

Consequences of the Bayh-Dole Act

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Introduction

The Bayh-Dole Act of 1980 is arguably one of the most influential pieces of legislation to impact the field of intellectual property law in the twentieth century. The Bayh-Dole Act permits a university, small business, or non-profit institution using federal funds for research to produce an invention to retain the title on any patent issued for such inventions. Prior to this act, the government retained ownership of all patents granted using government money. The government also retained the right to license out the inventions to the private sector, which it did non-exclusively. This, however, was detrimental to the growth of the U.S. because companies wanted to develop products it had the exclusive rights to sell. Thus, universities were creating new and exciting technology using government funds that were never reaching the industry or the public. The Bayh-Dole act changed the way these government funded patents were handled and there was an explosion of university patenting following 1980. For a good while it seemed the Bayh-Dole Act produced only positive consequences for academia and the private sector. However, especially recently, there have been some issues raised about the effects of the act upon trends in research, conflicts of interest and the problems with biomedical patents. The effects of the Bayh-Dole Act and the concerns raised about it are significant to intellectual property and it is an important task to review the act and determine its effectiveness.

History of Federally Funded Patents Prior to 1980

The transfer of technology from research laboratories in American universities to the U.S. commercial market place is a crucial part of the growth of the United States technologically and financially. The funding for the research carried out at the

universities has come in a large part from the federal government. For the greater portion of the 20th century this process, known as technology transfer, was very slow and often stifled by government policy. The reason for the small amount of technology moving from universities to industry was due mostly to the fact that the United States government retained the rights to all inventions produced by universities using government funding. Prior to 1980, the federal government retained the licenses to all patents granted to universities using federal money to support their research. This slowed down the process of technology transfer because many government agencies were reluctant to relinquish ownership of the patents to universities or industry. Instead these agencies granted non-exclusive licenses to anyone who wished to produce the inventions ([2] 1). The non-exclusive licenses were the major factor in suppressing the flow of technology. As a result of the non-exclusive licenses companies were turned off to the idea of manufacturing the inventions owned by the government. Companies resisted purchasing licenses for government owned patents because their competitors could just as easily acquire the same license, and develop and sell the same product ([2] 2). There was no incentive for a company to purchase the licenses so they simply did not. In fact, prior to 1980, only 5% of government owned patents had ever been used in industry ([4] 2). This was an extraordinarily low number and it concerned the government beginning in the 1970's ([3] 10).

The Bayh-Dole Act

There were many attempts to increase the flow of technology from universities prior to 1980, but none have been as successful or as important as the Bayh-Dole Act. The act was enacted into law on December 12, 1980. Specifically the Bayh-Dole Act

allows universities, small businesses and other non-profit organizations to elect to retain any “subject invention” made with federal funds. The institution retaining the title must commit to the commercialization of that invention ([4] 6). The university is also required to share a portion of the royalties from the invention with the inventors and must use a portion of the royalties for laboratory purposes. The government does reserve certain rights to protect the public interest. It retains a “nonexclusive, nontransferable, irrevocable, paid-up license to practice on behalf of the United States any subject invention” ([4] 5). The government also has the right to require the contractor who owns either the title or an exclusive license to the invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant ([4] 6). This right is reserved to protect the public from having universities withhold licenses for patents that could affect the safety of the public.

Because of the act, the universities can control the title for any inventions and have the right to exclusively license out the invention to private industry. The Bayh-Dole Act works positively for all parties involved and creates incentives for research. The university is able to retain the title to the patents and create revenue by licensing the patent or selling it entirely to a private company. The private sector is provided with the incentive to develop the inventions created because they can purchase the exclusive rights to produce the inventions from the university. Although the government loses the funds from the sale of the non-exclusive licenses, it gains revenue from the taxes levied on the sales of the products that the private sector sells because of the exclusive licenses companies can now purchase. Also, only 5% of government owned patents had been used

in industry prior to 1980 so the government was not losing much from the sale of its licenses after the passage of the act.

Positive Effects of the Bayh-Dole Act

Following the passage of the act, the number of patents granted to universities increased exponentially. Figure 1 shows the percentage of all domestic patents granted assigned to United States research universities. It is clear that since Bayh-Dole the number of research related patents has dramatically increased. There was an increase in the rate of patenting as far back as 1975 as indicated in Figure 1, but it is clear that there was a turning point in 1980. There are arguments that the Bayh-Dole Act did not begin, but merely helped along a period of change in the number of university patents ([3] 15). Regardless, it is clear that after the act was passed into law, universities gained a much larger share of total patents granted.

