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Incentives for Pharmaceutical Research and Development: Investigating the Implications of the Bayh-Dole Act on Nonprofit Basic Science Research

Adam Harvey
University of Puget Sound

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1. Introduction

Scientific research has redefined our society in the past 30 years, where technological growth and scientific development have redefined everyday life. Specifically, the research and development of pharmaceuticals, with the development of viral vaccinations and antibiotics, have permanently changed our society. Over the past 20 years there has been a dramatic increase in spending on the biomedical sciences, as scientists, as well as investors and venture capitalists, have begun to estimate and anticipate new major breakthroughs in biotechnology (Pisano, 2006). This apparent increase in scientific research has been partially accredited to the Bayh-Dole Act in 1980, which explicitly allowed the patenting of federally funded research. However, as time has passed, research has shown that the increase in spending has not caused a any increase in the output of new pharmaceuticals, where instead the marginal increase of drug output has hovered around 0 (Mowery, *et al.*, 2001). This is perhaps indicative of some fundamental flaw in the current policy-based incentive structure for the process of scientific research and development.

Theoretically, the path that science inventions take, from an initial novel discovery to a marketable drug is a linear process. "Basic" science is scientific inquiry where new discoveries are made, i.e. the discovery of a novel gene mutated in cancer. This is usually done in model organisms, such as the fruit fly, *Drosophila melanogaster*. "Applied" science is scientific inquiry, based on discoveries made in basic science, which examine the discovery's potential application to disease treatment. These studies are done on mammalian organisms, where often inquiries will first examine a simple mammal, usually a rat or mouse, and then eventually lead to studies in human tissues *in vitro* (outside the body in tissue cultures). Once a good understanding of the mammalian drug target is achieved, the information is published, and large

pharmaceutical companies take that knowledge and begin to synthesize compounds that inhibit the gene target or protein. Usually, 6000 compounds are synthesized before a "safe" inhibitor can be produced. Finally, drug companies run clinical trials in 3 phases to empirically test whether or not their drug is effective and safe, before the drug can ultimately be brought to market and distributed to the public.

The majority of "basic" science research is conducted by universities, for-profit biotech firms, large pharmaceutical companies, and non-profit research institutions. Both universities and nonprofit research institutions are primarily classified as 501 c(3) nonprofit organizations. In the non-profit sector for science research, the majority of funding is provided by government grants. Often in literature, research at nonprofit universities is simply referred to as "public research;" however, it is the case that some university research is done at least in part by donations, foundations, and other university resources. It is therefore important to note that non-profits have revenue sources other than government grants to do science research, although most literature uses the terms interchangeably.

The path from "basic" science to drug marketing is very costly. On average it takes 10 years for a possible drug target to be first discovered in basic science, a drug developed, and eventually brought to market. Along this pathway, there are many things to consider. One is the cost of massive investment in the capital required to conduct scientific research and another is the risk involved with funding any long-term scientific, where investments may take 10 years to see any potential returns.

In scientific research, risk can take the form of both competitive risk, and scientific risk. Competitive risk is the risk from working on a project or discovery, and then having the results of the study be published and potentially patented by another laboratory. This potential for

redundancy occurs often and represents a huge waste of resources, especially if the only results of one project simply repeat and confirm the results of another. The other form of risk is scientific risk. Scientific risk is the chance that a given project will either fail or produce null results. Although null results are common and usually helpful in basic scientific research at the drug discovery level, some drug targets that are selected prove to be too unsafe or incapable of being successfully interacted with by a synthesized molecule. The duality and extremity of risk involved in science creates a massive cost, as most science requires upfront investment without knowing the outcome of the project.

Another interesting aspect of the pharmaceutical research and development industry is the requirement for broad, inter-collaborative work. Specialization in the natural sciences is often an extremely specific focus, where a Ph.D.'s research focus becomes limiting in the area in which one person has the ability to make a novel contribution. For example, one area in "basic" science research is done by specialists who work only on fruit flies. Even in fruit flies, often times genetic or biochemical analyses require collaboration with chemists. This is true for every step of drug discovery and development. Often times so many specialists are required to understand the methods and results of a novel discovery, the progress on the project becomes limited at best. This will eventually be analyzed as an additional cost to drug development.

In 1980, the Bayh-Dole Act was passed by congress. The act shifted the world of science research, as it legally gave permission for all scientists performing federally funded research to seek patents for their results, and then license them (even exclusively) to other parties (Mowery, *et al.*, 1999). The passing of this act does correlate with the change the output of the quantity of patents issued to researchers, as reported in a case study to be examined in the Literature Review (Mowery and Ziedonis, 2002). The impacts of the Bayh-Dole Act will be the focus of this thesis.

Research and development produces a majority of intellectual property, with comparatively few marketable drugs. Patent law created a change in the incentives for work in the research and development industry, as discoveries have become able to be patented as intellectual property, under the Bayh-Dole Act. This allows the institution and primary researcher to own scientific discoveries as personal, intellectual property. Patent law creates the potential for any discovery to be very profitable, and creates an incentive for drug companies to focus research funding towards low-risk marketable products.

