

# The Role of Intellectual Property in Collaborative Research: Crossing the “Valley of Death” by Turning Discovery Into Health

Nathan Pauly      College of Arts and Science, Vanderbilt University

**Technology transfer is the process of transforming basic scientific discoveries into commercial products that can be sold to the public. Historically, the federal government has been the country’s largest funder of basic biomedical research through institutions such as the National Institute of Health (NIH). Private corporations utilize scientific knowledge generated at the NIH to design drugs and medical devices that are then marketed to the American public. As a taxpayer-funded institution, the NIH has a fundamental responsibility to optimize the technology transfer process so that the American public receives the greatest return on its investment in the form of new healthcare products. Various laws passed in the 1980s have set up the technology transfer system to revolve around the dispensation of intellectual property rights. In recent years, several prominent critiques of the technology transfer system’s use of intellectual property rights have emerged in academic literature. In order to assess the validity of these critiques, I conducted ten oral history interviews with administrators at the NIH that are deeply involved in the technology transfer process. This paper will demonstrate that many of the criticisms that are posed in academic literature do not impact research at the NIH. However, interviews with officials at the NIH indicate that there is still friction in the system that prevents the American public from receiving the maximum return on its investment.**

## INTRODUCTION

The National Institutes of Health in Bethesda, Maryland is one of the largest biomedical research organizations in the world. With a research budget of almost \$30 billion a year, the NIH is dedicated to fulfilling its motto of “turning discovery into health.” Basic research performed at the NIH establishes a foundation of scientific knowledge that is utilized by private corporations, academic institutions, and non-profit organizations to create new drugs and medical devices. The process of transforming scientific discoveries supported by the NIH into commercial products is known as technology transfer. Metaphorically, technology transfer is the bridge that allows complex scientific discoveries to be delivered to consumers in the form of novel and useful products that improve health outcomes. Without this bridge, the scientific discoveries made at organizations like the NIH would never be fully accessible to the American public.

Since the 1940s, technology transfer in the United States has revolved around federally-funded scientific research being utilized by the private sector for product development and commercialization. In this sense, the United States government supports basic scientific research while the industry funds applied or commercial research. In the 1950s, federal agencies such as the NIH freely collaborated with private industries with both sides sharing materials, informa-

tion, and expertise to advance the complimentary goals of both parties<sup>1 2</sup>. At this time the federal government retained title to all patents stemming from federally supported collaborative research, and it rarely offered exclusive patent licensure to private corporations. The easy-going collaboration of the 1950s did not last long, as private corporations increasingly sought exclusive patent licenses as bargaining chips for engaging in collaborative research. Initial resentment to exclusive licensure eventually yielded and gave out completely with the passage of intellectual property laws in the 1980s. This legislation now allows for organizations collaborating with federal agencies to receive first rights to exclusive licenses on patents discovered during the course of collaborative research.

Now, many criticisms exist against the technology transfer system in the United States. Some critics contend that the liberal dispensation of exclusive licenses has made the process of biomedical research slower and the resulting products more expensive to consumers. Scientists and academic researchers have also claimed that the financial allure of exclusive licensure has made research unduly commercially oriented.

The purpose of this manuscript is to provide an overview and critical evaluation of these criticisms in light

1 Eisenberg, “Public Research and Private Development.”

2 Sampat, “Patenting and US Academic Research in the 20th Century.”

of evidence collected from technology transfer administrators at the NIH. Oral history interviews with ten administrators at the NIH reveal that the nation's largest biomedical research organization does not suffer from these issues to a large extent, yet is still plagued with unnecessary friction in the system. As an organization funded by taxpayers, the NIH has a responsibility to provide a meaningful healthcare return to the American public, and the primary way of doing so is through technology transfer. This means that any kinks in the modern technology transfer system are diminishing the returns on taxpayer investments in biomedical research.

## METHODS

This analysis is based on a historical review of the published academic and policy literature and on oral history interviews with technology transfer administrators at the NIH. Non-fiction books and peer-reviewed academic journals were the primary sources from which information was gathered. Reports prepared by the Congressional Research Service were also utilized as a source of objective information regarding modern technology transfer. When jointly analyzed, objective reports, combined with subjective criticisms, provide a well-rounded view of problems associated with technology transfer. Articles from the 1980s-90s were used to develop a historical perspective of how researchers have previously viewed problems with technology transfer.

In order to assess and refine the validity of problems presented in academic literature, oral history interviews were conducted with administrators at the NIH. Interviewees were chosen based on their professional experience with technology transfer at the NIH. Most interviewees were Technology Development Coordinators (TDCs) at individual institutes at NIH. These individuals assist scientists in organizing Collaborative Research and Development Agreements (CRADAs) and Material Transfer Agreements (MTAs) and serve as liaisons to the general Office of Technology Transfer at the NIH. These individuals were chosen due to their intimate knowledge of the technology transfer process. In order to implement successful CRADAs and MTAs, TDCs must form personal relationships with scientists both at the NIH as well as in the academic and industrial research communities. This means that TDCs are well-acquainted with the different goals and criticisms presented by a variety of researchers involved in technology transfer.

Interviewees were also chosen based off their previous work experience and tenure at the NIH. Most

interviewees had some prior background as scientific investigators. Interviewees with research backgrounds were able to explicate how individual scientific goals impact the technology transfer process. Additionally, interviewees who had worked at the NIH for several decades were able to expound on the historical perspective presented in academic literature by explaining how the technology transfer process has evolved over time.