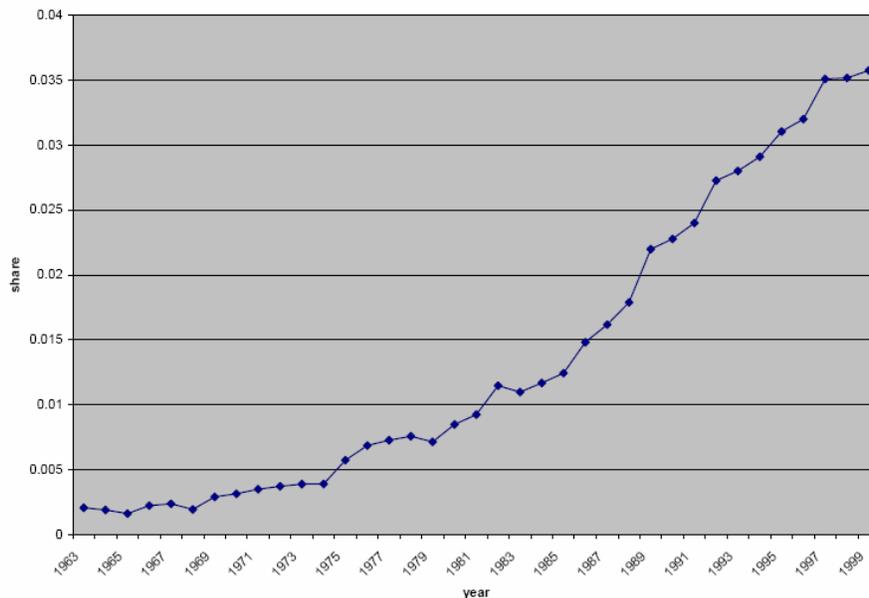


Figure 1: The Percentage of Patents Granted to Research Universities [3].

Besides an increase in the sheer number of patents granted to research universities, several other cited stats show the positive impact of the act. For example, it

has been estimated that since 1980 there has been a ten-fold increase in the number of universities actively engaging in patenting their research ([2] 1). This statistic can help explain the jump in Figure 1 around 1980 which was on top of what looks like an already steadily increasing percentage of patents granted to universities. There were several research universities in the early 1970's who began to file for an increasing number of patents. In 1980, with the passage of the act, new universities saw the incentive to patent and began doing so. This explains the increase in the percentages in Figure 1 in the 1970's and the subsequent increase following 1980.

Today, about thirty billion dollars of economic activity per year and 250,000 jobs can be attributed to technologies born in academic institutions. Also, over 2200 new companies have been formed since 1980 that were based on the licensing of an invention from an academic institution ([2] 2). These statistics all lead to the conclusion that the Bayh-Dole Act has significantly contributed to the development of technology transfer in the latter quarter of the twentieth century.

Issues and Concerns

Generally, the Bayh-Dole Act is regarded as having a large positive impact on U.S. research and on the U.S. economy. It certainly has been influential in increasing the number of university-based patent applications and has aided the growth of the economy and the growth of technology. There are, however several issues that have been raised due to the passing of this act which will be elaborated upon here.

One of the major incentives for universities is that they have the right to grant exclusive licenses for their patented invention or sell the title to the patent to private industry. There have been concerns that because of this there will be conflicts of interest

created between industry and the research universities. According to senior research scholar Mildred Cho of Stanford University states:

The Bayh-Dole Act has created opportunities for conflict of interest for university faculty members because academic-industry partnerships can offer direct financial rewards to individual faculty members in the form of consulting fees, royalties, and equity in companies while simultaneously funding these faculty members' research. ([4] 16)

Many researchers have consulted for and worked for the private sector which creates ties to certain companies. This may lead researchers to favor certain companies when licensing out the patents, which would not promote fair competition. It may also lead to skewed research, which is another possibility that concerns critics of the act.

Universities have remained the main institutions where fundamental scientific research has taken place. With the passage of the Bayh-Dole Act there is much more incentive for universities to shy away from basic research which will produce less patents and applicable inventions, and move towards applied research to gain more royalties from patenting. Mildred Cho "asserts that university research is 'skewed' toward marketable products and not basic research" ([4] 16). This issue seems like a viable possibility, but a study of 3,400 faculty at six major research institutions showed that the ratio of applied research projects to basic science research has not changed over the period between 1983 to 1999 ([5]). According to the National Science Foundation from 1980 to 2001 the percentage of basic science research actually increased from 66.6% to 74.1% and applied researched decreased from 33.4% to 25.9% ([1] 42). While conflicts of interest and a skewing in choice of research may be reasonable concerns associated with the Bayh-Dole Act, there has been insufficient proof of these issues creating actual negative effects.

The criticism of the act with the most clout is the argument concerning biomedical research that is funded by the government. The largest portion of federal funding for academic research falls within the realm of medical and biological sciences ([4] 20). Since the passage of the act, the support for biomedical research has increased from \$4.296 million (in 1996 dollars) in 1980 to \$13.652 million (in 1996 dollars) in 1996 ([4] 20). This jump sparked some concern about the patenting of fundamental research ([4] 21). Patents are designed to foster innovation, but there is an argument that universities patenting biomedical discoveries made with federal dollars inhibit the creation of final products, which are available to sell. Many of the discoveries made by universities in the biomedical field are the first steps in a process to create new drugs and therapies ([4] 20). These university patents are called research tools. Research tools are not final products and are not available to commercialize.