This thesis will examine the effects of the Bayh-Dole act, and present evidence that it has led to a socially inefficient outcome, defined by the over-patenting of basic science discoveries, creating a needlessly high cost to applied research, and limiting information exchange of basic science knowledge. Both information exchange and lower costs are essential to forward progress. The remainder of this paper is organized as follows: a literature review presents the current market structure and report empirical studies suggesting these market inefficiencies; an economic theory section presents relevant theoretical economic models; a results section combines the economic theory with the information presented in the literature review; finally, a conclusion sections synthesizes the arguments presented, and suggests policy changes in light of the conclusions; a bibliography is available for acknowledgements and further reading.

2. Literature Review

2.1 History of Biotechnology Development Pre and Post Bayh-Dole

Until 1980, for-profit firms were mostly large, vertically integrated companies, which did everything from molecule design to drug marketing (Cockburn, 2004). The market structure for these firms was somewhat like an oligopoly, where barriers to entry and the use of extensive patenting created market power and allowed just a few, very old firms, to control the market.

Notably, of all the inventions and discoveries that came from the process of scientific research that was produced by these firms, patents were, by a vast majority, only issued for sellable drugs. Rights to sell the synthesized drugs would be sold to maintain efficient levels of marketing, but also sold internationally, where local distributors controlled the supply at a socially efficient level (Cockburn, 2004).

Development of drugs by pharmaceutical companies was mostly dependant on the acquisition of "basic" science, which was conducted by non-profit organizations such as universities research institutions, and teaching hospitals (Cockburn, 2004). These non-profit firms were funded primarily by government research grants, but also by direct donations of interested people. For example, science at the University of Puget Sound is funded by government NIH grants, direct University resources, as well as by private donations given by alumnae. The competitive nature of acquiring government grants fueled innovation, as the grants were awarded according to the potential impact of individual studies, as well as the reputation of the primary investigator (determined by previous research). Almost all basic science produced was not patented in the pre-1980 era, with the exception of innovative discoveries that were produced by large, well established and respected research universities, such as the University of California at Berkley and Stanford University (Mowery and Ziedonis, 2002).

The post-1980 era is defined by its complexity, as thousands of smaller, venture capital biotech firms inserted themselves in between the research institutions and the larger pharmaceutical companies. This was largely due to the realization of the potential to make a substantial profit at all points in the linear model of research and development (Cockburn, 2004). These small biotech firms sought out and employed "star" researchers from the world of

academia, resulting in an exodus of university employed faculty from the nonprofit realm, into for-profit firms. This is completely different than the simplified market structure of the pre-1980 era, where post-1980 a market for scientific research included both nonprofit and for-profit firms.

Another potential reason to differentiate the two time periods is the developments in genetic, molecular, and biomedical techniques. One of the big breakthroughs in molecular techniques was first discovered in 1976, which was the purification of Taq Polymerase (Chein, Edgar, and Trella, 1976), and its future implications in the PCR reaction. Taq Polymerase is an enzyme which replicates DNA based on a primer sequence, and is used today as the primary component in Polymerase Chain Reactions (PCR) reactions. This is used as a basic tool to copy DNA and, through analysis of its molecular weight, determine what DNA is present in a given sample. The ability to detect the presence of different DNA present in a cell revolutionized the entire biomedical field. The discovery of Taq Polymerase, and other polymerases like it were discovered by basic science at the University of Cincinnati (Chein, Edgar, and Trella, 1976), and was not patented. Yet, its application in PCR was perhaps the most revolutionary tool to molecular biological techniques, which when invented in 1983 was patented instantly, and has since yielded approximately $2 billion in royalties (Fore Jr., Wiechers, Cook-Deegan, 2006).

It is debated to what extent both the Bayh-Dole Act and advancements of biotechnology contributed to the increase in patenting. A recent study found that from the pre-Bayh-Dole (1975-1979) and post-Bayh-Dole (1984-1988) there was an increase in patent intensity and a decrease in patent yield (Mowery and Ziedonis, 2002). Patent intensity refers to indicators of faculty propensity to patent their biomedical discoveries, modeled by such things as "(disclosures resulting in issued patents)/(invention disclosures)" (Mowery and Ziedonis, 2002,

Table 1). Patent yield is a measure of the benefit gained by each patent, which was modeled by indicators such as "(patents licensed)/(patents issued)" (Mowery and Ziedonis, 2002, Table 1). Once they suggested that there was in increase in patenting intensity, but a decrease in yield, they used regression analysis to show that these changes between the two time periods were due to the "rise in biomedical research and inventive activity," and not due to Bayh-Dole (Mowery and Ziedonis, 2002).

2.2 Intellectual Property Rights

Intellectual property rights are thought to promote invention and discovery by creating ideas and thoughts into theoretical goods. The creation of strong incentives for invention is always in balance with the cost associated with the idea that all new inventions and ideas are based on ideas or inventions of the past. For example, DVD movies could never have been invented before CDs were invented. Therefore, in policy making, there must always be a delicate balance between protecting the interests of the inventor and preventing an extremely high cost to forward progress (Harrison and Theeuwes, 2008).