In total, ten oral history interviews were conducted from July 23<sup>rd</sup>, 2013—August 12<sup>th</sup>, 2013, with an equal representation of both men and women. Since several interviewees requested anonymity, the names and identifying characteristics of *all* interviewees have been redacted for consistency. Interviewees were recruited using the online NIH staff directory (<http://www.ott.nih.gov/technology-development-coordinators>) and were contacted via email. The response rate (interviews conducted/interviews solicited) was 43% (10/23). Interviews lasted 24 to 88 minutes and were tape-recorded and subsequently transcribed verbatim. Nine of the interviews took place on the NIH's campus and one was conducted over the phone.

## HISTORY OF TECHNOLOGY TRANSFER IN THE U.S.: THE ADVICE OF VANNEVAR BUSH

The federal government's historical perspective on biomedical research is largely based off a report composed by Dr. Vannevar Bush in 1946.<sup>3</sup> In 1944, President Franklin Roosevelt requested that Bush make recommendations on how the federal government could increase its support of the interrelated and mutual research goals of the private and public sectors. The driving theme of Bush's report, entitled "Science: The Endless Frontier," is that the government should only be responsible for supporting basic scientific research, while the private sector should handle all applied or developmental research.<sup>4</sup> In this sense, "basic research" is used to describe the study of fundamental biological or chemical mechanisms and scientific practices. On the other hand, "applied research" refers to research that is done on a specific tool or product, usually with commercialization as the ultimate goal.

In his seminal manuscript, Bush argued that the most effective means of improving America's public health was through the generation of abundant scientific capital, which could only be accomplished through financial support of basic scientific research.<sup>5</sup> At the time, the amount of basic medical research being performed at

<sup>3</sup> Gozner, "The \$800 Million Pill"

<sup>4</sup> Bush, "Science"

<sup>5</sup> Bush, "Science"

academic institutions was on the decline, so the government took the important step of significantly increasing their financial support to external research institutions.<sup>6</sup> This was an appropriate role for the federal government because it allowed them to have an extensive impact on public health by supporting a wide variety research. The scientific capital funded by the government also benefited the private sector. Corporations were able to use this capital as a source of new ideas that could be turned into potential products. With many new industries on the rise in the 1950s, and support of scientific research at an all time high, the government was increasingly responsible for promoting the flow of new scientific information and discoveries between the public and private sectors.<sup>7</sup>

### THE GOLDEN DAYS OF COLLABORATIVE RESEARCH

In keeping with the government's new aim to stimulate the flow of scientific information, the years from 1946 to 1962 saw an unprecedented amount of collaboration between government agencies and the private industry. During the 1950s, pharmaceutical companies would conduct preliminary tests free of charge on new chemical entities discovered by NIH investigators as potential drug candidates.<sup>8</sup> <sup>9</sup> Dividing the labor while also sharing brainpower and resources was viewed as the most effective method of advancing the goals of both the government and the private sector. At the time, the federal government retained the title to all patents that were based off discoveries made with federal funding. However, NIH grantees could petition the government to waive federal rights to the patent, and instead award it to the grantee or their institution.

It is noteworthy that this system allowed grantees and their institutions to offer non-exclusive licenses to any collaborating firms such as pharmaceutical companies. Since the prospect of obtaining an exclusive patent was rare, most pharmaceutical companies relied on brand loyalty and detailing to physicians to obtain a foothold in the market.<sup>10</sup> Overall, the 1950s and early 1960s were an era where collaborative research was unhindered by intellectual property agreements.

The prescription drug market grew rapidly from the 1940s to early 1960s, and as a result the largest pharmaceutical companies in the United States began

increasing funding for research and development, advertising, and detailing<sup>11</sup>. These changes coincided with the passage of the 1962 Federal Food, Drug, and Cosmetic Act, which included the groundbreaking Kefauver-Harris Amendments. The Kefauver-Harris amendments revolutionized the drug approval process by requiring pharmaceutical companies to demonstrate both the safety *and* efficacy of potential new drugs.<sup>12</sup> This amendment introduced the standard four phase clinical trial process that is still utilized by the Food and Drug Administration (FDA) to this day. Senator Estes Kefauver (D-TN) was also interested in lowering the cost of drugs to consumers by reducing patent protections and increasing competition from the generic market.<sup>13</sup> Ironically, the amendment went on to have the exact opposite affect that Senator Kefauver had intended. The stipulation to prove the efficacy of a new chemical entity meant that pharmaceutical companies had to significantly increase spending on research and development, which prevented many smaller firms with limited capital from entering the market. Additionally, the new four-phase clinical trial process meant that it took much longer for a potential drug to enter the market and actually caused Congress to extend patent protections for pharmaceutical products to compensate for the time lost while demonstrating efficacy.

To compensate for the high costs of research and marketing, pharmaceutical companies increasingly relied on patent licenses from NIH grantees to secure their market share and discourage competition.<sup>14</sup> In response to this trend, the NIH instituted a new patent policy in 1962, which required all NIH-funded investigators who collaborated with third-party contractors to sign intellectual property agreements *prior to* engaging in collaborations.<sup>15</sup> Although superficially benign, this new policy severely restricted the scope of patent rights that could be assigned to contractors—both for their contributing work and for their research on other “neighboring” research projects.<sup>16</sup> The new policy at the NIH resulted in almost every major pharmaceutical company refusing to collaborate with NIH grantees on any form of research.<sup>17</sup> This signaled an abrupt end to the so-called “golden days” of collaborative research between industry contractors and investigators funded by NIH grants. For several ensuing years, any form of collaborative research involving NIH grantees

6 Bush, “Science”

7 Bush, “Science”

8 Eisenberg, “Public Research and Private Development”

9 Sampat, “Patenting and US Academic Research in the 20<sup>th</sup> Century”

10 Mazzoleni, “Before Bayh-Dole”

11 Mazzoleni, “Before Bayh-Dole”

12 Greene and Podolsky, “Reform, Regulation and Pharmaceuticals”

13 Greene and Podolsky, “Reform, Regulation and Pharmaceuticals”

14 Mazzoleni, “Before Bayh-Dole”

15 Eisenberg, “Public Research and Private Development”

16 Mazzoleni, “Before Bayh-Dole”

17 Mazzoleni, “Before Bayh-Dole”

and the pharmaceutical industry was mired by excessive paperwork and regulations regarding intellectual property agreements.

