotechnological patenting, they fail to acknowledge the reliance the biotechnology field places on patenting;[187] the ease with which the university can assert rights over its invention because of Bayh-Dole led to the ability to patent biotech inventions early and often. This can be substantiated by the fact that after 1980 there "was a dramatic rise in the propensity to patent on the part of

183 *See* Vickie Loise and Ashley Stevens, *The Bayh-Dole Act Turns 30,* les Nouvelles 185, at 190 (December 2010) (at figure 2).

184 *See* Mowery, supra note 5, at 126-27.

185 *See* Bremer, *supra* note 175 , at 3-5. The IPA, or Institutional Patent Agreement system was the clear precursor of the Bayh-Dole Act. It allowed universities to manage their own inventions, but became undermined in future years. The desire for the "IPA program be made statutory and binding on all federal agencies, and that it be extended to small business contractors" led to the drafting of the Bayh-Dole Act.

186 *See* David C. Mowery et al., *The growth of patenting and licensing by U.S. universities: an assessment of the effects of the Bayh-Dole act of 1980*, 30 Res. Pol. (Elsevier) 99, 104 (2001).

187 *See* Burrone, *supra* note 84.

universities that had never applied for patents before and that universities that had always patented began to do so more intensely."[188]

c) Anticommons Concerns

While some Bayh-Dole opponents admit that the Act had a positive effect on patenting, especially in biotechnology, they advance the argument that the rise in patenting will lead to an anticommons concern and deter innovation in the long run.[189] Two potential routes to an anticommons issue exist, one being "creating too many concurrent fragments of intellectual property rights in potential future products" and the other being "permitting too many upstream patent owners to stack licenses on top of the future discoveries of downstream users."[190] Both examples are potentially exacerbated by the presence of Bayh-Dole, where early-stage patenting is encouraged and the ability to grant many nonexclusive licenses is incentivized.

The real-world effects of an anticommons scenario would be a reduction in use, commercialization, and further research and development of inventions. Empirical evidence points against the anticommons concern being prevalent today, even in the biotech industry, where upstream patenting occurs frequently. The next section produces evidence in support of this contention.

2. Bayh-Dole's Effect on Commercialization

Whether or not the BDA has achieved its policy objective of "promot[ing] the commercialization and public availability of inventions" is a major factor in determining the success of the Act.[191] An increase in commercialization would effectively refute the hypothesis that the BDA creates an anticommons effect.[192]

Economists at the Max Planck Institute for Economics have undertaken to determine how technology is being transferred, and what factors affect the flow of

188 Charles R. McManis and Sucheol Noh, The Impact of the Bayh-Dole Act on Genetic Research and Development: Evaluating the Arguments and Empirical Evidence to Date 13, *available at* papers.ssrn.com/sol3/papers.cfm?abstract_id=1840639.
189 *See, e.g.* Heller and Eisenberg, *supra* note 103.
190 *Id.* at 699.
191 35 U.S.C. § 200 (2009).
192 By showing an increase in commercialization, it would be clear that the resource at issue (the patent) is not being underused. *See* Chapter IV-B-1, *supra*.