Intellectual property can be broken up into two categories: industrial property and copyrights. Copyrights cover intellectual property concerning artistic and literary works and industrial property covers invention patents, trademarks, industrial design, and geographic indications of source (Harrison and Theeuwes, 2008, pg.146). A patent is an exclusive property right awarded for an invention and is only valid for a given time span, usually about 18-20 years (Harrison and Theeuswes, 2008). The owner of the patent may then allow other people to use the invention by the process known as licensing (Harrison and Theeuswes, 2008). Licensing rights can either be given or sold for revenue.

Intellectual property exists to protect ideas as having some value and prevent them from being simple "public goods." Public goods are defined as both non-exclusive and non-rival. The idea of non-exclusivity is that if a good is a public good, it cannot be prevented from use. Non-rival means that private consumption of the good does not diminish its available stock (Harrison and Theeuswes, 2008). Information is a classic public good. Ideas, such as mathematics, are thought up, created, and are used both non-exclusively, and in a non-rival way. Public goods are often subject to the free rider problem where, as a consumer of a public good, a person has no incentive to pay for the good if it will exist regardless if that person pays for it or not. Therefore, one can consume a public good, and ride free by not paying for it. Intellectual property rights therefore exist to eliminate the free rider problem by preventing ideas and discoveries from becoming public goods for a certain period of time.

A problematic part of intellectual property in the biotechnology field is that information goods are generally known as "experience goods" (Harrison and Theeuswes, 2008). Experience goods are goods whose value is impossible to determine until after the good is used. In biotechnology, this is relevant because many discoveries in basic science are potential drug targets by private firms, but it is impossible to tell which drug targets will be effective until after much research. Therefore, if the basic science discoveries are all protected under patents, then this creates a huge cost to the firm, as research and development of drugs has a very high degree of risk associated with it, as previously described.

Another very large limitation of patent law in biotechnology is the necessity to patent both the idea or invention itself, and the implications of the invention or idea (Friedman, 2000). Many times the fact that inventions are "experience goods," meaning that there is an inability to determine their full potential value, spills over into the inventor not being able to fully predict the

implications of a given discovery. Often times a researcher will discover a novel gene, and not fully comprehend its down stream effects. For example, the scientists who discovered *Taq polymerase*, were unable to anticipate that the enzyme they had discovered would come to be the fundamental piece to a process which, once patented, created over $2 billion in revenues.

2.3 Effects of Bayh-Dole on Number of Patents Issued and Licensing Revenues

A case study examined the patenting activity of two Universities, the University of California and Stanford University, and the effect of the Bayh-Dole Act on patent content and implications on scientific research. In 1969, 188 patents were issued by colleges and universities, which increased at an increasing rate and by 1989, reached to 1228 (Mowery, *et al.,* 2001). This was paralleled by an interesting and unprecedented change, where the (number of patents issued by universities)/(spending on research and development) increased, during a time when (overall patenting across the United States)/(R&D spending declined) (Mowery, *et al.*, 2001). Therefore, during this time period there was a shift in patenting, where more patents were proportionally issued to universities, compared to the rest of the R&D community in the United States. The study implicated both the Bayh-Dole Act and novel developments in biomedical knowledge for this massive increase in patenting by universities.

The massive surge in the number of patents issued by universities caused a massive gain in revenues from licensing those patents. These revenues grew at an increasing rate in the decade from 1985 to 1995, growing so much as 60 fold at Columbia University (Mowery *et al.*, 2001). At Columbia, approximately ninety percent (90 %) of this massive growth is accredited to the 5 top inventions, of 125 patented and licensed discoveries (Mowery *et al.,* 2001). This trend seems to be consistent with other leading research universities. At the three leading

universities, (California at Berkley, Stanford, and Columbia) the revenues in the fiscal year of 1995 from licenses exceeded $125 million in 1992 dollars (Mowery, *et al*, 2001).

2.4 Current Market for Biotechnology

The insertion of biotech firms completely reorganized the entire market for scientific knowledge. It inspired close collaborations between the nonprofit research institutions and the for-profit venture capitalist firms. Furthermore, it began to blur the distinction between the non-profit and for-profit organizations, as the two types of firms started to collaborate and coauthor publications. As of 1994, a case study analyzing 10 different, well established, for-profit firms, showed that 19-35% of the papers written were coauthored by University employed faculty, indicating a very high degree of collaboration (Cockburn and Henderson, 1996).

The collaborative effort between the for-profit and nonprofit sectors is also indicative of a bidirectional relationship between the two sectors. A study conducted numerous field interviews with industry scientists, who reported that the relationship was dependent on a high degree of mutual trust. The need for mutual trust and collaboration caused the for-profit firms to begin investigating basic science, so that information could be exchanged and traded between the different organizations. This shift by some for-profit firms, toward overlapping scientific inquiry is also known as an "investment in absorptive capacity," so that the for-profit firm had the capacity to take in knowledge and discoveries, and incorporate that information into their own system of applied scientific research (Cockburn and Henderson, 1996).