In 1968, the NIH finally revised the terms of the 1962 patent policy and began overtly encouraging the patenting and licensing of inventions discovered by NIH grantees.<sup>18</sup> In a very short period of time, this amended agreement was able to successfully rekindle the collaborative relationship between NIH-funded investigators and the pharmaceutical industry. With this revision, the NIH also began explicitly allowing industry contractors to seek exclusive licenses for inventions that could not have been developed without this provision.<sup>19</sup> Since a significant financial investment may be required to commercialize a basic patent, exclusive licenses are often necessary so that companies can guarantee an appropriate return on their initial investment. This argument is bolstered by the fact that the vast majority of patented pharmaceutical compounds never successfully pass the four stage clinical trial process required by the FDA. According to one logic, if a pharmaceutical company is willing to invest millions of dollars on a product that may never make it to market, they at least deserve some guarantee that any successfully commercialized products will be protected from market competition in the future.

#### COLLABORATION IN THE SHADOW OF BAYH-DOLE

The origins of the NIH's modern technology transfer system can be traced back to the passage of the Bayh-Dole Act of 1980. At the time, the federal government was investigating how it could create an efficient system for transporting federally funded basic research into the private sector for commercialization. Supporters believed that such a system could provide a better return on taxpayer investments, by providing them with new drugs and medical devices, while also accelerating the output of American industries. The Bayh-Dole Act, along with several other pieces of legislation that shortly followed, put in place a system that allowed NIH grantees—instead of the federal government—to hold title to patents that were developed with federal sources of funding. In addition to this, NIH investigators were explicitly encouraged to offer exclusive licenses to private corporations.<sup>20</sup> The potential for exclusive licenses meant that businesses were more likely to pick up discoveries where the government left off. This was an especially important goal

18 Eisenberg, "Public Research and Private Development"

19 Mazzoleni, "Before Bayh-Dole"

20 Rai and Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine"

after a study conducted in the 1970s found that less than five percent of the patents held by the federal government had ever been licensed.<sup>21</sup> If a patent is never licensed to a private corporation, it likely will never be commercialized and the public will not benefit from its discovery. Therefore, the public advocates that it is imperative that the federal government seeks the maximum public benefit in all of its research efforts so that taxpayers can potentially receive the maximum return.

Today's technology transfer system as set forth by the Bayh-Dole Act has fulfilled the research goals laid out by Dr. Vannevar Bush 44 years before the law's passage. Now, the government is able to focus on performing and funding basic research, which can be turned over to NIH investigators or academic institutions in the form of patents. These patents are then licensed by private industries that seek to gain a profit from commercialization. This partnership accommodates the Roosevelt Administration's belief that the ideal research system is one in which the government only performs basic research while the private sector funds applied research for commercialization.

#### HISTORICAL REVIEW OF CRITICISMS: ARE EXCLUSIVE LICENSES NECESSARY?

Original critics of the Bayh-Dole Act argued that it forced Americans to pay twice for many medical products<sup>22</sup>: once as the tax payer who funded research performed by government investigators, and again for the actual product once it had been licensed and commercialized by a private corporation. Furthermore, the exclusive licenses allowable to companies under the Bayh-Dole Act are widely blamed for the relatively high cost of drugs and medical devices in America.<sup>23</sup> Public opinion surveys continue to show that American citizens vastly disapprove of the costs associated with pharmaceutical products.<sup>24 25</sup> In a 2008 study, almost 75% of respondents claimed that they would like to see additional price controls for pharmaceuticals, even if it meant that companies would perform less research and consequently release fewer products.<sup>26</sup>

21 Goozner "The \$800 Million Pill"

22 Schofield, "The Demise of Bayh-Dole Protections Against the Pharmaceutical Industry's Abuses of Government-Funded Inventions."

23 Schofield, "The Demise of Bayh-Dole Protections Against the Pharmaceutical Industry's Abuses of Government-Funded Inventions."

24 *The Public on Prescription Drugs and Pharmaceutical Companies.*

25 Palosky, *Americans Value the Health Benefits of Prescription Drugs, But Say Drug Makers Put Profits First.*

26 *The Public on Prescription Drugs and Pharmaceutical Companies.*

Assuming that the government is operating in the best interest of the American public, this issue raises several questions: do the results of these public opinion surveys indicate that the government is mismanaging taxpayer money, by allowing it to contribute to the procurement of exclusive licenses by pharmaceutical corporations? Or are exclusive licenses, and consequently expensive pharmaceutical products, inevitable outcomes of any technology transfer system in today's medical economy?

The authors of the original Bayh-Dole Act included "march-in rights" for the federal government. These rights vest in the government a non-exclusive, paid-up license to utilize or distribute any government funded invention if the original licensing partner has not achieved appropriate "practical application" of the patent.<sup>27</sup> In the language of the law, practical application is taken to mean that, "the invention is being utilized and its benefits are... available to the public on *reasonable* terms."<sup>28</sup> This clause was originally meant to ensure that any federally funded discovery would be disseminated in a way that was optimally beneficial to the public. However, due to the ambiguity of the aforementioned "reasonable terms," the government has only employed its march-in rights on a handful of occasions.

