Abstract

This thesis undertakes to examine the effect of the United States Bayh-Dole Act on technology transfer, specifically with respect to universities. The Bayh-Dole Act was enacted in 1980 to promote utilization of inventions that arise from federally funded research and development. The United States Government had a renewed focus on research and development after World War II, and the Act undertook to maximize the public benefits of such R&D. This paper examines two components of the Act: the general shift in ownership away from the government, and the march-in provision that the government can use to assert certain rights in specific circumstances.

The thesis begins by surveying the technology transfer sector in the United States before and after the passing of the Act, and notes the historical shifts in tendencies and preferences on the part of the government that led Congress to pass the Bayh-Dole Act. The introductory portion of the paper also notes the trends in university patenting and portfolio management in the years leading up to Bayh-Dole, and proceeds by providing a brief overview of the legislative history of the Act. The second chapter of the paper examines specific provisions of the Act which will be analyzed in later chapters, notably the disposition of rights that includes the shift in ownership, as well as the march-in provision.

After a brief summary of perceived strengths and weaknesses of the Act, this paper will analyze one of the Act's most controversial components – the government's march-in provision. This provision allows for the government to require the contractor to license, or even grant a license itself, if the contractor is not achieving practical application, or the action is necessary for certain other policy reasons. The thesis will detail two petitions to the NIH requesting the agency to use its march-in rights to license a patent, and note that in these cases and every other case since the passing of the Act, the government has failed to utilize its march-in rights. The thesis will then derive the conclusion that a march-in provision is necessary in theory, but the provision as currently interpreted needs to be amended to ensure that the government does utilize its right to force a license when the need arises.

The second area of analysis focuses on the crux of the Bayh-Dole Act – the ability for a contractor to assert patent ownership. Prior to the Act, the government retained all rights to inventions created with any government funding, and the government's failure to commercialize its patent portfolio led to many underutilized patents and a general failure to provide the public with the fruits of the R&D. The Act has been examined by many academics to determine whether or not this "shift

in ownership" has ultimately benefited the technology transfer system in the United States. This paper will present empirical analysis that acknowledges that while Bayh-Dole was surely not the only factor leading to a more dynamic, efficient, and successful commercial marketplace for university-created and federally funded inventions, it did have a significant effect on the system.

Specifically, the paper will examine the increase in patenting subsequent to Bayh-Dole, and determine the level that the statute itself was key to this increase. The paper will empirically examine the "quality" of the patents, in an effort to determine whether or not Bayh-Dole led to an increase in utility in addition to the increase in number. The paper will also look into the biotechnology field and assess its dependency on patenting and university research. The paper will note that the biotech field was particularly benefited by the Bayh-Dole Act, and explain how this reconciles with the fact that the rise in biotech patenting began slightly before the passing of the Act.

Critics of Bayh-Dole contend that early stage patenting by multiple inventors could lead to a license stacking problem as well as deter future R&D, which comprises an "anticommons" concern. The thesis will empirically examine the effect Bayh-Dole has had on commercialization, and conclude that the extreme success in this area negates the hypothesis that Bayh-Dole has contributed to such a problem. This portion of the paper will conclude by noting Bayh-Dole has neither hampered nor distorted research and scientific progress, despite the renewed focus on commercialization instead of research for pure academic pursuit.

After addressing the two main components of the Bayh-Dole Act, the paper will move to the future of the Act, beginning by assessing the Supreme Court decision in the recent *Stanford v. Roche* case. The *Stanford* case involved an invention developed by an employee of Stanford, who agreed to assign his rights to the university. However, the employee also assigned his rights to Cetus, a company that later sold its interests to Roche. The Supreme Court determined that the contract with Stanford involved only a future assignment of rights, while the contract with Cetus involved a present transfer of rights. Thus, Roche won the case on a contracting technicality.

Though the case was decided based partially on contract law, the implications of this case will be strong in the university technology transfer sector. First, the Supreme Court made it abundantly clear that Bayh-Dole does *not* trump the rights of an inventor to his invention. Thus, regardless of the Bayh-Dole Act, the true inventor of an invention keeps his ownership rights, absent any assignment or contract stating otherwise. If Bayh-Dole was interpreted to supersede this principle of patent law, Stanford would have won the case, and the implications for technology transfer could become dire if inventors became less willing to innovate because of

the fact that a university employer would automatically gain ownership in their work.

Though the court likely decided the case correctly from a policy perspective, this decision will still affect the university technology transfer sector. First, universities will have to draft contracts more strictly and do more research to determine if an inventor has already assigned his rights to another party. This could lead to a more regimented, formal relationship between universities and employees, which could ultimately impair the commercialization of technology.

The case also brings to light a formal gap between the Bayh-Dole obligations and patent rights. The government expects to gain its rights to march-in and a nonexclusive license, which would come if the contractor elects to enforce its ownership. The holding in the case contemplates that an inventor may assign away his rights, leaving the contractor and by extension, the government, without any rights. This could complicate the front end of technology transfer, where the government may be less willing to engage in funding certain research.

Finally, the case creates the possibility that there will be multiple parties claiming ownership of certain parts of patentable inventions, most notably the inventor and any of his assignees, as well as the university. This could exacerbate the anticommons concern that is already very prevalent in patent law. Multiple owners are less incentivized to commercialize or further innovate if their ownership is shared.

The thesis ultimately views the Act from an international perspective, and notes specific countries that have utilized or attempted to legislate "Bayh-Dole-esque" provisions. Japan created a "Bayh-Dole Act" twelve years ago, and is starting to see improvements in its technology transfer sector, despite fundamental differences in both university structure and cultural preferences as compared to the United States. Numerous countries in the European Union, including Germany, have legislated similar provisions in an attempt to enhance their technology transfer sectors. One developing country in particular, India, has been wrestling with a Bayh-Dole Bill for several years. India has been hesitant to pass its bill because of stark differences between the economies, university systems, and overall patent culture between itself and the United States. An assessment of these three countries leads to the conclusion that Bayh-Dole provisions can have a successful performance abroad, provided countries narrowly tailor the law to ensure their particular technology transfer tendencies are incorporated and commercialization is maximized based on their own structures and principles.