The success of a private, small biotech firm is very much dependent on the hiring of 'star' scientists at very handsome wages compared to non-profit wages (Cockburn and Henderson, 1998). 'Star' scientists usually acquire their 'stardom' by publishing innovative ideas, working within the academic environment. The value of stardom implies a possible

incentive for collaboration between private and non-profit firms. Furthermore, collaboration between for-profits and non-profits gives the small, venture capitalist firms a very important accreditation in the market for scientific research (Cockburn and Henderson 1998). However, in light of the Bayh-Dole act, some evidence indicates that efforts to realize a direct return on publicly funded research via patenting and licensing, weakens the incentives for non-profit, 'open science' research (Cockburn and Henderson 1998).

2.5 Returns on Investment in R&D

Very little research has been able to estimate the rates of return for private and public research on research and development. Though few studies have been done, the estimate for the gross rate of return on privately funded research is 33% (Hall, 1993). The estimates for the gross rate of return on publicly funded (both basic and applied) research is much more variable, with estimates ranging from 20-67% (Salter and Martin, 2000), however, these estimates focus on "successful" government programs, which is a highly subjective term, therefore causing the high degree of variability (Salter and Martin, 2000).

Aside from the rate of return differences between publicly and privately funded research and development, perhaps more important is the rate of return and impact of basic science research. A study sampled 76 US firms in seven different industries, and examined the amount of output in each firm's R&D department that depended on academic basic science research. The study found that 11% of new products and 9% of new processes were dependent on academic basic science research, and that from these estimates, the rate of return on basic science research is 28% (Mansfield, 1991; Salter and Martin, 2001).

Another way of examining the benefits and return on investments in basic science research is by qualitatively analyzing the benefits gained by the process of research, aside from

the discoveries made. According to a study by Martin, the benefits from publicly funded basic research can be broken down into six categories: 1) Increasing the stock of useful knowledge, 2) training skilled graduates, 3) creating new scientific instrumentation and methodologies, 4) forming networks and stimulating social interaction, 5) increasing the capacity for scientific and technological problem solving, and 6) creating new firms (Salter and Martin, 2001).

3. Economic Theory

Using the data and information listed above, there are many different economic theories to consider. The models that will be explained below are all derived from the information above.

3.1 Hansmen Screening- A market for basic science with both non-profits and for-profit firms

In a market where both nonprofits and for-profit firms exist, there must be a fundamental economic difference and reason for their coexistence (Hansmen, 1980). Generally, nonprofit organizations are constrained by the non-distribution effect, which means that nonprofit organizations cannot distribute any profit to an owner(s) for private gain. This means that nonprofits are generally most focused on providing the service that they were created to produce. This creates market signaling effects, where by the very nature of the for-profit or nonprofit aspect of an organization, things about the organizations can be assumed. Therefore, as a consumer, because non-profits are bound by the non-distribution effect, the signaling effects generate a predetermined understanding that an organization of this type is not only interested in fiscal compensation for their work, but primarily the quality and quantity of the work done itself (Hansmen, 1980). This is the case in the market for scientific research, where for-profit private biotech firms are created to make specialized discoveries for the profit of the researchers involved. Universities, on the other hand, generate signaling effects which suggest that they are most concerned with scientific discovery.

Given scientists have the ability to choose between two different types of firms, nonprofits and for-profits, a screening process tends to occur, where scientists most interested in the output of science will enter a non-profit or academic firm, whereas scientists most interested in fiscal compensation for their work will enter a for-profit firm. This screening process has many implications, as workers in different firms are theoretically pre-sorted according to their objective functions. This process is known as a *Screening Phenomena*, as described by Hansmen (Hansmen, 1980).

Then, according to the screening process, this creates a market where, given the option to choose, scientists concerned with the basic quest for scientific knowledge and research will tend to seek faculty positions at universities, while scientists most interested in the pursuit of fiscal compensation will enter for-profit firms. This has interesting policy implications, because the Bayh-Dole Act, which allows fiscal compensation for scientific research, is targeted towards scientists who appear to have been pre-sorted to not value fiscal compensation as highly as the ability to continue scientific research.

3.2 Bayh-Dole Seeks to Increase Marginal Private Benefit to the Researcher

The Bayh-Dole act explicitly allows the patenting of federally funded research and encourages its exclusive licensing. In a theoretical market for scientific research, the marginal private benefit of undergoing basic science research, pre-Bayh-Dole, was very small, fiscally speaking. This is because information is largely a public good, without any intellectual property rights; the value of the output of research to the investigator is minimal. The Bayh-Dole Act was passed to increase the marginal benefit to the researcher by allowing fiscal compensation for the output of research. This theoretically increases the quantity of research produced, given a constant marginal private cost. The corresponding increase in price would represent a

government subsidy, in the form of allowing the discoveries made to be patentable and sold exclusively as patent licenses.