One of these instances occurred in 2003 when the company Essential Inventions petitioned the NIH to prevent Abbot Labs from carrying out a 400% price increase of their antiviral HIV/AIDS drug, NORVIR. The NIH eventually ruled in Abbot's favor, citing that march-in rights are not meant to serve as a form of price control.<sup>29</sup> Though this issue was raised because of public outrage over drug prices, the heart of the matter is the availability of exclusive patents. If the NIH had stepped in to reduce the cost of NORVIR, they would have infringed on the exclusive license issued to Abbot Labs. This would have set a precedent of diminishing the value of exclusive licenses to pharmaceutical companies, which experts agree are critical incentives that drive investments in research and development.<sup>30</sup>

### THE PROBLEMS OF EXCLUSIVE LICENSING

The Bayh-Dole Act was passed based on the as-

sumption that exclusive licenses could be used as incentives for companies to invest substantial financial and human resources toward the development of a product. Additionally, the act further defrays the cost of research to licensing partners because it allows companies access to basic research that was performed with government funding. Ironically, the Bayh-Dole Act was meant to assist companies in coping with the high costs of research and development, but now some scholars contend that aspects of the law have actually made the process of research slower and more expensive. Critics argue that the Bayh-Dole Act and its associated legislation have placed undue importance on the procurement of intellectual property, which has resulted in the formation of what some call a "patent thicket" or "anti-commons" associated with biomedical research.<sup>31 32</sup>

The "tragedy of the commons" was a theory first proposed by biologist Garrett Hardin in 1968. Hardin argued that any resource that is available to every citizen—such as the atmosphere or ocean—will inevitably be overused and eventually depleted. The tragedy of the *anticommons* is used to describe situations that are the opposite of this. When a commodity is controlled by select group of people who can limit access to it, that resource will be underused and will not achieve its maximum beneficence. Critics of the Bayh-Dole Act argue that it has allowed for an increasing number of patents on basic or "upstream" research that can make it more difficult for competitors or other organizations to perform applied or "downstream" research.<sup>33 34</sup> Upstream patents can be beneficial when used as a bargaining chip to encourage investment into a potentially risky area of research. On the other hand, too many upstream patents can deter research in certain fields or prevent market competition, which can lead to commercial products that are unreasonably priced.

When a large number of upstream patents exist regarding a certain area of research, it can lead to a "patent thicket."<sup>35</sup> In these situations, companies or academic institutions maintain titles to patents that cover important research tools or techniques, which they can choose to license or not license to external organizations. It was originally thought that business-minded patent holders would be open to the idea of licensing technologies—for

27 Schofield, "The Demise of Bayh-Dole Protections Against the Pharmaceutical Industry's Abuses of Government-Funded Inventions."

28 35 U.S.C.A. § 201(f) (emphasis added)

29 Schofield, "The Demise of Bayh-Dole Protections Against the Pharmaceutical Industry's Abuses of Government-Funded Inventions."

30 Schacht, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*.

31 Rai and Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine"

32 Heller and Eisenberg, "Can Patents Deter Innovation?"

33 Heller and Eisenberg, "Can Patents Deter Innovation?"

34 Kesselheim, "An Empirical Review of Major Legislation Affecting Drug Development."

35 Rai and Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine"

a fee—to external investigators. However, it has been seen that some companies have intentionally withheld licensing privileges in order to suppress market competition. An example of this was the serious restrictions put on academic researchers wishing to license DuPont’s “oncomouse.”<sup>36</sup> The oncomouse is an important organism for cancer research but the research restrictions stipulated by DuPont hindered the types of experiments that could be performed. Although the licensing fee associated with the oncomouse may have been relatively low, the opportunity cost of preventing groups from performing certain types of research is incalculable. Situations such as this have been seen outside the biomedical industry as well.

### UPSTREAM PATENTS CLOGGING THE PIPELINE

In any research-based industry, excessive proprietary claims often impede the development of emerging technologies.<sup>37</sup> This is particularly true in regards to the pharmaceutical and chemical industries because discoveries in these fields almost always build on the findings of previous research. Discoveries made in these industries are also generally simple to replicate once made, making it especially important for companies to procure patents on upstream research.<sup>38</sup> Critics of the Bayh-Dole Act, argue that private corporations and academic institutions are increasingly seeking patents on upstream research because of the two aforementioned factors.<sup>39</sup>

This accusation is troubling especially when considering that the NIH still primarily funds basic research, which may require licensing of upstream patents. Though many companies are completely willing to license their upstream discoveries, the non-exclusive licensing fees increase the cost associated with an already expensive research process. Upstream patents can also make the research process significantly slower. When companies negotiate licensing agreements with external organizations it can take anywhere from minutes to months to reach a consensus. This impedes the pace of research and can increase the time it takes for ongoing projects to reach a stage of clinical significance. Even former NIH Director Harold Varmus shared these concerns. As stated in a July 2000 hearing, Varmus claimed that he was, “troubled by widespread tendencies to seek protection of intellectual

property increasingly early in the process that ultimately leads to products of obvious commercial value, because such practices can have detrimental effects on science and its delivery of health benefits.”<sup>40</sup> Upstream patents have the potential to be beneficial, but in many circumstances they merely act as tollbooths that make the road to discovery both slower and more expensive.