By allowing universities to retain the title to patents that are simply the beginning steps of the process to a final product, the cost of the final product increases. Industry must pay for the cost of the license to use the biomedical patent as well as its own R&D costs to develop the rest of the process to create the final drug or therapy. In the end, it is the consumer who ends up covering the cost of the original licensing fee ([4] 22). This is a problem because this process goes against everything the patent system was created for. It slows and may even stop innovation instead of promoting it. The private sector dealing with biomedical products must go through the process of purchasing the license and may even decide that it is not financially sound to pursue the development of the university patent. Of course, it can also be argued that the first steps in the process would never have been created if not for the Bayh-Dole Act promoting biomedical innovation, but

either way the general public is left to cover the cost of the new drug or therapy or may be left without it at all.

There have been few resolutions passed which protect against the concerns over the Bayh-Dole Act. The negative consequences are quite serious and need to be addressed as so. Just because there is little evidence concerning the existence of conflicts of interest does not mean that it does not take place. It would be easy to disguise and gathering data would be difficult. Many university researchers do have ties to private industry and may even own their own company ([2] 5). There must be more research done into this to determine the effects of conflict of interest. While research skewing seems to have not been an issue thus far there could potentially be problems in the future if the economy takes a dive or universities lose funding for some reason. The biomedical patent problem is a very real one and needs to be addressed more clearly than it has, which will be discussed below.

Conclusions

In general the benefits created by the Bayh-Dole Act greatly outweigh any possible negative consequences. The act was built quite soundly to allow incentives for all involved parties (government, academia, industry), but also has safety measures to ensure that the inventions are handled correctly. The act defines how the university must appropriate the funds created through royalties due to licensing fees and the government retains a special license to use when the invention is deemed critical to public interest. Financial and technological growths are promoted well in academia and the public and private sectors. The results speak for themselves as well. The number of research

university related patents has increased enormously since the passage of the act, the number of businesses created around an idea involved with a university patent has increased, the number of jobs involved with university patents has increased, and the American economy has certainly benefited from these positive consequences of the Bayh-Dole Act ([4] 20-22).

Unfortunately, the act is not flawless. While there have been few adverse effects that are directly linked to the act there is the possibility of certain issues becoming major problems. Just because there has been little evidence of conflicts of interest between university researchers and the private sector does not mean measures should not be taken to prevent this from happening. The same preventative measures should be taken to ensure the appropriate balance between basic and applied research. The government should require a committee to be created at any university electing to retain the rights to the title of their patent. Many universities have hired professional technology managers to work with the university and act as a liaison to the private sector ([4] 16). While this is a good step, it is not enough. The committee should consist of more than just an outside professional hired by the university. The Technology Transfer committee needs to consist of faculty from every department that uses federal funding for their research as well as an expert trained in the field. There needs to be a contact for the committee with the federal government. The committee should be required to report to this contact at least once every year.

The purpose of this committee will be to act as an interface between the university, the government and industry. Having multiple members of the faculty as well as reporting to a government agency designed to handle technology transfer allows for a

system of checks and balances to ensure that there will be no conflicts of interest present and that every company has a fair shot at acquiring the exclusive license to a patent. Having a member from every department that utilizes federal funds while ensure that the research is not swayed away from basic research towards applied research as faculty that does not often patent will have a say in the committee. Also, reporting to the government contact will allow data about university patenting and revenues due to licensing to be easily gathered and analyzed. Thus, it will be easy to locate trends in university patenting and technology transfer.

To alleviate the problems associated with biomedical patents there have already been steps taken by the National Institutes of Health (NIH) and the United States Patent and Trademark Office (USPTO). The NIH has created guidelines asserting that research tools (patents granted for processes that do not lead to commercialization) that are developed with federal funds must be made available to other scientists under reasonable terms ([4] 18). The USPTO has also changed their guidelines to determine the patentability of biotechnology discoveries ([4] 18). While these are good steps to ensure that licensing fees for biomedical patents are reasonable, they are not concrete. Congress needs to step in and develop a plan that will protect the inventors of the research tool while still making it available to the private sector to develop into drugs and therapies. Congress could set a licensing fee for research tools deemed important to the public sector that the university must abide by. After all, financial rewards from patenting comprised only 3% percent of total funding for university research in the 2000 fiscal year ([4] 18). Thus, a smaller licensing fee for only certain research tools will not significantly impact the university. It is more important to keep the public health in mind

when considering biomedical patents than funding for universities and their right to license out patents.

The Bayh-Dole Act of 1980 has played an important role in the field of intellectual property, and will continue to have significant consequences for years to come. The country has benefited as a whole from the legislation. Universities are patenting much more and industry is producing advanced technology for the general public. However, there are some foreseeable problems associated with the act. Universities, industry and the government must be made aware of the possible negative effects of the act and take a proactive stance in preventing them from occurring.

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