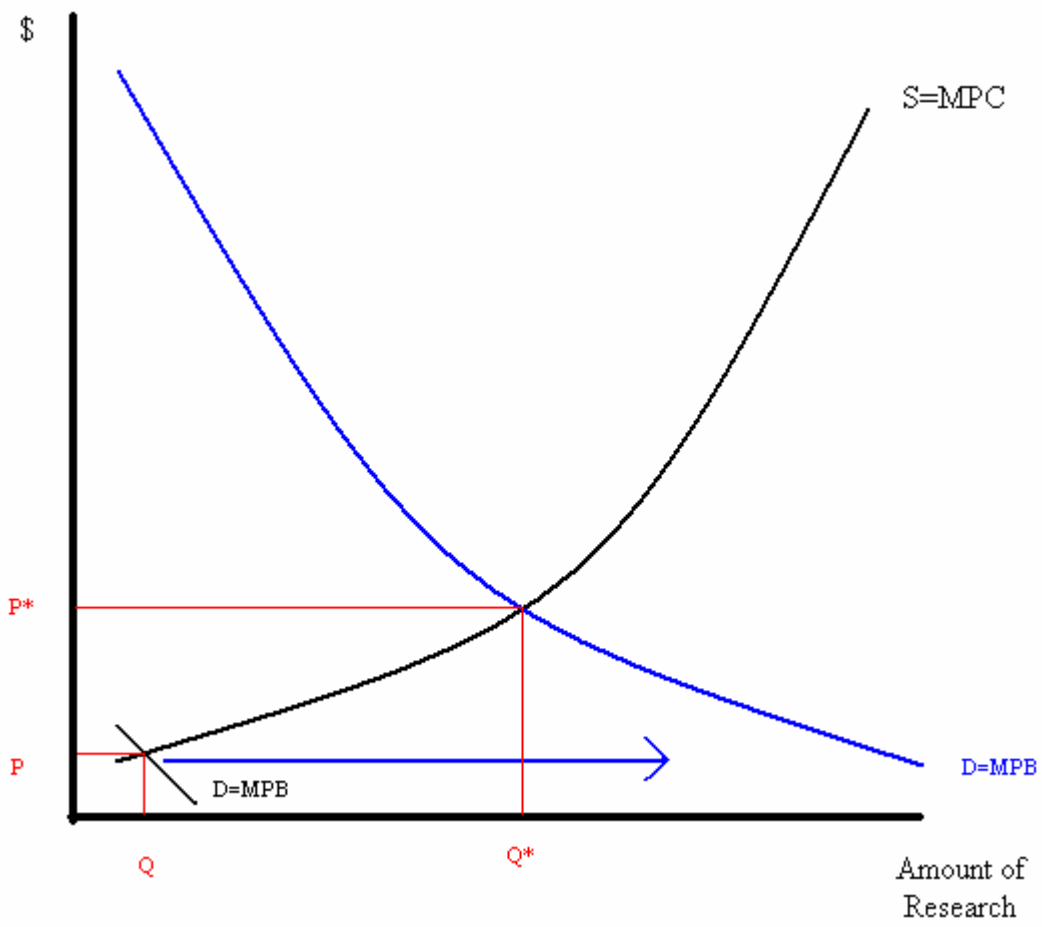


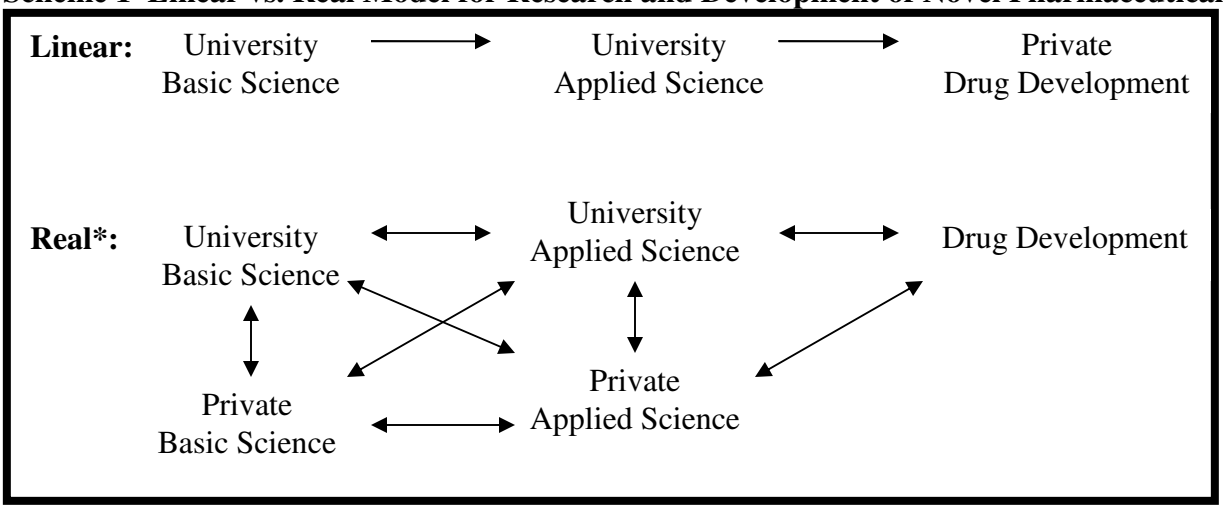
Figure 1. Theoretical Market for Research to a Nonprofit, Federally Funded Researcher
This graph depicts a theoretical market for scientific research. On the horizontal axis is the quantity of research done by the researcher and on the vertical axis, the value of the research done by a researcher. The graph shows that the Marginal Private Benefit (MPB) theoretically increases with the government subsidy. The Marginal Private Cost (MPC) is unchanged by policy decisions. The movement from Q to Q*, indicates an increase in the quantity of research done, and the movement from P to P* indicates an increase in the value of the research done to the researcher, which would be due to the theoretical potential for revenues gained from licensing patents from scientific discovery.