### COMMERCIALIZATION OF THE IVORY TOWER

Since the passage of the Bayh-Dole Act, the number of patents issued to institutions of higher learning in the US skyrocketed from 390 in 1980 to 2725 in 2005.<sup>41</sup> In addition, the number of technology transfer offices at US universities increased from 25 in 1980 to 200 in 1990.<sup>42</sup> The confluence of these trends has led some scholars to suggest that the passage of the Bayh-Dole Act has made government sponsored academic research more commercially oriented.<sup>43 44</sup> At first glance, this is not an entirely negative outcome. Indeed, one of the primary goals of the Bayh-Dole Act was to facilitate the commercialization of federally sponsored research. However, increased industry support of university research could lead to conflicts of interest that fundamentally compromise the values of academic research.<sup>45</sup>

Academic researchers can benefit from university-industry partnerships in the form of consulting fees, royalty payments and/or company stock options. These financial ties potentially create a conflict of interest that can affect, “the quality, outcome, and dissemination of research” in a way that is beneficial to the industry but not necessarily to public health.<sup>46</sup> Studies have also shown that universities that collaborate with the pharmaceutical industry on commercialization activities are more likely to delay publication and have restricted dissemination of research results.<sup>47</sup> Stymieing the free-flow of information out of academic organizations delays the advancement of scientific knowledge and impedes the innovation of new medical technologies.<sup>48</sup> Almost 80% of the NIH’s research

40 Schacht, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*.

41 Schacht, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*.

42 Shane, “Encouraging University Entrepreneurship?”

43 Kesselheim, “An Empirical Review of Major Legislation Affecting Drug Development.”

44 Culliton, “NIH, Inc.”

45 Schacht, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*.

46 Cho et al., “Policies on Faculty Conflicts of Interest at U.S. Universities.”

47 D Blumenthal, “Withholding Research Results in Academic Life Science. Evidence from a National Survey of Faculty.”

48 Florida, “The Role of the University”

36 Rai and Eisenberg, “Bayh-Dole Reform and the Progress of Biomedicine”

37 Rai and Eisenberg, “Bayh-Dole Reform and the Progress of Biomedicine”

38 Schacht, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*.

39 Rai and Eisenberg, “Bayh-Dole Reform and the Progress of Biomedicine”

budget goes towards extramural research, which is primarily conducted at academic institutions. Therefore, it is imperative that the NIH avoids the conflicts of interest associated with university-industry collaborations.

Universities are not the only institutions that have been asked to restrict the dissemination of research results or information due to collaboration with a pharmaceutical company—the NIH has faced similar problems when engaging in CRADA's with the private sector. In an article written several years after the passage of the Federal Technology Transfer Act, scientists at the NIH expressed concerns that the research culture was fundamentally changing to become more business oriented.<sup>49</sup> Director of the National Institutes of Allergy and Infectious Diseases, Anthony Fauci, was quoted in the article as saying, “for the first time in 21 years at the NIH, I detect an inkling of hesitation among scientists about sharing information.”<sup>50</sup> The NIH, which was once seen as one of the few research institutions that had the capacity to escape commercial influences, could no longer claim to be untainted by conflicts of interest. Since NIH scientists are now allowed to receive royalties from patents that arise from CRADA's, it must also be considered how this financial incentive plays into the individual decision to engage in research collaborations. This creates an opportunity for NIH scientists to operate in their own best interests instead of advancing the research goals at the NIH.

#### RESULTS: EXCLUSIVE LICENSES AS AN INCENTIVE TO COLLABORATE

In July of 2013, ten oral history interviews were conducted with administrators involved in technology transfer at the NIH, and it became clear that many of the criticisms leveled against the Bayh-Dole act do not significantly affect the NIH to a large extent. However, the interviewees were remarkably consistent in their assessments of other problems that generate friction and/or waste in the technology transfer system. Criticisms posed in the academic literature often assume that problems associated with technology transfer originate from the use of patents as incentives to perform research. This contrasts sharply with the views expressed by the technology transfer community at the NIH. The opinion of some NIH administrators is that the problem does not stem from the patents offered by Bayh-Dole—rather, the Bayh-Dole act has not been able to keep up with the rapid pace of modern biomedical research. The criticism that federally funded

research is becoming more commercially oriented is actually an idea that is embraced by Technology Development Coordinators at the NIH. If the government wants to optimally fulfill unmet health needs, then it has to do more to support research at the product end of the spectrum. One sentiment that was expressed by nearly every interviewee is that the government generally operates and changes at a slower pace than any private industry. Because of this, the NIH seems to be operating on an outdated philosophy and may need to recalibrate its research balance to truly optimize the technology transfer process.

Exclusive licensing agreements associated with pharmaceutical products are one reason why brand name drugs are relatively expensive in the United States. Market exclusivity prevents any form of competition for many pharmaceuticals meaning that companies can charge whatever price they see fit. Public opinion surveys show that as much as 79% of Americans believe the cost of prescription drugs are unreasonable,<sup>51</sup> however, the technology transfer community at the NIH offered a very different perspective. One Technology Development Coordinator (TDC) at the NIH believes that, “unless you give a company a certain period of exclusivity they're not going to invest their money into getting that drug out there... you need to have that patent to incentivize the original investment.”<sup>52</sup> A TDC at a different institute echoed her belief, saying that exclusive licenses are necessary “to use as a carrot, as a risk mitigation tool, to have a commercial entity come in and advance a development to commercialization.”<sup>53</sup>

During the interviews, administrators at the NIH did not try to refute the argument that the Bayh-Dole act forces consumers to pay twice for pharmaceutical products. Instead, they accepted that allowing private corporations access to exclusive licenses is the only way to ensure that new discoveries will eventually reach the marketplace. In their minds, paying twice for a product is a better option than having nothing to buy.

A technology transfer system that revolves around the assignment of intellectual property is essential to American research, “because the government doesn't market anything directly, we don't produce consumer goods but we produce the technology that will enable a company to produce a consumer good. We're basically like a source of innovation.”<sup>54</sup> Other TDC's agreed that the NIH's role,

51 *The Public on Prescription Drugs and Pharmaceutical Companies*.

52 Smith, Wendy. Personal Interview. 23 July 2013

53 Williams, Matt. Telephone Interview. 12 August 2013

54 Smith, Wendy. Personal Interview. 23 July 2013

49 Culliton, “NIH, Inc.”

50 Culliton, “NIH, Inc.”

as a source of innovation and consequently intellectual property will become more prominent in the near future, as many large pharmaceutical corporations have begun dissolving their basic research departments. A senior member of the Office of Technology Transfer asserted that at many pharmaceutical companies, “it used to be almost like 80% internally generated products, and now it’s 80% externally generated intellectual property.”<sup>55</sup> This is beneficial for industry because companies are not locked into research they are already doing—instead, they can wait and choose which discoveries to invest in. On the other hand, this can increase costs for the NIH because now:

“Big pharma wants all of the preclinical work to be done with no investment. Pre-clinical is talking many millions and 7-8 years of work... and then if it fits pharma’s interest, having done zero developmental work for it, they are ready to take it, see if they can get a product, and make money from it.”<sup>56</sup>

This reflects an increased propensity for the pharmaceutical industry to sit back and wait for external organizations to perform preliminary development on new discoveries. This “wait and see attitude” could significantly contribute to prolongation of the well-publicized “valley of death” associated with pharmaceutical research.<sup>57</sup>

Critics of the Bayh-Dole Act lament that the government’s march-in rights have never been successfully used to challenge the pricing of pharmaceutical products. However, interviewees at the NIH maintained that excessive use of march-in rights would only further widen the valley of death because it would frighten potential industry partners away from collaboration. It is important to note here that both aforementioned situations involving the valley of death are largely beyond the control of the NIH and the federal government. In fact, the NIH may be one of the primary organizations responsible for mitigating the affects of the valley on public health. This situation has arisen due to fundamentally different research goals at the NIH and in the industry. Any publically traded corporation has a responsibility to maximize profits for their shareholders. On the other hand, the only shareholder of the NIH is the American public, so the agency’s goal is to serve the public by “turning discovery into health.”<sup>58</sup> The pharmaceutical industry’s “wait and see attitude” and

denouncement of march-in rights are financially beneficial to an industry whose success is not directly related to the optimization of public health outcomes. Ironically, when drugs are too expensive or new products are few and far between, it is often the federal government that takes flak for not providing taxpayers with a better return on their investment in biomedical research.

### TRANSCENDING THE PATENT THICKET

The technology transfer community at the NIH is well-aware of the criticisms associated with the Bayh-Dole Act, and particularly with the argument that intellectual property has created a patent thicket or anti-commons in biomedical research. When questioned about the validity of a patent thicket at the NIH, interviewees had a variety of responses, claiming it was nonexistent at best or an annoyance at worst. Regardless of how individual participants assessed the issue, it was clear that this is not a pressing problem for the NIH. Several participants discounted the patent thicket as hypothetical, partially because it is propagated by scholars that are not members of the scientific community. “That has been proposed by some, I believe law school faculty,”<sup>59</sup> responded a member of the Office of Technology Transfer when asked about the potential anticommons. Other interviewees referred to a complete lack of empirical data to support the patent thicket theory. The patent thicket is typically argued to primarily affect the basic or upstream aspects of research. Since most of the interviewees at the NIH were members of intramural research divisions, this is the area where they have the most expertise. Therefore, the opinions of technology transfer administrators at the NIH should be understood as a more accurate assessment of problems than the assumptions of scholars outside the scientific community.

The main reason why the NIH escapes the effects of any patent thicket associated with biomedical research is that NIH scientists typically are not overtly concerned with obeying intellectual property rights. Several TDC’s in different institutes attested to the statement that, “usually they’re [NIH scientists] not reviewing patent literature.”<sup>60</sup> Scientists neglect to review intellectual property rights because, “there are so many patents out there it takes an inordinate amount of time to know if you have the freedom to operate because you have to search through so much literature.”<sup>61</sup> When asked about the potential legal

55 Crawford, Joel. Personal Interview. 25 July 2013

56 Michaels, Rick. Personal Interview. 25 July 2013

57 Butler, “Crossing the Valley of Death.”

58 NIH.gov. National Institutes of Health, 2013. Web. 18 January 2014

59 Crawford, Joel. Personal Interview. 25 July 2013

60 Crawford, Joel. Personal Interview. 25 July 2013

61 Jones, Debra. Personal Interview. 25 July 2013

ramifications of using a patented research tool off license, one TDC candidly answered, “We don’t worry about it... what are they going to do, sue us?”<sup>62</sup> Many organizations are happy to overlook the NIH’s use of patented research tools or techniques because private corporations realize that federally-funded research probably contributed to any patent that the NIH may be violating. Even if this is not the case, a senior member of the Office of Technology Transfer asserted that companies are hesitant to enforce patent rights at the NIH because, “it’s been sort of a public relations disaster for anyone who has tried it.”<sup>63</sup> Furthermore, any individual scientists that a corporation could prosecute likely would not have sufficient financial capital to make legal action worthwhile for the company.

If an NIH scientist requires the use of a patented reagent that is not commonly available, they can procure that item through a material transfer agreement (MTA) with the licensing organization. The licensing fees associated with procuring a reagent are small in comparison to the overall cost of research, and in the words of one TDC, “we don’t sting out, if something’s for sale we buy it”<sup>64</sup> Usually the cost is not a primary point of concern because many companies do not require payment for licensing if the tool or reagent is only being used for research purposes, and not to develop a commercial product. Although this makes it sound as if scientists at the NIH can easily acquire anything they need, procuring the research tools can actually be an arduous process. Some companies will simply refuse to share their discoveries, while others will insist on restricting use of their tools. When asked about the effects of this defensive patenting strategy on research, one TDC said, “I think it does add cost and time to research, you know, whenever you involve lawyers in things it adds cost and it adds time.”<sup>65</sup> While individual negotiations may not be particularly expensive, it can add up to a significant amount over. Additionally, the opportunity costs of delaying a research project are incalculable. However, it is important here to note that these problems are not the result of patents themselves, but rather the way that they are employed by certain organizations.