3.3 Co-Authorships Reject the Linear Model of Scientific Research

The theoretical linear of model of research claims that basic science research is done by universities, published as open science, and then passed on to private, for-profit firms, which develop the invention into a marketable good. Cockburn's study models the process for scientific, pharmaceutical research by co-authorships, where the number of academic

publications coauthored by researchers of different firms indicates co-operative efforts, and the flow of information. They found significant evidence that rejects the linear model and suggests a very open, bi-directional flow of information. This is also in part due to the previously described, "investment in absorptive capacity," where private, for-profit firms conduct basic science experiments that are fundamental to their applied focus and then collaborate with basic science researchers at universities whom share a similar inquiry. The resulting flow of information is represented in **Scheme 1.**

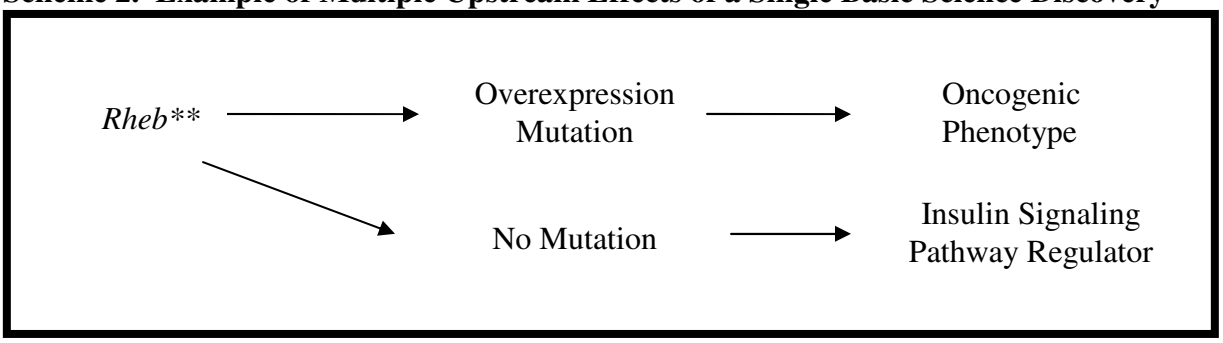
Scheme 1 Linear vs. Real Model for Research and Development of Novel Pharmaceuticals



*Based on Cockburn and Henderson (1996)

The flow of information above is based on a given discovery. The complexity of this model is compounded by the multiple implications of a single basic science discovery. For example, a gene *Rheb* is normally active in the insulin signaling pathway, but when mutated promotes various cancerous phenotypes. Therefore, this may further negate the idea of a linear pathway to drug discovery from a basic science discovery. This can be explained by **Scheme 2** below:

Scheme 2. Example of Multiple Upstream Effects of a Single Basic Science Discovery



** Based on work by Leslie Saucedo (2003)

In combining the two schemes, it seems that there is a multiple ripple effect for one basic science inquiry. Not only is one project collaborated on between both universities and other types research organizations, but also basic science can have multiple upstream applications, therefore resulting in a web-like requirement for efficient exchange of information. As the Bayh-Dole Act was created under the assumption that promoting the linear exchange of information via exclusive licensing would increase efficiency, there is potential to call into question its foundational basis.

3.4 Bayh-Dole Act Causes to Over-Patenting

After the passing of the Bayh-Dole act in 1980, the number of patents issued to US colleges and universities grew substantially, from 264 to 2436, in 1995. A case study was done at Columbia University which, before the Bayh-Dole Act, strictly prohibited the patenting of any discoveries made, mostly as a signal that the institution served the interest of science. After the act was passed, Columbia was forced to begin patenting discoveries in order to compete with other high caliber research institutions. The revenues from licensing patents from 1981 to 1995 increased from $0 to $35,000,000 (Mowery, 2001). This massive increase in revenues was due to only the top 5 of 125 patents issued to Columbia over the same time interval. Therefore, all of

the above indicates that there is a tendency to over patent and protect discoveries made by universities.

This over-patenting is likely due to a combination of scientific discoveries being "experience goods" and the low costs to patenting. As "experience goods," it is very difficult to determine the value of any basic science discovery, especially in molecular biotechnology. This is due to a few reasons: first, since basic science is conducted usually in model organisms, the function of a gene or enzyme could potentially be very different in mammalian systems. Also, often times discovery of an enzyme can happen without ever understanding its potential application, the results are published and never patented. And yet, that discovery could later turn out to be fundamental to a very valuable process, such as the discovery of *Taq polymerase* and its application in PCR as described previously (Fore, 2006).

The patenting application process is generally provided by the university or organization under which a researcher works, and therefore the acquisition of a patent for a discovery is usually provided relatively free of cost to the researcher (Fore, 2006). What little cost to the researcher that may exist in the form of the considerable time, energy, and resources required to create a patent for a discovery. The low cost of patent application combined with the ambiguity of the upstream value of scientific discovery, creates a strong incentive for the patenting scientific results, regardless of its anticipated value.