Much like it has with the valley of death, the NIH has also taken the lead on mitigating the negative consequences of any anticommons associated with biomedical research. According to one TDC, the “NIH has been really at the forefront of trying to discourage patents on

things that are strictly research tools.”<sup>66</sup> These tools are the upstream research products are the primary contributors to any perceived patent thicket, so this is the most important intervention point to impede the phenomenon. Since the late 1990s, the NIH has encouraged more academic institutions to adopt their philosophy, and now the “NIH is a little ahead of the curve and more of them have been taking the same type of approach over time.”<sup>67</sup> Now, the NIH freely licenses any of its patented research tools to non-profit or academic organizations and has taken additional steps to foster an open biomedical research environment. For example, if the NIH funds the development of a transgenic animal, they require funded investigators to have a plan in place for widely distributing any resulting discoveries. These animals are recognized as valuable research tools, so it will benefit all researchers as well as public health as a whole to have them openly available to any qualified investigator.

#### NIH NOT SELLING OUT

Shortly after the passage of the Bayh-Dole Act, some scientists at the NIH expressed concern that the ability for scientists to engage in CRADAs with the pharmaceutical industry could make research more commercially oriented. However, several decades later, it is apparent that this has not been the case. Research at the NIH has not become more commercially oriented primarily because individual scientists are generally not driven by the goal of receiving royalty payments. Scientists at the NIH derive importance from the problem solving aspects of research rather than the potential monetary benefits of pursuing patents. When asked if royalties are something that scientists at the NIH strive for, the executive officer of one institute summed up this sentiment perfectly:

“It’s not really a driving factor at all, to them it’s the scientific discovery. In fact, when I talk to them about filing the employee invention report and what the potential benefit could be, they’re surprised that they could financially benefit from us getting a royalty from their invention.”<sup>68</sup>

Individual scientists at the NIH were not able to receive royalty payments for their patents until the passage of the Federal Technology Transfer Act of 1986. The fact that some scientists still do not realize this opportunity exists

62 Combs, Mary. Personal Interview. 24 July 2013

63 Crawford, Joel. Personal Interview. 25 July 2013

64 Combs, Mary. Personal Interview. 24 July 2013

65 Deed, Bill. Personal Interview. 25 July 2013

66 Smith, Wendy. Personal Interview. 23 July 2013

67 Smith, Wendy. Personal Interview. 23 July 2013

68 Deed, Bill. Personal Interview. 25 July 2013

is a clear indication that potential royalties are not the primary driving factor when deciding what research to pursue.

An additional reason why research at the NIH has not become more commercially oriented is simply that researchers are not evaluated on the quality or quantity of their patents. “At NIH, research is our goal, and publication is our currency,”<sup>69</sup> claimed one TDC when asked about motivation for patents. This analogy captures the notion that peer reviewed publications are still the gold standard of judging research performance. When scientists are considered for tenure, they are evaluated based on the quality and quantity of their publications, not on their patents or royalties they received. This is beneficial for many scientists who believe too much focus on commercialization could corrupt the pristine basic research environment at the NIH. However, there are signs that some scientists are moving against this trend. A senior member of the Office of Technology Transfer said, “We are getting requests now more than before where people will ask for a list of their patents... to include them in their CV or their list of publications.”<sup>70</sup> The NIH still operates on a publish first patent later philosophy, but patents seem to be gaining ground in terms of importance, at least in the eyes of some individual scientists.

### ELIMINATING FRICTION

The NIH has escaped the influence of many problems associated with the Bayh-Dole Act, while also working to mitigate the effects of the valley of death and patent thicket for other institutions. That being said, interviews with technology transfer administrators revealed a host of other problems that currently plague the technology transfer process. If addressed properly, the elimination of these problems will reduce friction in the technology transfer system and optimize the taxpayer investment in biomedical research. However, in order to truly fulfill its motto of, “turning discovery into health,”<sup>71</sup> the NIH needs to change its research culture in a way that will make it more supportive of applied research. Technology transfer is the bridge that brings federally funded discoveries and innovations to American consumers. Without supporting applied research, the NIH will never allow that bridge to span its full potential.

Although the NIH is not unduly impeded by the patent thicket associated with some biomedical research,

69 Long, Amy. Personal Interview. 23 July 2013

70 Crawford, Joel. Personal Interview. 25 July 2013

71 NIH.gov. National Institutes of Health, 2013. Web. 18 January 2014

there are still several aspects of the technology transfer system that could be significantly improved to increase efficiency and the time frame of innovative delivery to the public. One source of waste identified by numerous interviewees is the inordinate time spent in negotiations that may be required for the NIH to engage in a CRADA or MTA. These agreements are important to the NIH because they are the primary avenues by which NIH investigators collaborate with the private industry. However, the amount of time and money it often takes to reach a successful compromise can possibly discourage federal and industry scientists from engaging in collaborations. When discussing the regulatory hurdles that are required to implement a CRADA, one official said:

“For the whole CRADA mechanism everybody tries to avoid it if they can because industry finds it much too slow and for us it’s an awful lot of hours and hours of work to put that in place... we might have slowed ourselves down so much that we just aren’t very competitive in today’s world.”<sup>72</sup>

Thus it seems that the reluctance of NIH investigators to engage in CRADAs may be hindering the research potential of the NIH by preventing new collaborative endeavors. Many CRADAs yield intellectual property, which is used to spur further product development. In neglecting to participate in CRADAs, researchers may be restricting the creation of novel products that are potentially beneficial to public health.