4. Results

Based on the economic theory and the review of literature, the effects of the Bayh-Dole Act seem to contradict its intended purpose. The following concepts are based off resulting combinations of the economic theories aforementioned and empirical data presented in the review of literature.

4.1 Rejection of the Linear Model implies efficiency loss by exclusive licensing

One of the primary functions of the Bayh-Dole Act was created to increase efficiency by promoting exclusive licensing of inventions upstream to private drug developers. Though in the pre-Bayh-Dole era this may have been accurate, the current market for scientific research seems to demand more cooperative work by more specialists. This is supported by the paper by Cockburn and Henderson, which rejects the linear model of science discovery in pharmaceutical research. Under the proposed, non-linear model of scientific research (See **Scheme 1.**), the encouragement of exclusive licensing seems to reject the cooperative effort that is required for drug discovery in the present conditions.

Also, the exclusive licensing of federally funded basic science discoveries is potentially limiting upstream applications when the multiple-implication aspect of basic science research is considered. For example, the gene *Rheb*, which has been previously described as having multiple implications in both diabetes and in cancer, cannot be exclusively worked on by a small, specialized firm. If the discovery was patented properly, it would cover all of *Rheb*'s implications, yet its exclusive licensing seems to limit its upstream potential by 50%.

The total efficiency loss due to exclusive licensing, considering both the non-linear model for pharmaceutical development and the multiple implications of basic science research, suggests that the Bayh-Dole Act encourages a process which, under current scientific demands, is fundamentally inefficient. Furthermore, this encouragement to exclusively license discoveries gives an incentive for a process which contradicts the actual necessity for forward scientific progress, which is an increase in collaborative effort from multiple organizations.

4.2 Hansmen Screeening suggests a smaller effect of fiscal incentives for scientific research

The Hansmen screening model suggests that in a market for basic science research, where there are both nonprofits and for profit firms, the signaling effects of both organizations will result in a sorting of those who choose to enter either type of firm. Their result of this choice is that at nonprofit universities and research centers, researchers will tend to be employed in these type of firms because their objective is to conduct as much scientific research as possible.

The screening process represents a strong argument that researchers at universities and nonprofit organizations primary goal is to publish as many solid, novel discoveries as possible. By publishing more and more articles as primary literature, researchers gain accreditation and begin to acquire "stardom" (Cockburn and Henderson, 1998). The value of researcher stardom is based in being able to acquire more government grants and produce more research. The idea can be represented in the diagram below.

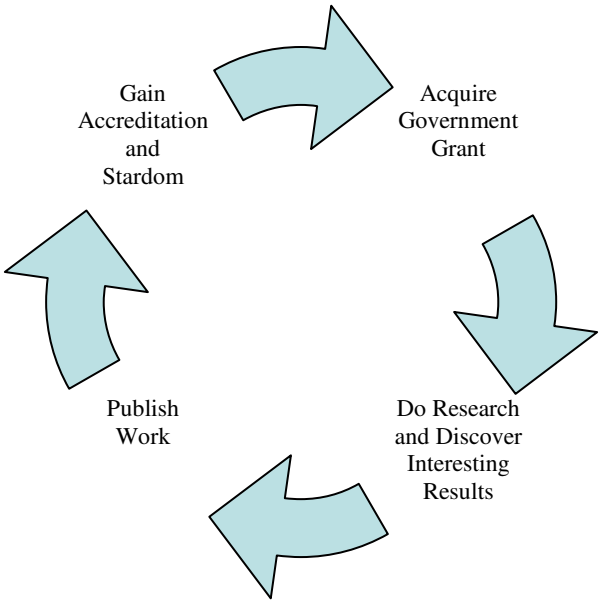


Diagram 1. Process of Acquiring More Government Grants

Given this circular incentive structure and the Hansmen sorting phenomena, it seems that the fiscal incentives to protect intellectual property are at least somewhat exogenous and over-

valued for scientists pre-selected to be more focused on acquiring stardom and accreditation, so that they may do more research. Considering this, the extent of the increase in marginal private benefit created by the Bayh-Dole Act may be much smaller than anticipated, especially in comparison to the marginal private benefit of gaining stardom.

4.3 Over Patenting is Costly

Considering a possible over-inflation of the theoretical marginal private benefit, it is also important to consider the cost side of patenting information. From the case study at Columbia University, it was found that 90% of revenues from licensing came from just 4% of the patents issued (Mowery, *et al.*, 2001). A conservative estimate would suggest that 80% of patents received very little or no revenues from licensing. Considering the biotechnology market, licenses are purchased by either specialized biotech firms or large industry firms, so that they may be made into marketable drugs. Within the purchasing of licensing rights is an extremely high fixed cost to doing pharmaceutical research. The high risks involved in drug research provides a strong incentive to focus on the lowest risk research, in order to avoid paying a high price for intellectual property whose value is determined by its use. The combination of the two ideas suggests that 80% of the patents issued are being needlessly patented, which strongly discourages their use. This causes firms to only invest in low-risk research, because the price is too high given the high degree of risk. This block to forward scientific progress represents a very high social cost, because the drug developers are being limited by their inability to invest in high-risk research, which has the potential to benefit society.