Technology transfer officials at the NIH indicated that streamlining the agreements associated with CRADAs could greatly improve the technology transfer process. The same opinion was expressed, although to a lesser extent, regarding MTAs. Decades ago many academic institutions agreed to a Universal Biological Material Transfer Agreement (UBMTA), which standardized the process of sharing biological materials with the NIH. However, many institutions have ceased use of this universal agreement and instead conduct individual negotiations for any material being shared. If more academic organizations revert to using the UBMTA and share the agreement in an electronic format (i.e. via email), it could greatly expedite biomedical research, according to one Technology Advancement Officer.<sup>73</sup> If the NIH makes it easier to engage in CRADAs and MTAs, it will save the organization both time and money while also attracting

72 Adams, Jane. Personal Interview. 25 July 2013

73 Jones, Debra. Personal Interview. 25 July 2013

additional collaborative partners.

Interviewees also suggested that strict conflict of interest laws at the NIH discourage scientists from entering collaborative partnerships with private companies. In the late 1990s, new laws intended to mitigate conflicts of interest at the NIH resulted in a significant dip in the formation of CRADAs with industrial scientists. These laws were passed after allegations that some NIH scientists were benefitting too much from their intimate partnerships with corporations. Now, one member of the Office of Technology Transfer believes that, “NIH scientists are afraid if (sic) they work with industry they will get in trouble, that the rules might change and they will be left hung out to dry.”<sup>74</sup> Instead of partnering with companies, “the safe way would be to not collaborate at all.”<sup>75</sup> This sentiment was reinforced by the testimony of several Technology Development Coordinators. If the NIH seeks to make the most of its basic research enterprise, then it is imperative that these laws be revised or at least clarified so as to not discourage collaborative research.

Presently it seems that the pharmaceutical industry may have depleted much of the low hanging fruit from the NIH’s invention profile. In an attempt to avoid risky investments, companies are waiting until products are further along in the development process to pursue licensing. Ultimately, in order to avoid widening the valley of death associated with biomedicine, the NIH must find a better balance in terms of its support for applied and basic research. The NIH has already taken steps to shift this balance with the formation of the National Center for Advancing Translational Sciences (NCATS). This NIH institute uses federal funding to advance product oriented research projects specifically addressing rare and neglected diseases. NCATS fulfills needs that are not met by the pharmaceutical industry, and although their work may not benefit the majority of the American public, obviously their work is critically important to those affected by these disorders.

### CONCLUSION: TURNING DISCOVERY INTO HEALTH

In 2011, President Barack Obama released a presidential memorandum requiring all federal agencies to accelerate the process of technology transfer. This memorandum reflects that even at the highest level of office, there is recognition of the importance to optimize technology transfer. The purpose of this paper is to delineate sources of friction in technology transfer and to make recommen-

dations regarding ways to ameliorate the situation. Not just accelerating, but optimizing, technology transfer will provide taxpayers with the greatest return on their investment and will allow for improved health outcomes in future generations.

Technological and intellectual advancements have made modern research faster than ever before. In order to keep pace with the constantly evolving research environment, the NIH must create additional incentives that promote rapid and efficient translation of discoveries into useful products for improving health. The NIH can maintain its reputation as an ivory tower of basic research, but it must encourage its scientists at all levels to be cognizant of the potential practical applications of all aspects of their ongoing research projects. The number of patents that a scientist holds should be considered as important criteria when NIH directors make decisions regarding tenure, funding allocations or promotions. Putting emphasis on patents that are successfully licensed and impact public health will encourage scientists to perform research that is potentially beneficial to the public. If the NIH can increase its revenue from patent royalties, individual institutes can use these funds to reinvest back into new research projects. Some innovative TDCs are already using this as a revenue-building model in the face of ongoing federal budget cuts. Increasing the emphasis placed on patent royalties will allow the NIH to escape the traditional “publish or perish” paradigm and will make it easier for NIH scientists to accomplish the agency’s mission of “turning discovery into health.”

The valley of death associated with biomedicine is an ongoing problem that is seriously imperiling federal research agencies, private corporations and the American public as a whole. This paper has demonstrated why an improved technology transfer system is necessary to translate basic discoveries into commercial products, and it has presented the history of that system as established by intellectual property laws passed in the 1980s. Additionally, this paper has summarized common criticisms posed by academic scholars regarding the modern technology transfer system. Oral history interviews conducted with technology transfer administrators at the NIH revealed that the government agency has largely eluded the negative ramifications of these criticisms. However, interviewees revealed a host of other problems afflicting the NIH that have impeded the agency’s ability to mitigate the valley of death.

In order for the NIH to maximize the taxpayer investment in biomedical research, they must implement

<sup>74</sup> Crawford, Joel. Personal Interview. 25 July 2013

<sup>75</sup> Crawford, Joel. Personal Interview. 25 July 2013

long-term product oriented collaborative projects with private corporations. Encouraging these collaborations, which would be longer and more product-oriented than normal CRADAs, would benefit every party involved. This sort of collaboration will benefit the NIH as a whole by allowing it to address its mission through the creation of novel products that are useful to the public. Individual NIH scientists would benefit because potential royalties are an alluring way to supplement federal income. Industry partners would benefit because it would afford them additional financial and intellectual resources as well as first dibs on any intellectual property stemming from the collaboration. And most importantly, the public health of society as a whole would benefit from an increased emphasis placed on translating discoveries into medical products. Not only will these collaborations offer a higher yield of beneficial products, but they could also be cheaper as well. Extensive collaboration with NIH scientists would reduce the cost of research to private corporations and ideally would reduce the subsequent product cost to consumers as well.

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