4.4 Basic Science and Government Investment

The government invests heavily in research and development. The primary federal funding of research and development in Biotechnology is done through the NIH (National

Institute of Health), which has an annual $26 billion dollar budget. Not only does this budget fund the actual scientific research, but as stated earlier in the review of literature, there are many qualitative benefits. These benefits include training skilled graduates, promoting social networks, and creating new firms. These are benefits which the government is providing exogenous to the actual funding of the research.

The value of the benefits aforementioned is highly disputable. Some economic theories suggest that nonprofit organizations provide a unique venue for investments in social capital. Social capital is the idea that through investment of time spent in networking and communication with others, mutual trust is built in a social or professional relationship (Putnam, 1995). This can work to increase efficiency, through lowering transaction costs of exchanges. In the scientific community, the lack of professional trust is a huge inhibitor of efficiency. The barrier to professional trust is due to competitive risk in scientific discovery, which results from novel discoveries only being able to be published once. Therefore, trusting peers with information that is potentially publishable requires a high degree of trust that peers will not take shared ideas and publish them as their own. The government's promotion of trust, through the creation social networks, potentially has a very high marginal social benefit. Though research and development of pharmaceuticals is not quite the same as involvement in the social groups that Putnam studied, the fundamental value of networking is similar. As the government is promoting social networking by funding basic science research, the value of the grant to the researcher exceeds its value in terms of potential for scientific research.

5. Conclusions and Policy Suggestions

The Bayh-Dole Act was passed in a different time in scientific history. Discoveries were still very fundamental in nature and there was no private sector for basic and applied scientific

research. It was passed in order to prevent an exodus of highly trained scientists from the nonprofit academic world into the private sector and claimed to theoretically promote efficiency. The analysis of this paper has shown that the Bayh-Dole Act has resulted in over-patenting, a limiting of information sharing, and an incentive system that is not applicable to a market focused on scientific research and not on making a substantial profit.

Current arguments for the Bayh-Dole Act argue that the apparent over-patenting and decline in fiscal yield/patent in science is partially due to lack of experience with patent law in the biomedical sciences (Mowery and Ziedonis, 2002). This may to some extent be true, as current patent lawyers in biomedicine require both a Ph.D. in a biological science and a degree in law. The development of this field was to a large extent re-created with the passing of the Bayh-Dole Act. Over the last 30 years, it has had to deal with a significant lag due to the amount of schooling required and available professionals in the field. Therefore, some argue that the passage of time and development of greater patenting knowledge may lead to an increased selectivity for patentable discoveries (Mowery and Ziedonis, 2002). Though this may be true, the fact remains that the output of the biomedical market, in terms of novel drugs approved by the FDA, has not changed over the past 40 years, which includes both the pre and post Bayh-Dole eras (Pisano, 2006). However, as stated earlier, this lack of growth has been parallel by a massive increase in spending. Given that theoretically, an increase in scientific investment will cause an increase in output, there still remains evidence that the Bayh-Dole Act has promoted inefficiency in the market.

The classic economic struggle in intellectual property is the fine balance between protecting and providing proper incentives for novel inventions and discoveries for researchers, while still allowing low enough costs to forward progress. It seems that in today's world, the

Bayh-Dole Act is over protecting and placing too much incentive for the researchers to patent discoveries, and limiting scientific forward progress. Therefore, new policy should be enacted that still protects an inventor's intellectual property, but discourages the current over-patenting and the limiting of forward progress.

The massive over patenting, as indicated by the Columbia case study (Mowery, 2001), suggests that the current policy-based incentive structure is encouraging over-patenting because there is not a high enough barrier to patent. In a more efficient world, only patents with large potential licensing revenues should be patented. On the supply side of publicly funded scientific research, the government is granting huge theoretical subsidies to researchers by allowing researchers to take all of the revenues from the licensing of patented discoveries without any barrier to application. This is perhaps the problem of the over-patenting. Therefore, the nexus of the need for less patents and the government's apparent over subsidizing of scientific research is recommending that under the current structure, any revenues from patent licensing must first be paid to the government until the original amount of federal funding in the research has been repaid. This would hopefully discourage the frivolous over-patenting of discoveries that would most likely never earn more than the original amount of government's investment in the research, and yet still reward and give incentive for breakthrough discoveries that would potentially earn many times over the value of the original federal investment. This change under the Bayh-Dole Act would represent a resetting of the balance between giving appropriate incentives for scientific research, while lowering the cost to future research.

Future research should empirically investigate the degree of the Hansmen sorting effect in the market for scientific research. Conversations with experts and primary researchers in basic biomedical research have indicated that the patenting of discoveries and information is

always an afterthought to the primary goal of publishing, which supports the sorting effect, but in no way confirms it. If the sorting effect could be empirically confirmed, that would represent strong evidence that fiscal incentives for basic and applied federally funded scientific research may be not be weak, while meanwhile creating massive inefficiency within the market for scientific research.

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